

Hearing of the United States House Committee on Energy and Commerce Subcommittee on Health On "An Examination of How Reining in PBMs Will Drive Competition and Lower Costs for Patients" Testimony By Sheila Arquette, President and CEO National Association of Specialty Pharmacy (NASP) February 26, 2025

Chairman Carter, Ranking Member DeGette and Members of the Subcommittee:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) to express support for the House Committee on Energy and Commerce Subcommittee on Health's efforts to address unfair and anticompetitive practices that narrow the pharmacy marketplace and negatively impact patients. We are so grateful for the leadership of Chairman Carter and the bipartisan support of Ranking Member DeGette to address and advance these important policy reforms at the beginning of the 119th Congress.

NASP represents the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies. The association represents all types of specialty pharmacies: independent pharmacies, academic medical center and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store-owned specialty pharmacies, some health plan-owned specialty pharmacies.

What is Specialty Pharmacy

Specialty pharmacies support patients who have complex health conditions like rheumatoid arthritis, multiple sclerosis, hemophilia, cancer, organ transplantation and rare diseases. The medications a specialty pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to specialty drugs. Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a smaller number of patients and require significant patient education and monitoring on

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utilization and adherence. Unless accredited as a specialty pharmacy by an independent, nationally recognized, third party accreditation organization, typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require. Though many specialty medications are taken orally, still many need to be injected or infused. The services a specialty pharmacy provides include patient training in how to administer the medications, comprehensive treatment assessment, ongoing patient monitoring, side effect management and mitigation, and frequent communication and care coordination with caregivers, physicians and other healthcare providers. A specialty pharmacy's expert services drive patient adherence, proper management of medication dosing and side effects, and ensure costly and complex drug therapies and treatment regimens are used correctly and not wasted.

Anticompetitive Practices and Impact on Specialty Pharmacy

While the number of specialty medications only comprises 2.2 percent of the total number of prescriptions dispensed in the United States, these medications represent approximately 50 percent of overall drug spend in the U.S., which by the end of 2021, was estimated to be about \$301 billion.¹ Distribution for most specialty medications is limited, with payers working to keep them even smaller. The specialty dispensing market is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

Over the years, anticompetitive market practices, including significant reductions in reimbursement to non-affiliated pharmacies² have led to a significant narrowing of pharmacy networks. Timely effort by Congress is needed to address comprehensive pharmacy and patient protections that allow all types of specialty pharmacy businesses to fairly compete and ensure patients have access to the specialty pharmacy of their choice. These comprehensive protections are included in PBM reforms that gained overwhelming bipartisan and bicameral support during the 118th Congress and were packaged together for congressional consideration at the end of the 2024 calendar year.

Background

In 2022, after over a decade of pharmacies facing DIR clawback abuse, CMS finalized a Medicare Part D rule, eliminating a regulatory loophole (exception) that had long permitted the significant growth of pharmacy DIR fees. Beginning in January 2024, CMS required that all pharmacy price concessions – as newly defined for the first time – be applied at the point-of-sale, when a beneficiary receives their prescription. The specific purpose of this change was to ensure that patient out-of-pocket costs are assessed with all concessions applied, giving the

¹ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). *Trends in U.S. Prescription Drug Spending: 2016-2021*. ASPE, U.S. Department of Health and Human Services, 2021.

² The term non-affiliated pharmacies refers to pharmacies that are not owned or controlled by the major health plans or their owned/affiliated Pharmacy Benefit Managers (PBMs).

beneficiary the lowest possible price, and therefore, the lowest possible co-pay. However, the Biden Administration's final Part D rule did not establish any standards or protections to ensure that the negotiated price inclusive of all price concessions that is paid by plans to pharmacies is reasonable to cover a pharmacy's costs.

NASP immediately raised the alarm with CMS and Congress that to prevent ongoing anticompetitive Part D practices, further action was needed.

Congressional Effort to Protect Pharmacies – Any Further Delay is Detrimental to Pharmacy Businesses and Patients

Prior to the 2022 Part D final rule, pharmacy DIR claw back fees significantly harmed specialty pharmacies, forcing many to decline participation in Medicare Part D networks, resulting in limiting beneficiary access and pharmacy choice; causing others to restructure their operations, laying off staff and cutting back on higher-cost inventory; and ending the stocking and dispensing of certain drugs to treat certain conditions. Many specialty pharmacies were forced to sell their pharmacies due to the harm caused by excessive pharmacy DIR claw back fees, with many being purchased by the large vertically integrated pharmacies.

While the final 2022 Part D rule took a first step toward needed reform of DIR, we want the Subcommittee and the Trump Administration to understand the problems that are negatively impacting pharmacy network participation and patient access continue to persist because the Biden Administration's action did not go far enough. Specialty pharmacies have faced significant upfront reimbursement reductions, putting their finances underwater. There is no negotiated rate at the point-of-sale. More patients are being steered to certain PBM-affiliated pharmacies and rates paid to specialty pharmacies have plummeted to record low levels.

During the 118th Congress, a bipartisan effort led by Chairman Carter and others on the Health Subcommittee and Committee leaders in the Senate advanced bills in the House and Senate that would address two key priorities for non-affiliated specialty pharmacies:

- Ensure plans no longer violate the any willing provider statute, ensuring reimbursement to pharmacies and other Part D network terms are reasonable to ensure network participation by pharmacies.
- Eliminate spread pricing practices in Medicaid that reduce payments to pharmacies.

Any Willing Provider Statute - Reasonable Pharmacy Reimbursement to Support Pharmacy Network Participation

CMS currently does not provide regulatory protections for ensuring that pharmacies will not be reimbursed at such a low level that they are unable to remain in a network, and therefore, accessible to patients.

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Over the years, CMS has recognized that any willing provider statutory requirements permit the agency to regulate reasonable reimbursement provisions.³ NASP has commented to CMS that the agency exercise its authority in enforcing this part of the statute to protect pharmacy payments going forward. CMS acknowledged these comments, stating in the final Calendar Year 2023 Part D rule that the agency would consider future rulemaking to address stakeholder concerns over CMS establishing safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement.⁴ However, nothing was done, requiring Congress to act. The House Energy and Commerce Committee and the Senate Finance Committee collaborated to address pharmacies' concerns, negotiating on a legislative proposal at the end of 2024 that would, for the first time, establish real pharmacy protections that would support specialty pharmacy businesses and those across the pharmacy community and the patients they serve. NASP now urges the House Committee on Energy and Commerce Subcommittee on Health to take action out of the gate in the 119th Congress and advance PBM reform legislation to request that the agency begin the rulemaking process to address pharmacies' concerns without further delay.

FTC Action – PBM Reform and Pharmacy Market Concerns

In 2024⁵ and 2025⁶, the Federal Trade Commission (FTC) released reports, following a multiyears long investigation, highlighting significant concerns regarding some PBM activities and their impact on specialty drug access and pharmacies. The FTC's July 2024 report found that pharmacies affiliated with some of the largest PBMs received 68% of the dispensing revenue from specialty drugs in 2023, up from 54% in 2016. The FTC reported that this trend indicates a growing concentration of dispensing revenue among PBM-affiliated pharmacies, potentially limiting access to specialty drugs through non-affiliated pharmacies. This practice results in the steering of patients toward PBM-affiliated pharmacies, thereby limiting competition and choice for beneficiaries.

The FTC highlighted that some PBMs impose unfair, arbitrary, and harmful contractual terms on non-affiliated pharmacies, adversely affecting their financial viability and ability to serve patients and communities.

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³ 79 Fed. Reg. 1918, 1970 (Jan. 10, 2014).

⁴ 87 Fed. Reg. at 27845 (May 2022).

⁵ Federal Trade Commission. Interim Staff Report: Prescription Drug Middlemen: An Analysis of the Role of Pharmacy Benefit Managers in the Pharmaceutical Supply Chain (July 2024). Available at:

https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen

⁶ Federal Trade Commission. Second Interim Staff Report: Prescription Drug Middlemen: An Analysis of the Role of Pharmacy Benefit Managers in the Pharmaceutical Supply Chain (January 2025). Available at:

https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen

The FTC's findings underscore the need for increased transparency and regulatory oversight of PBM practices to ensure fair pricing and access to specialty and retail medications for consumers.

Conclusion

NASP is pleased that with the Subcommittee Chairman's leadership and Ranking Member's support and the additional leadership of the Chairman of the Full Committee, the PBM reforms discussed today can advance, supporting the viability of pharmacies, network competition, and beneficiary access to the specialty pharmacy of their choice. We urge the Subcommittee to insist that action be taken early this year to establish protections to ensure pharmacies are no longer exploited by plans or their partners.

NASP appreciates the opportunity to provide testimony for the record for today's hearing. If we can provide additional information as the Committee proceeds with its effort to advance PBM reforms that protect pharmacies, please call on us.