July 20, 2026

Submitted electronically via www.regulations.gov (Docket No. CMS-2026-2212)

The Honorable Mehmet Oz, MD
Administrator
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

RE: Request for Information: Pharmacy Benefit Manager Compensation and Data Collection; File Code CMS-4218-NC; RIN 0938-AW09

Dear Administrator Oz:

On behalf of the National Association of Specialty Pharmacy ("NASP"), thank you for the opportunity to comment on the "Pharmacy Benefit Manager Compensation and Data Collection" Request for Information ("RFI")[1], which seeks technical input to inform implementation of Section 6224 of the Consolidated Appropriations Act, 2026.[2] The new statutory requirements outlined in Section 6224 of the law restrict the remuneration that pharmacy benefit managers ("PBMs") and their affiliates may receive in connection with the utilization of covered Medicare Part D drugs, and imposes new PBM data reporting requirements, both effective for plan years beginning January 1, 2028.

NASP is the leading national organization representing the full continuum of the specialty pharmacy industry, including independent, health-system, and other specialty pharmacies, along with the manufacturers, some pharmacy benefit managers, technology companies, group purchasing organizations, and other supply-chain partners that support specialty pharmacy patients. NASP's specialty pharmacy members serve patients who require complex, high-touch therapies for conditions such as cancer, multiple sclerosis, rheumatoid arthritis, cystic fibrosis, HIV, organ transplantation, and rare and orphan diseases. These patients depend on the clinical management, adherence support,

[1]Request for Information: Pharmacy Benefit Manager Compensation and Data Collection, 91 Fed. Reg. 36776 (June 18, 2026) (CMS-4218-NC; RIN 0938-AW09), https://www.federalregister.gov/documents/2026/06/18/2026-12344/request-for-information-rfi-pharmacy-benefit-manager-compensation-and-data-collection.
[2]Consolidated Appropriations Act, 2026, Pub. L. No. 119-75, div. B, § 6224 (Feb. 3, 2026), https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf.

financial assistance navigation, and rapid-access dispensing services that nationally accredited specialty pharmacies uniquely provide.

NASP shares CMS's goal of ensuring that PBM and PBM-affiliate compensation is transparent, tied to real and necessary services, and does not distort drug costs, pharmacy reimbursement, or patient access. NASP is concerned, however, about two distinct but related risks in how CMS implements Section 6224. First, absent careful, ownership- and control-based line drawing, the very rules intended to rein in anticompetitive market practices could be misapplied to independent and non-PBM-affiliated specialty pharmacies that have no ownership, control, or agency relationship with any PBM — simply because those pharmacies participate in a designated limited distribution network or a Plan Sponsor's restricted specialty network. Second, the long-standing practice of some PBMs extracting pharmacy compensation through fees assessed after the point of sale or at the point of sale based on unreasonable or irrelevant quality performance measures or other factors — whether labeled direct and indirect remuneration ("DIR"), brand effective rate ("BER"), or any other title selected by certain PBMs — continues to inflate those PBMs' compensation while eroding specialty pharmacy reimbursement. Section 6224 will only achieve its intended purpose if CMS enforces current laws and DIR reform regulations, ensuring Plan Sponsor bids are accurate; and actively audits and oversees compliance rather than relying exclusively on self-reported PBM data.

Importantly, NASP believes that before CMS can effectively implement many of the provisions addressed in this RFI, it must first have a consistent understanding of what constitutes a specialty pharmacy. Unlike traditional retail pharmacies, specialty pharmacies provide comprehensive clinical management and patient support services for individuals receiving complex therapies, including care coordination, benefits investigation, prior authorization support, adherence monitoring, financial assistance navigation, REMS compliance, and specialized product handling. These operational and clinical distinctions are central to evaluating affiliate relationships, reimbursement practices, network participation, pharmacy compensation, and the reporting requirements contemplated by Section 6224. Accordingly, NASP believes that establishing a clear, objective framework for identifying specialty pharmacies is foundational to ensuring that CMS can consistently evaluate the operational, clinical, and financial issues discussed throughout this letter and implement Section 6224 in a manner that supports both patient access and meaningful regulatory oversight.

NASP's comments below are offered in response to the six topic areas identified in Section II of the RFI.

Summary of NASP's Comments

- CMS should establish a uniform, accreditation-based definition of "Specialty Pharmacy" as a foundational prerequisite to implementation of Section 6224. A consistent definition is essential to meaningful PBM reporting, enabling CMS to accurately compare pharmacy reimbursement, network tier placement, and affiliate-retained revenue, and other compensation practices across PBMs and Part D sponsors. It will also provide a consistent regulatory framework that reflects the evolution and increasing complexity of the specialty pharmacy market.
- CMS should adopt an ownership- and control-based definition of "affiliate" that never sweeps in an independent, non-owned, or non-shared specialty pharmacy merely because it participates in a manufacturer-imposed or plan-compelled limited distribution or restricted network channel, regardless of that channel's degree of exclusivity.
- CMS should recognize that ownership, control, and payment flows differ fundamentally between an independent specialty pharmacy and a PBM-owned or PBM-affiliated specialty

pharmacy, and should collect data sufficient to detect discriminatory reimbursement, network-tier placement, or product-mix steering based on ownership status.

- CMS should distinguish, throughout the affiliate and bona fide service fee ("BFSF") analysis, between (a) entities owned by, controlled by, or contractually performing PBM or Part D sponsor functions on behalf of a PBM or PDP sponsor, and (b) independent group purchasing organizations ("GPOs") and other supply-side entities that act on behalf of pharmacies — not PBMs or plan sponsors — which should not be deemed "PBMs" or "affiliates" subject to the BFSF restrictions merely because they negotiate drug acquisition or purchasing terms.
- CMS should require that every PBM-imposed pharmacy compensation adjustment — regardless of the label a PBM assigns it (DIR, GER, BER, network fee, performance fee, or otherwise) — be reflected in the negotiated price at the point of sale or in the Part D plan bid, consistent with existing CMS policy, and CMS must actively audit compliance rather than rely on self-reported PBM data.
- CMS should ensure that the fair market value (FMV) standard cannot be self-referential: PBMs and their affiliates must not be permitted to use intra-enterprise or PBM-set pricing as the benchmark for determining the fair market value of their own compensation. FMV thresholds should be set by reputable and experienced third parties, not by PBM determined benchmarks, and updated on an annual cadence as service offerings are introduced or changed regularly.
- CMS should clarify that when a PBM reduces pharmacy payment through a DIR, GER, BER, or similar after-the-fact (post point of sale) fee or an at point of sale adjustment based on performance or other metrics that are not reasonable or relevant to the drugs dispensed by a pharmacy or services provided by a pharmacy, then that payment is not considered a fair or protected pharmacy payment as defined in the RFI and future proposed rule. A payment that looks compliant when first made, but is then clawed back or otherwise unreasonably adjusted, should be treated as an improper, disguised transfer of compensation to the PBM — not as protected pharmacy payment.
- CMS should require PBM data reporting granular enough to show claim-level reversals, reconciliation amounts, fees retained by affiliated entities, and payment differentials by pharmacy ownership, network tier, and channel, and should cross-validate that data against Prescription Drug Event ("PDE") records and approved plan bids.

I. Comments on Section II.A – Definition of "Pharmacy Benefit Manager"

The RFI asks what "related services" PBMs typically perform, whether there are PBM-like entities that do not self-identify as PBMs, and how intermediaries between PBMs and Part D sponsors are structured and compensated. NASP urges CMS to anchor this inquiry in function, not label or corporate form, consistent with the statutory instruction that the PBM definition applies "irrespective of whether such person or entity calls itself a ‘pharmacy benefit manager.’"

At the same time, NASP cautions CMS against defining "related services" so broadly that pharmacy dispensing, clinical management, and patient support functions performed by specialty pharmacies independent of a PBM’s or Part D Sponsor’s corporate structure or ownership are mistaken for PBM functions. A specialty pharmacy that verifies benefits, coordinates prior authorization on a patient’s behalf, provides medication therapy management, or reports adherence data to a manufacturer-sponsored patient support program is not thereby negotiating drug prices, adjudicating claims, or managing a Part D sponsor’s drug benefit — the core functions that Congress identified in the statutory

PBM definition. These patient-facing clinical services are among the defining characteristics of specialty pharmacy and distinguish specialty pharmacies from traditional dispensing operations. They are performed on behalf of the patient and the prescribing clinician—not on behalf of a PBM or Part D sponsor—and therefore should not be confused with PBM administrative functions. NASP asks CMS to make this distinction explicit in any forthcoming rule so that certain specialty pharmacies are not inadvertently classified as PBMs, or as performing "PBM-like" functions, based on the ordinary scope of specialty pharmacy practice.

II. Comments on Section II.B – Definition of "Affiliate"

The RFI asks whether specialty pharmacies, GPOs/rebate aggregators, and a list of other entity types should be considered PBM "affiliates," and requests information on ownership, contractual relationships, services performed, and payment flows for each category. NASP's comments focus on ensuring that the affiliate definition is applied based on actual ownership, control, or agency — and never based on network participation status alone.

A. Affiliated and Non-Affiliated Specialty Pharmacies Are Fundamentally Different Businesses, and Only Ownership, Control, or Agency — Never Network Participation — Should Determine Affiliate Status

Section 1860D-12(h)(7)(A) of the Social Security Act defines "affiliate" to include an 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, and/or that acts as a contractor, principal, or agent of the PBM or PDP sponsor in performing PBM functions, which includes exercising discretion over core PBM functions like benefit design, formulary, and network design. This is an ownership-, control-, and agency-based test. It is not a network-participation test, and NASP urges CMS not to convert it into one.

There is a fundamental and easily documented difference between (1) a specialty pharmacy that shares governance with a PBM or Part D sponsor — where profits, losses, and compensation can be shifted across the corporate family through intercompany pricing, spread retention, or affiliate rebate-sharing — and (2) a specialty pharmacy that has no equity, governance, or contractual agency relationship with or through a PBM, and that bears economic risk of below-cost reimbursement with no offsetting affiliate revenue available to the pharmacy within the corporate structure. The first is properly an "affiliate" under the statute. The second is not, no matter how the PBM structures its network.

This distinction is not theoretical and has been considered by government entities. The Federal Trade Commission's ("FTC") Second Interim Staff Report found that pharmacies affiliated with the three largest PBMs received 68 percent of specialty drug dispensing revenue in 2023, up from 54 percent in 2016, and that these PBMs marked up numerous specialty generic drugs dispensed at their affiliated pharmacies by hundreds or thousands of percent — generating more than $7.3 billion in revenue above estimated acquisition cost from 2017 through 2022 — while unaffiliated pharmacies dispensing the same drugs were reimbursed at markedly lower rates.[3] The U.S. House Judiciary Committee reached similar conclusions, finding that pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug revenue, that affiliated pharmacies were often paid 20 to 40 times the

[3]Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Second Interim Staff Report (Jan. 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

National Average Drug Acquisition Cost ("NADAC") for certain specialty generics, and that affiliated pharmacies retained nearly $1.6 billion in dispensing revenue in excess of NADAC on just two case-study drugs over less than three years.[4] Sweeping non-owned, non-controlled pharmacies into the same category would not address this problem; it would only dilute enforcement against the entities Congress intended to reach with the new law.

B. Participation in a Limited Distribution Network Does Not Create Ownership, Control, or Agency, and Must Not Be Treated as an Affiliate Relationship

Many specialty drugs, particularly in oncology and for rare diseases, are subject to manufacturer-imposed limited distribution network ("LDN") or limited distribution drug programs, under which only a manufacturer-selected subset of accredited pharmacies may dispense a given product.[5] Independent non-affiliated specialty pharmacies can be selected for LDN participation because of their accreditation status, demonstrated clinical capabilities, disease-specific expertise, cold-chain and handling infrastructure, and patient-access track record — not because they are performing a service for, or being compensated by, a PBM.

A pharmacy's selection into an LDN is driven by the manufacturer's distribution strategy — patient safety, REMS compliance, specialized handling requirements, or limited initial supply. The same is true where a plan sponsor designates a "preferred" or restricted specialty network: an independent pharmacy that is required to join a restricted channel in order to reach patients is not thereby placed in an ownership or control relationship with the PBM that designed the channel. NASP therefore asks CMS to state clearly, in any forthcoming rule or sub-regulatory guidance, that:

- CMS should not treat a specialty pharmacy as a PBM "affiliate" merely because it participates in a limited distribution, limited access, or plan-mandated restricted network channel for specialty drugs, regardless of the degree of exclusivity of that channel.
- Network-participation status, LDN designation, or "preferred" or "in-network" status is not, by itself, evidence of ownership, control, or agency and must not be used as a proxy for affiliate status.
- Only entities that are actually owned by, are owned in whole or part by, controlled by, or that contractually perform PBM or Part D sponsor functions on behalf of a PBM or PDP sponsor — pharmacy network design and contracting, formulary design/administration, utilization management, or rebate negotiation on the PBM's or sponsor's behalf — should be treated as affiliates.

This clarification is essential to preserving patient access and choice. If independent, clinically qualified specialty pharmacies risk being reclassified as PBM affiliates simply because a manufacturer or plan has placed them in a restricted channel, manufacturers and plans may respond by narrowing LDNs to only the largest, most PBM-adjacent pharmacies capable of absorbing that regulatory uncertainty — the opposite of CMS's and Congress's intended outcome, and one that would further concentrate specialty

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[4]U.S. House Committee on the Judiciary, Subcommittee on the Administrative State, Regulatory Reform, and Antitrust, Pharmacy Benefit Managers, at 38, 40, 44 (Sept. 11, 2024), https://docs.house.gov/meetings/JU/JU05/20240911/117633/HHRG-118-JU05-20240911-SD006.pdf.

[5]NCODA, Beyond Limits: Rethinking Limited Distribution Networks in Oncology and Their Impact on Access & Care, https://www.ncoda.org/wp-content/uploads/2025/05/Beyond-Limits-Rethinking-Limited-Distribution-Networks-in-Oncology-Their-Impact-on-Access-Care.pdf.

dispensing in PBM-owned channels at the expense of patient access, while reducing patient access to clinically appropriate specialty pharmacy providers, disrupting continuity of care, limiting patient choice, and diminishing competition among qualified specialty pharmacies.

C. Group Purchasing Organizations and Rebate Aggregators Must Be Evaluated Based on Whom They Serve, Not Their Label

The RFI specifically lists "group purchasing organizations/rebate aggregators" among the entity types CMS is considering for affiliate status. NASP agrees that this category requires careful analysis — but that analysis must distinguish between two very different kinds of entities that are often confused simply because both are called "GPOs."

The FTC and other regulators have documented that the largest PBMs have formed their own wholly owned or controlled "rebate aggregator" or "GPO" subsidiaries — entities whose sole function is to negotiate manufacturer rebates on behalf of the PBM and its affiliated health plan clients, often while retaining a share of those rebates and manufacturer fees before any pass-through calculation is applied.[6] These PBM-created and PBM-controlled rebate aggregators plainly meet the statutory affiliate definition: they are owned or controlled by the PBM, and they perform a core PBM function — negotiating drug prices/rebates on behalf of a PDP sponsor — on the PBM's behalf. NASP supports treating these PBM-owned or PBM-controlled rebate aggregators as affiliates fully subject to the BFSF restrictions, and encourages CMS to require the same ownership, control, contractual, and payment-flow data from these entities that it seeks for PBMs themselves.

On the other hand, specialty pharmacies — like other providers — frequently participate in independent group purchasing organizations that are not owned, controlled by, or contractually bound to act on behalf of any PBM or Part D sponsor. These traditional GPOs negotiate drug acquisition costs, wholesaler terms, and administrative and data services on behalf of their pharmacy members and are compensated by pharmacies for services rendered, not by a PBM or Part D sponsor for managing a drug benefit. These entities do not negotiate drug prices on behalf of a prescription drug plan or PDP sponsor, do not manage a Part D sponsor's drug benefit, and have no ownership, control, or agency relationship with any PBM.

NASP therefore recommends that CMS adopt a two-part test for any entity described as a "GPO," "rebate aggregator," or similar intermediary:

- Whom does the entity act for? An entity that negotiates rebates, discounts, or pricing terms on behalf of a PBM or Part D sponsor — including a PBM-owned or PBM-controlled rebate aggregator — is performing a PBM function and should be an affiliate subject to the BFSF restrictions. An entity that negotiates purchasing or acquisition-cost terms on behalf of pharmacies (the buy-side) is not performing a PBM function merely because it aggregates purchasing volume.
- Is there an ownership, control, or contractual agency relationship with a PBM or Part D sponsor? Absent such a relationship, an independent, pharmacy-side GPO should not be deemed a "PBM" or an "affiliate," and its ordinary purchasing-service and data fees to member specialty

[6]Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Staff Report, at 35-38 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

pharmacies should not be forced into the flat-fee BFSF framework designed for PBM compensation for managing a Part D drug benefit.

This distinction matters directly to specialty pharmacies' continued ability to negotiate favorable drug acquisition terms. If an independent, non-PBM-affiliated purchasing cooperative that a specialty pharmacy uses to negotiate acquisition costs were mistakenly deemed a "PBM" or "affiliate" — with no ownership or agency relationship to any PBM or plan sponsor — its customary administrative, data, and purchasing-service fees would be subjected to a flat-dollar-amount BFSF test that was never designed for buy-side purchasing arrangements, potentially disrupting the acquisition-cost efficiencies that keep independent specialty pharmacies economically viable. NASP urges CMS to make explicit in any implementing guidance that no entity in the specialty pharmacy supply channel that is not itself performing PBM functions on behalf of a PBM or Part D sponsor — including independent, pharmacy-side GPOs — should be treated as a "PBM" or "affiliate" for purposes of the limited BFSF exception, regardless of how the entity is labeled.

NASP notes that this concern is consistent with independent analysis of the RFI, which observes that PBMs themselves may argue for a narrow reading of "affiliate" that would exclude their own rebate aggregators, data subsidiaries, and owned specialty and mail-order pharmacies from BFSF scrutiny.[7] A useful legislative model is Illinois's 2026 PBM law, which similarly distinguishes "affiliated" rebate aggregators (owned or controlled in part by a PBM, subject to 100 percent rebate pass-through) from non-affiliated rebate aggregators, and separately prohibits PBMs from requiring enrollees to use only a pharmacy in which the PBM or its affiliate holds an ownership interest.[8]

III. Comments on Section II.C – Definition of "Bona Fide Service Fee"

This section of the RFI and the fair payment issues it raises warrants CMS' closest attention. In NASP's experience, there is widespread misunderstanding, both in public discourse and in some plan and PBM communications, about how post-point-of-sale fee adjustments to pharmacy compensation actually function. These adjustments are frequently mischaracterized as pharmacy "performance" programs or "quality" incentives, when in practice they operate as a mechanism to increase PBM and PBM-affiliate compensation by retroactively reducing amounts already paid, or scheduled to be paid, to specialty pharmacies.

A. DIR, GER, BER, and Other Named Fees on Specialty Pharmacies Have Long Functioned to Increase PBM Compensation While Reducing Pharmacy Compensation

CMS itself has recognized that direct and indirect remuneration - compensation adjusted after the point-of-sale - changes the final cost of the drug for the payer, the price paid to the pharmacy for the drug and resulted in increased cost sharing for patients.[9] What began as a mechanism to capture manufacturer rebates had been extended by many PBMs to "pharmacy DIR" — mandatory, PBM-defined price concessions imposed on pharmacies as a condition of network participation, often disguised as generic

[7]Frier Levitt, Stakeholder Alert: CMS Seeks Public Input to Inform PBM Rulemaking (July 2, 2026), https://www.frierlevitt.com/articles/cms-pbm-rulemaking-rfi-2026-stakeholder-guide/.
[8]Ogletree Deakins, Illinois PBM Law to Limit Steering, Other Plan Design Features in 2026 (Oct. 31, 2025), https://ogletree.com/insights-resources/blog-posts/illinois-pbm-law-to-limit-steering-other-plan-design-features-in-2026/.
[9]CMS, Medicare Part D – Direct and Indirect Remuneration (DIR), Fact Sheet, https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-indirect-remuneration-dir.

effective rate ("GER") or brand effective rate ("BER") reconciliations, or as "performance-based" or "quality" fees.

NASP documented as early as 2018 that performance-based DIR fees imposed on specialty pharmacies had no basis in the Medicare Modernization Act, CMS regulation, or CMS guidance, and that some PBMs assigned specialty pharmacies the average "quality metric" score of the PBM's broader retail network — including metrics such as statin or diabetes adherence that have no clinical relevance to a specialty pharmacy's patient population — in order to justify assessing a fee calculated as a percentage of gross drug reimbursement. Because specialty pharmacies frequently dispense high-cost drugs for complex and rare patient conditions, a percentage-of-reimbursement fee structure extracts a disproportionately large dollar amount from specialty claims. These reimbursement practices not only threaten the financial sustainability of specialty pharmacies but also undermine their ability to provide comprehensive clinical services, patient education, care coordination, adherence support, and ongoing monitoring that distinguish specialty pharmacy and are essential to achieving optimal outcomes for patients with complex conditions. Fees that are not tied to fair-market-value service but instead function as a mechanism to shift compensation from the dispensing pharmacy to the PBM, are inconsistent with the statutory purpose of Section 6224.

Senator Ron Wyden's June 2024 letter to CMS likewise found that "PBM contracting practices are straining the finances of pharmacies and directly contributing to their closures" and raised specific concerns that PBMs were not adhering to CMS's rule reining in DIR fees.[10] NASP urges CMS to bring this same scrutiny to Section 6224 implementation: whatever label a PBM assigns to a post-adjudication fee — DIR, GER, BER, network access fee, data fee, administrative fee, or "incentive" payment — the label itself must never be confused to be a BFSF. The statutory test is substantive: is the fee a flat dollar amount, reflective of fair market value, for an itemized service actually performed, that is not contingent on drug price, rebate amount, formulary placement, or referral/business volume? A fee that varies with drug price, claim volume, or is calculated as a percentage of reimbursement fails this test regardless of what it is labeled, and CMS should adopt a rule that expressly prohibits PBMs and their affiliates from recharacterizing volume, price, or rebate-contingent payment reductions as "bona fide service fees" or as compliant "incentive payments" under section 1860D-12(h)(1)(A)(ii).

B. DIR and Any Other Fee Adjustments Must Be Captured at the Point of Sale as required by rulemaking or in the Part D Plan Bid, and CMS Must Enforce This Requirement

CMS has already established the correct policy framework for pharmacy price concessions, and NASP urges CMS to carry that same framework directly into Section 6224 implementation and enforcement. In its CY2023 Final Rule, CMS redefined "negotiated price" at 42 C.F.R. § 423.100, effective January 1, 2024, as "the lowest possible reimbursement [a] network pharmacy or dispensing provider will receive, in total," for a covered Part D drug — meaning that all pharmacy price concessions, howsoever named, must be reflected in the price reported at the point of sale rather than reported later as DIR.[11] CMS subsequently reminded Part D sponsors that "the maximum possible reduction in payment must be treated as a pharmacy price concession and reflected in the negotiated price available at the point of

[10]Sen. Ron Wyden, Letter to CMS Administrator on Oversight of PBMs (June 24, 2024), https://www.finance.senate.gov/imo/media/doc/062424_wyden_letter_to_cms_on_oversight_of_pbms.pdf.

[11]CMS, Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, Final Rule, 87 Fed. Reg. 27704, 27851 (May 9, 2022) (CMS-4192-F), https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.

sale and reported to CMS on a PDE record," that retained DIR must be reflected as a reduction to gross claim cost in the plan bid rather than reported separately as DIR, and that CMS's Office of the Actuary would "closely review[] the DIR and gross cost estimates" in plan bid pricing tools to confirm compliance.[12]

NASP asks CMS to make clear, in implementing Section 6224, that it applies with equal force to any fee, adjustment, clawback, reconciliation, or offset assessed against a pharmacy's reimbursement for a covered Part D drug — regardless of whether the PBM characterizes that adjustment as DIR, GER, BER, a "performance" fee, a "network" fee, or an "incentive" payment under section 1860D-12(h)(1)(A)(ii). Any adjustment that is not captured at the point of sale, and that instead reduces pharmacy compensation after the claim has already been adjudicated and paid, should be treated the same way CMS already treats pharmacy price concessions: as an amount that must be reflected in the negotiated price and the plan bid, not as a permissible after-the-fact BFSF or incentive payment. Framing DIR, GER, or BER adjustments as bona fide service fees rather than as price concessions subject to point-of-sale disclosure would create a loophole that would let PBMs simply re-label the same conduct Congress and CMS have already moved to restrict.

NASP also asks CMS to clarify that this point-of-sale requirement, and the BFSF restrictions under Section 6224, operate together, not as alternatives: a PBM or affiliate must not be permitted to avoid the point-of-sale negotiated-price requirement by recharacterizing a price concession as a "bona fide service fee," and it may not avoid the BFSF flat-fee, non-contingency requirements by recharacterizing a disqualifying fee as a permissible pharmacy price concession or "incentive payment." Both frameworks must be enforced in tandem to close the gap that has allowed DIR-style fees to persist despite regulations aimed to stop the practice.

C. CMS Must Actively Audit — Not Merely Collect — Data Demonstrating Compliance with the Point-of-Sale and BFSF Requirements

NASP is concerned that any CMS reporting requirements alone will not stop the misuse of named fees; CMS must pair the new Section 6224 data reporting requirements with active, ongoing audit of PBM compliance. NASP recommends that CMS commit, in its implementing rule, to the following minimum audit practices:

- Cross-validate PBM and PDP sponsor Section 6224 annual reports against Prescription Drug Event (PDE) records and the plan's approved bid, so that any gap between the negotiated price reported at the point of sale and the pharmacy's actual reimbursement is identified and investigated as a potential undisclosed price concession or improperly labeled BFSF.
- Require PBMs to itemize, for every fee category assessed against pharmacy reimbursement, the specific service performed, the methodology used to calculate the fee, and proof the fee is not contingent on a drug price, formulary placement, or referral/business volume. Sample audits should occur of pharmacy assessed fees each plan year with the results made public to ensure accountability.
- Impose meaningful consequences, requiring retroactive correction of the negotiated price and repayment to affected pharmacies when audits identify fees that were not applied at the point of sale or in the plan bid, or that were falsely claimed a BFSF.

[12]CMS, Reminder of Regulatory Requirements for Pharmacy Price Concessions in the Negotiated Price, at 1-2, https://www.cms.gov/files/document/pharmacydirreminder508g.pdf.

Congress reinforced CMS's authority to pursue this kind of oversight by separately enacting Section 6223 of the CAA, which requires CMS to define and enforce "reasonable and relevant" Part D pharmacy network contract terms, establish a pharmacy appeals process, and giving CMS new monetary penalty authority and dedicated implementation funding.

D. Non-PBM Entities in the Specialty Channel Should Be Treated as a PBM for Purposes of the Limited BFSF Exceptions

NASP asks CMS to confirm that the BFSF restrictions, which were intended by Congress to limit and oversee compensation paid to PBMs and their affiliates for performing PBM functions, do not extend to entities in the specialty pharmacy supply channel that are not PBMs, are not owned or controlled by a PBM, and do not act as a PBM's or Part D sponsor's contractor or agent. This includes independent group purchasing organizations that negotiate drug acquisition costs on behalf of specialty pharmacies, as well as other non-PBM specialty channel participants such as accreditation bodies, specialty pharmacy technology vendors that are not owned by, controlled by, or contractually performing PBM functions on behalf of any PBM or Part D sponsor.

IV. Comments on Section II.D – Determination of "Fair Market Value"

The RFI asks what methods are currently used to determine fair market value for PBM services, whether those methods differ by entity type, and how PBM market concentration and vertical integration should factor into the fair market value analysis. NASP urges CMS to adopt a fair market value standard that considers how payment to pharmacies factors into PBM compensation.

- Fair market value must be assessed against independent market data — for example, third-party compensation surveys or published acquisition-cost benchmarks such as NADAC for drug costs and cost to dispense studies -- and applied uniformly across the pharmacy network. Fair market value must never be established by reference to a PBM's own pricing of the same or a similar service to its own affiliate. NASP asks that CMS ensure the standard is not to allow whatever a plan sponsor is willing to pay to be defined as "fair market value." Instead, we ask that fair market values be set by reputable and experienced third parties and updated on an annual cadence to reflect changes and updates to service offerings.

V. Comments on Section II.E – Pharmacy Payment

Section 1860D-12(h)(4) of the Social Security Act clarifies that Section 6224 should not be construed to prohibit flat dispensing fees or reimbursement for ingredient costs, including customary industry-standard discounts retained by pharmacies or wholesalers, or to modify existing regulatory or sub-regulatory guidance on pharmacy payment. NASP strongly supports this carve-out and asks CMS to protect it as it follows the RFI with rulemaking.

A pharmacy payment arrangement that provides ingredient-cost reimbursement plus a dispensing fee and any service fees — paid and disclosed at the point of sale — falls squarely within the statutory carve-out and should be recognized by CMS as such. By contrast, an arrangement that facially provides ingredient-cost reimbursement plus a dispensing fee, but where that payment is later reduced through DIR, GER, BER, clawbacks, reconciliations, or below-cost retroactive adjustments, does not actually deliver ingredient-cost reimbursement plus a dispensing fee — it delivers something less, disguised as compliant pharmacy payment. NASP asks CMS to state clearly that the carve-out in section 1860D-

12(h)(4) protects the pharmacy reimbursement established at the point of sale and reflects fair market value, and that the pharmacy payment cannot subsequently be reduced through post-adjudication PBM-imposed fees.

NASP further recommends that CMS request, and specialty pharmacies be prepared to provide, side-by-side data comparing (1) the ingredient cost plus dispensing fee reflected in the negotiated price at the point of sale, and (2) the pharmacy's actual final reimbursement after all post-adjudication adjustments, for a representative sample of specialty claims. A material, systematic gap between these two figures is strong evidence that DIR-style fees are being used to convert protected ingredient-cost and dispensing-fee payments into a vehicle for shifting compensation to the PBM or its affiliates.

VI. Comments on Section II.F – Data Collection

CMS asks what additional data elements, beyond those already required by statute, would help CMS implement and monitor Section 6224. NASP recommends that CMS require PBMs to report the following additional data elements, each broken out at a level of granularity sufficient to inform CMS decision making:

- Reimbursement by ownership status. Pharmacy reimbursement data broken out by whether the dispensing pharmacy is owned by, controlled by, or otherwise affiliated with the reporting PBM or the Part D sponsor, versus independent and non-affiliated, for each drug and network tier.
- Network tier and product mix by ownership. Data showing network tier placement (preferred, standard) and product mix assignment for affiliated versus non-affiliated specialty pharmacies, so CMS can identify whether affiliated pharmacies are systematically favored in tier placement or product allocation.
- Claim-level reversals and reconciliations. Data on claim-level payment reversals, GER/BER reconciliation amounts, and any other post-adjudication adjustment to pharmacy reimbursement, reported separately from up-front point-of-sale payment, regardless of the label the PBM applies to the adjustment.
- Fees retained by affiliated entities. The dollar amount of fees, rebates, and other remuneration retained by each PBM affiliate (including affiliated rebate aggregators, specialty pharmacies, and data vendors) in connection with covered Part D drugs, reported separately from amounts retained by the PBM itself.

A. A Uniform, Accreditation-Based Definition of "Specialty Pharmacy" Is a Prerequisite to Meaningful PBM Reporting on Affiliated and Non-Affiliated Compensation

The data reporting recommendations above depend on CMS's ability to compare pharmacy reimbursement, network tier placement, and affiliate-retained revenue across PBMs and Part D sponsors on a consistent basis. That comparison is only possible if "specialty pharmacy" means the same thing in every PBM's Section 6224 report. Today it would not. In the absence of a CMS-defined term, each PBM remains free to classify pharmacies as "specialty" — or to decline to do so — using whatever internal, self-selected criteria it chooses, including criteria tied to the PBM's own network-tier design, formulary placement, or drug-cost thresholds that the PBM itself sets. A PBM with an incentive to minimize the reported reimbursement, DIR, or affiliate-retained revenue attributable to its own affiliated specialty pharmacies can do so simply by defining "specialty pharmacy" narrowly, broadly, or inconsistently across its various data submissions. NASP therefore urges with emphasis that CMS adopt,

for purposes of implementing Section 6224's data reporting and affiliate provisions, a single, objective, and externally verifiable definition of "specialty pharmacy."

NASP recognizes that CMS has, for nearly a decade, consistently declined to define "specialty pharmacy" by regulation. Most recently, in the CY2019 Final Rule, CMS explained that it was declining to adopt a definition because it believed that the specialty pharmacy landscape is changing rapidly and because CMS was "concerned that any definition could be premature and could inappropriately interfere with the marketplace."[13] CMS added, however, that it would "continue to monitor the evolution of specialty pharmacy and may consider defining specialty pharmacy in the future if appropriate." NASP raised this same issue in its own comments on that rulemaking, urging CMS "to reconsider its decision to abstain from defining specialty pharmacy" and explaining that CMS "could define specialty pharmacy without prematurely and inappropriately interfering with the marketplace if the definition focuses on quality and third-party independent accreditation."[14] Section 6224 now presents the first meaningful opportunity—and practical necessity—for CMS to establish a clear, objective definition of specialty pharmacy. Without such a definition, CMS cannot consistently evaluate PBM reporting, compare reimbursement and compensation practices, assess affiliate relationships, or ensure meaningful transparency across the specialty pharmacy marketplace.

CMS's 2018 rationale reflected market conditions that no longer exist. At that time, the number of accredited specialty pharmacy locations nationwide only recently having climbed past several hundred.[15] Eight years later, the accreditation landscape has consolidated and matured considerably. Two organizations — URAC and the Accreditation Commission for Health Care ("ACHC") — are now the dominant national accreditors of specialty pharmacy, each maintaining detailed, regularly updated standards; URAC released its sixth-generation Specialty Pharmacy Accreditation standards in October 2025, and commercial payers already prefer URAC accreditation for roughly two-thirds of specialty network access decisions.[16] Manufacturers, payers, and PBMs alike have, for years, increasingly required third-party accreditation as a practical condition of network and limited distribution participation, to the point that accreditation now functions as a de facto industry requirement rather than a voluntary credential.[17] What CMS worried, in 2018, would be a premature intervention into a still-forming market

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[13]CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, Final Rule, 83 Fed. Reg. 16440 (Apr. 16, 2018) (CMS-4182-F), https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.

[14]National Association of Specialty Pharmacy, Comments on Medicare Program; Contract Year 2019 Policy and Technical Changes Proposed Rule (Jan. 16, 2018), https://naspnet.org/wp-content/uploads/2018/01/NASPs-comments-to-Part-D-Proposed-Rule-Final-Version-011618.pdf.

[15]LexisNexis Risk Solutions, Specialty Pharmacy: Meeting the Operational Challenge, at 2 (citing Drug Channels Institute data showing growth from 381 unique accredited specialty pharmacy locations in 2015 to 729 in 2017), https://risk.lexisnexis.com/-/media/files/healthcare/white-paper/specialty-pharmacy-pov%20pdf.pdf.

[16]Integral Healthcare Solutions, URAC vs. ACHC Specialty Pharmacy Accreditation Comparison (noting URAC Specialty Pharmacy Accreditation v6.0, announced October 2025, and that URAC accreditation is preferred by approximately 66 percent of commercial payers for specialty pharmacy network access), https://www.integralhs.com/urac-specialty-pharmacy-comparison.

[17]Pharmaceutical Commerce, Specialty Pharmacy Accreditation – Burden and Benefit (Sept. 21, 2018) ("specialty drug makers, payers and pharmacy-benefit managers (PBMs) are increasingly urging — if not

is, by 2026, simply a codification of a standard the market itself has already adopted and relied upon for years.

The stakes of leaving this definitional gap unaddressed have also grown substantially since 2018. Specialty dispensing revenue more than doubled between 2016 and 2023, and pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug dispensing revenue.[18] A definitional gap that may have had modest practical consequence in 2018, when specialty pharmacy was a smaller and less consolidated segment of the market, would, if left unaddressed today, allow inconsistent or self-serving PBM reporting to obscure exactly the kind of affiliate compensation shift that Section 6224 and this RFI are designed to make transparent.

CMS's own past guidance further supports, rather than counsels against, an accreditation-based definition. In addressing Part D plan sponsors' use of specialty pharmacy credentialing criteria, CMS has already stated that it "does not support" the use of "Part D plan sponsor or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations," apart from narrow, drug-specific dispensing criteria necessary to meet extraordinary handling or coordination requirements that a network pharmacy cannot otherwise satisfy.[19] CMS has, in other words, already recognized that independent, nationally recognized third-party accreditation — not a PBM's own internal criteria — is the appropriate benchmark for identifying a legitimate specialty pharmacy for network-participation purposes. Adopting that same accreditation-based benchmark for the narrower purpose of Section 6224 data reporting and affiliate analysis would not depart from CMS's existing policy; it would simply extend a standard CMS has already endorsed to a new, and lower-stakes, regulatory purpose.

Plan sponsors, PBMs and drug manufacturers have, for their part, never treated the definition of "specialty pharmacy" as open or unresolved. Both routinely require independent accreditation before permitting a pharmacy to dispense the highest-cost, most clinically complex therapies in the drug supply chain — precisely because accreditation is the only independent, standardized proxy available for a pharmacy's demonstrated ability to safely manage cold-chain handling, REMS compliance, prior authorization and benefits investigation, financial assistance navigation, and ongoing adherence and side-effect monitoring for complex specialty therapies. If plan sponsors and manufacturers already trust independent accreditation to decide which pharmacies may be entrusted with the most sensitive, highest-risk, and highest-cost drugs on the market, CMS can rely on that same, already-proven standard for the comparatively modest purpose of ensuring that PBM compensation reporting under Section 6224 uses a single, consistent definition of "specialty pharmacy."

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outright requiring — third-party accreditation... this once-voluntary undertaking now feels more like a de facto requirement than ever"), https://www.pharmaceuticalcommerce.com/view/specialty-pharmacy-accreditation-burden-and-benefit.

[18]Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Staff Report, at 35 (July 2024) (specialty dispensing revenue grew from approximately $113 billion in 2016 to approximately $237 billion in 2023, and pharmacies affiliated with the three largest PBMs accounted for nearly 70 percent of all specialty drug dispensing revenue), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[19]Mintz, CMS Tries to Clarify Any Willing Pharmacy Rules (Nov. 29, 2017) (quoting CMS's discussion, in its proposed CY2019 Part D rule, of specialty pharmacy credentialing requirements), https://www.mintz.com/insights-center/viewpoints/2017-11-29-proposed-medicare-advantage-and-part-d-regulations-cy-2019.

NASP recommends that CMS define “specialty pharmacy,” for purposes of implementing the reporting and affiliate provisions of Section 6224, as a pharmacy that is currently accredited by a single national, independent, third-party specialty pharmacy accreditor, such as URAC, the Accreditation Commission for Health Care (ACHC), or the Joint Commission. Consistent with CMS’s own prior guidance disfavoring the use of multiple or duplicative accreditation requirements as a barrier to network participation, NASP recommends that accreditation by any one qualifying national accreditor be sufficient to satisfy the definition; CMS should not require a pharmacy to hold accreditation from more than one accrediting body in order to be recognized as a specialty pharmacy for reporting purposes.

Without this definitional anchor, the reporting and affiliate-analysis recommendations NASP has made elsewhere in this letter cannot be fully realized: any comparison of reimbursement, network tier placement, or affiliate-retained revenue between affiliated and non-affiliated specialty pharmacies is only as reliable as the definition of “specialty pharmacy” each PBM applies when compiling that data. A single, objective, accreditation-based definition would let CMS, plan sponsors, and the public compare PBM compensation data on an apples-to-apples basis across the entire specialty pharmacy channel — exactly the outcome Section 6224’s transparency mandate and this RFI are designed to achieve.

NASP also recommends that CMS require all reported data to be provided in a standardized, machine-readable format that permits direct comparison across PBMs and plan years, and that CMS commit to using this data — together with the audit practices described in Section III.C above — as the basis for ongoing compliance monitoring, not solely as a one-time rulemaking input.

Conclusion

NASP appreciates CMS’s effort to gather detailed, function-based input before finalizing rules that will govern PBM compensation and reporting for years to come. NASP urges CMS to adopt a definition of "affiliate" that is anchored strictly in ownership, control, and agency — never in network-participation status — so that independent, non-owned, or non-shared specialty pharmacies are never deemed PBM affiliates simply because they participate in a limited distribution or restricted network channel. NASP urges CMS to ensure that no non-PBM entity in the specialty channel, including independent group purchasing organizations, is treated as a PBM for purposes of the limited bona fide service fee exception. And NASP urges CMS, above all, to recognize that DIR, GER, BER, and similarly renamed post-adjudication fees have functioned for years to increase PBM and PBM-affiliate compensation at the direct expense of pharmacy compensation, and to require — and actively audit — that all such adjustments are captured transparently at the point of sale or in the Part D plan bid, exactly as CMS has already required for other pharmacy price concessions.

Ultimately, NASP believes that successful implementation of Section 6224 should improve transparency while preserving patient choice and access to clinically appropriate specialty pharmacy services. Clear definitions, objective reporting standards, and consistent application of these requirements will enable meaningful oversight while helping ensure that Medicare beneficiaries continue to receive the specialized clinical management, care coordination, and patient support services necessary to safely and effectively manage complex and chronic conditions.

NASP looks forward to continuing to work with CMS as it moves toward rulemaking implementing Section 6224, and would welcome the opportunity to provide additional data, case examples, or

technical assistance. Please do not hesitate to contact NASP with any questions regarding these comments.

Sincerely,

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National Association of Specialty Pharmacy