



NATIONAL
ASSOCIATION
OF SPECIALTY
PHARMACY

**Hearing of the United States Senate Committee on Finance
On
Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and
Taxpayers Hearing Testimony
By
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Chairman Wyden, Ranking Member Crapo and Members of the Committee:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) to express support for the Senate Committee on Finance's efforts to address unfair and anticompetitive practices that narrow the pharmacy marketplace and negatively impact patients. Thank you for holding today's hearing and for all of your efforts to work with specialty pharmacy.

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. With more than 170 corporate members and 3,000 individual members, NASP is the unified voice of specialty pharmacy in the United States.

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. Specialty pharmacies operate as independent pharmacies, academic medical center and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store owned specialty pharmacies, health plan-owned specialty pharmacies and home infusion pharmacies. The medications a specialty pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to brand specialty drugs. Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a limited number of patients and require significant patient education and monitoring on utilization and adherence. 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 \$600 billion. Distribution for most specialty medications is limited, with payers working to keep them even smaller. The market is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

Over the years, anticompetitive market practices, including the escalation in pharmacy DIR claw back fees have led to a significant narrowing of pharmacy networks. Efforts by Congress are needed to address comprehensive pharmacy DIR reform and ensure patient access to specialty pharmacies.

Pharmacy DIR Fees and Implications for Patient Access to Specialty Pharmacies

For many years, Medicare Part D Plans and their Pharmacy Benefit Managers (PBMs) have opted for higher negotiated prices to pharmacies, and in some cases, even preferred a higher net cost drug over a cheaper alternative because they plan to collect retroactive fees from pharmacies and rebates from manufacturers. Receipt of such fees and rebates contributes primarily to plan profits and does nothing to lower drug costs or drug cost sharing requirements for beneficiaries.

Retroactive fees on pharmacies include "Direct and Indirect Remuneration" fees—commonly known as "DIR Fees." Pharmacy DIR fees are collected through retroactive claw back charges on specialty pharmacy providers and other pharmacies months and sometimes a year after the pharmacy has dispensed the drug and after a beneficiary has already purchased the drug at a higher price. The Centers for Medicare and Medicaid Services (CMS) issued a Medicare Part D rule in 2022, showing that pharmacy DIR fees grew from \$8.9 million collected in 2010 to \$9.5 billion in 2020.¹ Fees on pharmacies *grew more than 107,400 percent*² with much of that growth occurring after Part D sponsors stood up so-called DIR "performance-based metrics" for pharmacy payment arrangements. CMS data shows that pharmacies are hardly ever paid for

¹ XIL Consulting. *Policy Alert: Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs*. February 11, 2020. <https://www.xilangconsulting.com/post/policy-alert>.

² 87 FR 1910.

meeting performance metrics and are instead financially penalized in relation to performance measures. For specialty pharmacies, nearly all of the metrics utilized by Plans/PBMs are irrelevant to the drugs specialty pharmacies dispense or services they provide.

In the 2022 Medicare Part D rule, CMS took some initial steps in addressing pharmacy DIR fees by eliminating the regulatory loophole (exception) that has permitted the significant growth of pharmacy DIR fees. Beginning in January 2024, CMS will require that all pharmacy price concessions – as newly defined for the first time – be counted at the point-of-sale, when a beneficiary receives their prescription. The specific purpose of this change is to ensure that patient out-of-pocket costs are assessed with all concessions applied, giving the beneficiary the lowest possible price, and therefore, the lowest possible co-pay. However, **the 2022 Part D rule did not eliminate the practice of pharmacy DIR claw back fees, allowing Plans to continue to impose claw backs and the rule did not establish any standards or protections to ensure that the negotiated price inclusive of all price concessions paid to pharmacies is reasonable to cover a pharmacy's costs.**

NASP supports CMS' effort to reduce prescription drug prices for Medicare Part D beneficiaries by removing the reasonably determined regulatory exception and adopting a revised definition of "negotiated price" for a covered Part D drug that includes all pharmacy price concessions, requiring them to be applied at the point of sale. It is our hope that doing this will better align marketplace competition with the interests of Medicare beneficiaries and lead to lower out-of-pocket costs. However, NASP is concerned that the final rule did not address comprehensive DIR reform, which is necessary to meet patient needs. To prevent anticompetitive DIR practices, we request further action by Congress.

Impact of the Part D Rule on Beneficiary Access to Pharmacies

Over the years, pharmacy DIR claw back fees have significantly harmed specialty pharmacies forcing many to decline participation in Medicare Part D networks, resulting in limiting beneficiary access and pharmacy choice; restructuring 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. Other specialty pharmacies have been forced to sell their pharmacies or be acquired due to the harm caused by excessive pharmacy DIR claw back fees.

While the Calendar Year Part D rule is viewed as a first step toward needed pharmacy DIR reform, we want the Committee and CMS to understand the problems that are negatively impacting pharmacy network participation and patient access persist. Specialty pharmacies have faced significant 2023 upfront reimbursement reductions and continue to see terms in their contracts that say their pharmacies will continue to be subject to retroactive DIR claw backs.

Congress can help address these significant concerns by taking action to pass legislation that

would allow for comprehensive pharmacy DIR reform. **NASP recommends that the Senate Finance Committee work to advance legislation that will:**

- **Encourage CMS to ensure pharmacy reimbursement does not violate the any willing provider statute and is reasonable to ensure network participation by pharmacies;**
- **Require the standardization and oversight of Part D pharmacy performance measures; and**
- **Ensure pharmacies are provided pricing transparency.**

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

NASP is very concerned that the Calendar Year 2023 Medicare Part D rule continues to permit post-sale pharmacy price concessions. That allowance in addition to the continued significant reductions to the “negotiated price” pharmacies receive, could continue to escalate pharmacy acquisitions and closures. CMS provides no 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.

In other Medicare Part D rules issued 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 Considering that the final rule did not address the impact that retroactive DIR fees have had on pharmacy viability and beneficiary access to pharmacies, we are pleased that CMS acknowledged the need for this long-overdue rulemaking, and we urge the Senate Finance Committee to request that the agency begin the rulemaking process immediately through legislative action or direct request.

Pharmacy Performance Evaluations and Metrics

The final Calendar Year 2023 Part D rule continues to permit contract agreements between pharmacies and plans that allow for performance-based evaluations to determine price concessions and/or incentive payments. Also, the final rule provided no incentives for plans/PBMs to offer incentive-based opportunities to pharmacies and the rule did not establish any process for standardizing pharmacy performance metrics or any parameters to ensure pharmacy performance evaluations are appropriate, fair, and relevant based on the drugs a pharmacy dispenses and the services a pharmacy provides. In the absence of these important

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

⁴ 87 Fed. Reg. at 27845 (May 2022).

issues being addressed by CMS, pharmacy cannot expect or rely on incentive payment opportunities to address reimbursement concerns and there is serious concern that metrics will continue to be abused in an effort to claw back fees from pharmacies.

NASP continues to advocate for the standardization of pharmacy performance-based metrics. We also want to ensure that there are CMS requirements for fair pharmacy performance evaluation, and regulatory incentives for plans to offer pharmacy performance-based agreements to pharmacies. We believe it is important that CMS immediately work with pharmacy stakeholders to conduct a review to ensure pharmacy performance evaluations are fair and are associated with Part D plans' Star Ratings, thus aligning incentives for Part D plans and pharmacies toward better quality, equity, and reductions in preventable spending for beneficiaries.

Specifically related to action we believe CMS can and must take immediately, in the 2023 Part D final rule, CMS stated the following:

We addressed reporting of pharmacy performance measures to CMS in the January 2021 final rule (86 FR 5864). In the January 2021 final rule, we finalized a proposal to give CMS the authority to establish a Part D reporting requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. This authority to establish a reporting requirement is effective January 2022; however, the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package.⁵

CMS' delay in exercising its authority to establish a Part D reporting requirement for Part D sponsors to disclose the pharmacy performance measures they use is especially disconcerting, given the concerns expressed by the pharmacy community and CMS' reporting that such measures have directly resulted in the substantial growth of pharmacy DIR fees. We implore the Committee to address this delay and urge CMS action to conduct this oversight. **We also urge the Committee to request that CMS work in collaboration with the Federal Trade Commission on this review, as the FTC considers anticompetitive market practices impacting pharmacies that are not affiliated with plans or PBMs.**

Part D Bidding Process

Under the current Medicare Part D bidding process, Plans are encouraged to underestimate their DIR fees, which they submit to determine the total bid amount, the direct subsidy payment the Plan will receive from Medicare, and the premiums that beneficiaries pay. If a Plan underestimates their pharmacy DIR fees, they can keep subsidy overpayments up to five

⁵ 87 Fed Reg. at 27704 (May 2022)

percent, this process has encouraged Plans to underestimate their DIR fees to make a profit.⁶ Current regulations concerning the bid and reconciliation processes do not meaningfully protect unaffiliated specialty pharmacies (those not owned by Plans/PBMs) from post-sale price concessions or unreasonably low reimbursement.

The overbidding (and underestimation of DIR fees) directly harms beneficiaries by inflating the premiums they pay. This is because CMS calculates premiums based on the Plan's bid amount. CMS uses approved Plan bids to calculate a national average monthly bid which determines CMS's subsidy payments to Plans and a national base beneficiary premium.⁷ The base premium is then used to determine the actual beneficiary premium for each Plan.⁸ For example, if a Plan's bid exceeds the national average bid, its beneficiaries are responsible for the excess through a higher monthly premium which the beneficiary must pay. The bid-reconciliation profit incentive harms: beneficiaries through inflated premiums, pharmacies through unreasonable post-sale price concessions that are used to generate overpayments, and taxpayers through retained Medicare overpayments through reconciliation.

As the pharmacy negotiated price/DIR provisions of the Calendar Year 2023 Part D rule go into effect in 2024, **NASP urges the Committee to require CMS to closely review plan bid estimations and the reporting of pharmacy DIR and other fees placed on pharmacies. CMS must disincentivize plans from underestimating prospective DIR during their bid submissions and should be overseeing this process to understand to what extent plans are retaining overpayments obtained from DIR and administrative or other fees that are in excess of their DIR bid estimates. Ultimately eliminating this practice should be a priority focus of Congress and CMS.**

Transparency Regarding Pharmacy Claims Processes

In the 2023 Part D Rule, CMS notes that one of the purposes of the regulations addressing pharmacy negotiated price and remuneration is to foster price transparency and consistency among pharmacies with respect to their reimbursement.⁹ The 2023 Part D rule is intended to require Plans to calculate the lowest possible reimbursement to lower the patient's out-of-pocket costs; however, the Rule does not explicitly state whether the lowest possible price will be disclosed to pharmacies. Such information is of critical importance if CMS' goal of ensuring transparency with respect to pharmacy reimbursement is to be recognized. This data will be critical to business planning for specialty pharmacies who today and going forward have no understanding how or to what extent their reimbursement will be altered after the point of sale.

⁶ Neither the Bid Pricing Instructions nor Part D bid regulations *strictly* prohibit Plans from under-projecting expected DIR fees.

⁷ 42 C.F.R. § 423.279(a) (2021).

⁸ 42 C.F.R. § 423.286 (2021).

⁹ Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1914.

NASP requests that the Committee work with CMS to address the lack of clarity in the final 2023 Part D rule regarding pharmacy claims processes and information transparency to pharmacies. To ensure full transparency for pharmacies at the point-of-sale, we request that CMS clarify that Part D plans must provide a mechanism for pharmacies to know the lowest possible reimbursement at the point-of-sale. Part D plans must ensure that the appropriate fields are included and populated in the claims response so that this information is provided to the pharmacy.

Conclusion

NASP is pleased that with the Chairman's support and the efforts by the Senate Finance Committee on a bipartisan basis, initial efforts have been made to address pharmacy DIR fees and needed Part D reforms to reduce beneficiary drug costs. **We now want to work with the Committee and ultimately CMS to achieve needed comprehensive pharmacy DIR reform that will support the viability of pharmacies, network competition, and allow for beneficiary access to the pharmacy of their choice.** We urge the Committee to take additional action this year to establish protections as detailed in this testimony to ensure pharmacies are no longer exploited by Plans or their partners, particularly as the Calendar Year 2023 Medicare Part D rule addressing negotiated price and pharmacy remuneration (DIR fees) goes into effect in January 2024.

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 review of anticompetitive pharmacy market practices, please contact our organization.