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Statement for the Record
National Association of Specialty Pharmacy
Hearing before the Energy and Commerce Health Subcommittee
on
Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs
May 4, 2021

The National Association of Specialty Pharmacy (NASP) is pleased to submit a statement for the record to the House Energy and Commerce Committee's Subcommittee on Health hearing on "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs." NASP supports the goals of this hearing, including its focus on identifying opportunities to lower out-of-pocket costs for beneficiaries under Medicare Parts B and D and supporting patient access to the medications they need.

NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading specialty pharmacies and practicing pharmacists, nurses and technicians to small and mid-size pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies. NASP's members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs for conditions that require complex and often costly drug treatments, such as cancer, multiple sclerosis, cystic fibrosis, hemophilia, and HIV/AIDS. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies.

Pharmacy DIR Reform – Reducing Drug Costs for Seniors and Medicare

The Committee must ensure that any effort to advance legislation to address drug pricing reform include legislation to end retroactive pharmacy clawback fees – known as DIR fees – and recognize that these fees increase beneficiary and government drug costs.

NASP's members have seen dramatic growth in the collection of pharmacy Direct and Indirect Remuneration (DIR) fees by Pharmacy Benefit Managers (PBMs) since 2012, including last year during the public health emergency. Plan sponsors can opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative because any DIR received that is above the projected amount factored in a plan's

bid contributes primarily to plan profits, not lower premiums.[1] This ultimately increases Part D program costs and shifts costs from the sponsor to the beneficiaries and the overall Part D program, as beneficiaries are pushed into catastrophic coverage sooner than they otherwise would be.

Specialty pharmacies face significant financial uncertainty with DIR fees, as their actual reimbursement rate cannot be determined until well after they have dispensed the medication. Oftentimes when the reimbursement is reconciled, it is far less than the actual cost of the drug, which is further complicated by the cost of the requisite services needed to support the patient's journey on the drug. This situation threatens the ability for specialty pharmacies to remain network providers, risking access to pharmacies for beneficiaries.

CMS data shows pharmacy price concessions grew more than 45,000 percent between 2010 and 2017 with much of that growth occurring after Part D sponsors stood up so-called "performance-based" pharmacy payment arrangements that only serve to institute sizeable reductions in pharmacy reimbursement and zero savings for beneficiaries. The measures used today by plans and PBMs are often arbitrary and have primarily focused on drugs and disease states that specialty pharmacies do not manage and cannot control. For example, specialty pharmacies that dispense medication and provide patient care services for conditions like cystic fibrosis, hemophilia, or multiple sclerosis encounter DIR-related pharmacy performance scores associated with conditions like diabetes and cardiovascular disease applied against them with the purpose of reducing their reimbursement in the form of claw back fees. These measures have been used with no oversight, leading to the absence of transparency and the continued growth of pharmacy DIR fees.

As a result of DIR fees, Medicare beneficiaries pay far more in cost-sharing and a larger share of the actual cost of the drug when purchasing their medications. The drug price at the time of purchase does not reflect additional payment reductions that are made to a pharmacy by the plan sponsor/PBM. Beneficiaries never receive a discount or financial adjustment to their drug costs from fees collected by plan sponsors/PBMs after the point-of-sale. DIR fees ultimately shift financial liability away from the Part D Plan sponsor to the beneficiary, to the Medicare program and ultimately, to taxpayers. Medicare beneficiaries with high prescription drug costs often discontinue their drug regimens because of higher out-of-pocket costs. For patients with specialty conditions like multiple sclerosis, cancer, cystic fibrosis, and HIV/AIDS, disruption in treatment results in poorer health outcomes and significant health complications, costing Medicare more through avoidable emergency department visits and hospital admissions. **Pharmacy DIR reform would lower a patient's direct costs when they receive their medications, encouraging patients to begin their life saving therapies on time and as prescribed.**

[1] 82 Fed. Reg. 56420.

CMS estimates that beneficiaries would save $7.1 to $9.2 billion over 10 years from reduced cost-sharing if pharmacy price concessions were included in negotiated price.[2] NASP believes the savings could be considerably higher for those beneficiaries who are prescribed higher cost drugs to manage their care, particularly those that have limited alternative drug treatment options, such as when a generic or another lower cost clinically comparable drug option is unavailable or not clinically appropriate to address the specialty condition being managed.

CMS has stated that the variation in the treatment of price concessions by the plan sponsors may have a negative effect on the competitive balance under Medicare Part D– resulting in unnecessary spending by Medicare and its beneficiaries. Specialty pharmacies and other pharmacies have found themselves in a no-win situation, being disproportionately affected by so-called performance measure cuts they have no ability to affect. Non-transparent and often excessive pharmacy price concessions in the form of claw backs well after the point-of-sale, limit a specialty pharmacy's ability to remain in-network. Less market competition ultimately results in higher costs to the Medicare program and restricted patient access for beneficiaries, especially specialty patients with complex medication needs that often need the care management provided by specialty pharmacies.

NASP urges the Subcommittee to advance legislation that will eliminate retroactive pharmacy DIR fees, reducing beneficiary drug costs and implementing a system of fairly assessing pharmacy performance. NASP specifically recommends the following legislative actions be taken up by the Subcommittee and/or Full Committee as it seeks to address drug pricing reform:

- **Redefine "negotiated prices" to include all pharmacy price concessions (including all pharmacy DIR fees) at the point-of-sale.** Making this change will reduce beneficiary cost sharing and eliminate retroactive pharmacy price concessions, providing increased price transparency for patients and pharmacies.
- **Have the Department of Health and Human Services (HHS) work with stakeholders to establish and have HHS oversee the creation of standardized pharmacy performance metrics that are calculated and reimbursed separate and apart from the negotiated drug price at the point of sale** to ensure any incentive payments tied to metrics: (1) do not increase costs for beneficiaries; and (2) appropriately assess the actual performance of a pharmacy in a manner that is specific to the pharmacy type (including specialty pharmacy), drugs dispensed, and disease states being managed.
- **Have HHS establish a definition of specialty pharmacy** to ensure that performance metrics are appropriate by pharmacy type.

[2] 83 Fed. Reg. 62154.

Conclusion

NASP very much appreciates the Subcommittee convening this hearing and its continued desire to address the cost of drugs, as well as its ongoing engagement with the specialty pharmacy community. We urge the Subcommittee to ensure that any drug pricing reform initiative include pharmacy DIR reform. NASP looks forward to continuing to work with the Subcommittee to support policy reforms that will reduce costs to Medicare beneficiaries and the broader Medicare program for specialty drugs and ensure access to the specialty drugs and services needed to improve health and reduce overall healthcare costs. Please contact Sheila Arquette at sarquette@naspnet.org with any questions or if additional information is needed.