NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
300 New Jersey Ave., Suite 900
Washington, DC 20001
www.naspnet.org

September 25, 2019

The Honorable Anna Eshoo
Chairman
U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Health
Washington, DC 20515-6115

The Honorable Michael Burgess
Ranking Member
U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Health
Washington, DC 20515-6115

RE: Testimony before the House Energy and Commerce Committee's Subcommittee on Health hearing on "Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans"

Dear Chairwoman Eshoo and Ranking Member Burgess:

The National Association of Specialty Pharmacy (NASP) is pleased to provide a statement for the record to the House Energy and Commerce Committee's Subcommittee on Health hearing on "Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans." NASP shares the Subcommittee's goals of lowering out-of-pocket costs for beneficiaries and taxpayers under Medicare Parts B and D, improving the transparency of drug pricing, and ensuring a competitive balance under the Part D program. We want to acknowledge and thank the Subcommittee and the Full Committee for their ongoing effort to examine and consider issues that affect specialty patients and the specialty pharmacies that work to address and manage their complex health care needs.

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. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by, or in the process of specialty pharmacy accreditation 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. NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists 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; and technology and data management companies. With over 110 corporate members and 1,800 individual members, NASP is the unified voice of specialty pharmacy in the United States.

NASP supports the Subcommittee's and Full Committee's goals of reducing out-of-pocket costs and ensuring that policies are in place to reduce early beneficiary entry into the catastrophic phase of Medicare, such is often the case today. However, we continue to urge the Subcommittee and full Committee to consider bipartisan parallel legislative options to address this same concern that could work in tandem with proposals to cap out of pocket costs and reduce the government's liability under Medicare Part D.

Policy Reform Needed to be Addressed by the Committees - Background

The Committees should include in any drug pricing reform legislation policy reforms 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. Plan sponsors sometimes 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.

CMS has highlighted the growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all DIR.[2] This disparity is occurring partly because of the post adjudication of "performance-related" fees that some PBMs are collecting from pharmacies, especially specialty pharmacies that are pointedly impacted by this practice. **Instead of focusing on clinical outcomes, these DIR fees are typically assessed months after claims are submitted and reimbursed, and are based on wholly inapplicable performance or quality metrics tied to drugs that are NOT dispensed by specialty pharmacies and disease states not being managed by specialty pharmacies. Often times, such broader pharmacy measures are not even appropriate for pharmacy evaluation, as the pharmacy cannot influence the measure (e.g., generic pricing performance; formulary compliance).**

DIR fees ultimately shift financial liability away from the Part D Plan sponsor to the beneficiary, to the Medicare program and ultimately, to taxpayers. Specialty pharmacies face significant financial uncertainty, 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

[1] 82 Fed. Reg. 56420.
[2] 82 Fed. Reg. 56419–56428.

requisite services needed to support the patient's journey on the drug. This situation threatens the ability for specialty pharmacies – particularly independent specialty pharmacies that simply do not have the ability to offset lost revenues or costs with other portions of their businesses – to remain network providers, risking access for beneficiaries.

CMS data shows pharmacy price concessions grew more than 45,000 percent between 2010 and 2017[3] 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. Plan sponsors and their PBMs collected such fees by interpreting the current regulatory definition of "negotiated prices" to exclude DIR-related pharmacy price concessions at the point-of-sale. As a result, 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. **CMS characterizes the current treatment of price concessions under Part D as a system that has resulted in "distorted incentives" for Part D sponsors. The Plan Sponsors and PBMs clawing back DIR fees are the only ones to benefit by the growing fees, collecting profit on any DIR fees that exceed those they initially included in plan bids. Such profit is not reported to the agency and is never utilized to reduce premium or other cost-sharing for beneficiaries.**

As pharmacy price concessions increase on gross drug costs and are applied after the point-of-sale, specialty patients are paying higher and higher cost-sharing (copays and coinsurance). These beneficiaries pay far more upfront for the cost of their drugs and are forced into the catastrophic phase of Part D much sooner than if pharmacy price concessions were accounted for at the point-of-sale. Specialty pharmacies have seen first-hand how higher cost-sharing impedes beneficiary access to medications. For specialty patients, missing doses or stopping therapy altogether often results in serious setbacks in treatment, and increased visits to emergency departments. While some of the legislative proposals being considered by the Subcommittee would seek to address how quickly seniors enter the catastrophic phase of Part D by capping cost sharing, it's important to note that DIR reform is still needed to reduce beneficiary drug costs. **While the policies to adjust when a senior enters the catastrophic phase could support improvements in long-term medication access and adherence, the policies do not address the upfront cost of obtaining a newly prescribed specialty medication and ensuring such drugs are not cost prohibitive and result in the beneficiary abandoning the therapy before even starting it. Pharmacy DIR reform would lower a patient's direct costs at the counter at first pick-up, encouraging patients to begin their life saving therapies on time and as prescribed.**

[3] 83 Fed. Reg. 62174.

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.[4] 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 highlighted that PBMs have been recouping increased sums from network pharmacies after the point-of-sale for "poor performance" at a rate far greater than those paid to network pharmacies for "high performance." For specialty pharmacies, there has never been an upside in regard to the application of such PBM performance metrics. **Since certain plan sponsors and PBMs began to utilize their own select metrics that do not undergo a certification process overseen by CMS specialty pharmacies have found themselves unfairly subjected to metrics that are largely unrelated to the drugs the pharmacies dispense, conditions they treat, or the services they provide.** 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.

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. Independent 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 independent specialty pharmacies.

NASP Legislative Recommendations for Subcommittee and Full Committee Consideration – Support H.R. 1034, PHAIR Pricing Act of 2019

NASP urges the Subcommittee to include in their legislative effort, H.R. 1034, the PHAIR Pricing Act of 2019. This bipartisan bill would eliminate retroactive pharmacy DIR fees, reducing beneficiary drug costs and implementing a system of fairly assessing pharmacy quality. The provisions included in the PHAIR Pricing Act fall seamlessly in line with other Subcommittee objectives to reduce out-of-pocket drug spending and to protect seniors from prematurely falling into the coverage gap. NASP specifically recommends the following legislative actions be taken up

[4] 83 Fed. Reg. 62154.

by the Committee through inclusion of the bipartisan PHAIR Pricing Act in any drug pricing bill to be considered by the Subcommittee and/or Full Committee:

- **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.
- **Ensure reasonable reimbursement to pharmacies participating in the Medicare Part D program so that the payment received is not less than a pharmacy's cost to obtain medications, dispense and address related services, which are not separately paid for.** Reimbursement below cost forces pharmacies out of networks and even out of business, limiting beneficiary access to the pharmacy of their choice and needed for their specialty conditions. PBMs that have their own specialty pharmacy must not be permitted to provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share.
- **Have the Department of Health and Human Services 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 quality performance of a pharmacy in a manner that is specific to the pharmacy type (including specialty pharmacy), drugs dispensed, and disease states being managed.
- **Establish a definition of specialty pharmacy** to ensure that performance metrics are appropriate by pharmacy type – with specialty pharmacy defined as a type, similar to how retail is defined in regulation.

Conclusion

NASP very much appreciates the Subcommittee's efforts to advance drug pricing reform legislation and its ongoing engagement with the pharmacy community. We urge the Subcommittee and Full Committee to include in any drug pricing reform initiative pharmacy DIR reform to move all pharmacy DIR to the point of sale and establish a new system for pharmacy quality/performance measures. NASP looks forward to continuing to work 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. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila M. Arquette, R.Ph.
Executive Director