January 29, 2019

The Honorable Elijah E. Cummings, Chairman
The Honorable Jim Jordan, Ranking Member
United State House of Representatives
Committee on Oversight and Reform
2471 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Cummings and Ranking Member Jordan,

ASHP (American Society of Health-System Pharmacists) respectfully submits the following letter to the House of Representatives Committee on Oversight and Reform regarding the hearing on "Drug Pricing in America: A Prescription for Change, Part I."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.SafeMedication.com.

ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities. ASHP has been proactively addressing and tackling challenges related to drug pricing on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, our members, and the entire healthcare system.

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. CSRxP has developed a policy platform promoting market-based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product.

ASHP along with American Hospital Association (AHA), and the Federation of American Hospitals (FAH), recently released a report on the impact the cost of and access to prescription drugs are putting strains on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal years (FY) 2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7% while inpatient drug spending per admission increased by 9.6% between FY2015 and FY2017.
- A very large percentage increases (over 80%) of unit price were seen across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in four hospitals had to cut staff to mitigate budget pressures.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from our members that sudden, inexplicable price increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent — and are occurring on a nationwide basis.

In this letter, we address five additional issues as they relate to drug pricing: competition, Risk Evaluation and Mitigation Strategies (REMS), Direct and Indirect Remuneration (DIR Fees), importation of prescription drugs, and the 340B Drug Pricing Program.

COMPETITION

In particular, ASHP would like to learn more about the marketplace dynamics that could contribute to this issue, as we have worked diligently on the issue of drug shortages for well over a decade. Although drug shortages are caused by a number of factors, we have observed that drugs in short supply made by only one or two manufacturers often result in higher-than-normal prices for these drugs when they are available. If, for example, there is a lack of competition in the generic marketplace, we urge the committee to look at ways to stimulate more marketplace presence. ASHP supports bills such as S. 64, the "Preserve Access to Affordable Generics and Biosimilars Act." The bill would potentially increase competition by prohibiting companies from engaging in "pay-to-delay" tactics to stifle generic and biosimilar entry into the market.

RISK EVALUATION AND MITIGATION STRAGETY (REMS)

ASHP recognizes that there may be limited circumstances in which constraints on the traditional drug supply system may be appropriate for reasons of patient safety, often implemented under a manufacturer-driven REMS. However, we believe that these requirements are not appropriate to artificially inflate drug prices, nor should they interfere with the professional practice of pharmacists, physicians, nurses, and other providers. We believe that there may be current cases in which a

manufacturer-driven REMS using restricted distribution is causing higher prices for those drugs, having adverse effects on patient access, and delaying treatment. In some cases, there may be evidence to suggest that the use of restricted or limited distribution channels has resulted in the inability of a potential competitor to acquire enough of a drug to conduct the required testing to bring a generic competitor to market. We recommend that Congress require the Food and Drug Administration (FDA) to investigate restricted distribution under a REMS program as a potentially limiting factor in accessibility to critical medications.

DIRECT AND INDIRECT REMUNERATION FEES (DIR Fees)

DIR fees are a growing nationwide concern among pharmacies that dispense medications in a retail pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for CMS to account for the true cost of the drug dispensed, including any manufacturer rebates. Often these rebates were unknown until the drug was dispensed and the claim adjudicated. Moreover, the fees themselves, which are often arbitrary in nature, have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals in the tens of thousands of dollars.

Recently, a concerning trend has emerged where pharmacy benefit managers (PBMs) have begun to charge DIR fees to their pharmacy providers. Under this scenario, PBMs are applying their own plan performance measures as a way to assess fees on pharmacies. This is problematic for the following reasons:

- It is an arbitrary and unintended application of measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure medications or medications used to treat diabetes. These measures were never intended to be applied to specialty medications or to other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.
- Pharmacy providers are essentially being penalized with backdoor fees without any requirement that PBMs define, justify, or explain these charges to providers and to CMS.

DIR fees assessed on pharmacies providing specialty medications have been especially hard-hit, due to the fee structure. Fees could be a flat rate of per dollar per claim or a percentage (typically 3–9%) of the total reimbursement per claim. Using the percentage-based structure, the fees would increase markedly for specialty drugs, which are typically much more expensive than maintenance medications, sometimes resulting in thousands of dollars. A 9% fee on a drug costing $100,000 is $9,000. Additionally, these fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment.

The result of imposing DIR fees has led to higher cost-sharing responsibilities for Medicare beneficiaries, which have, in turn, caused more of these beneficiaries to enter the Part D donut hole, where the beneficiary is solely responsible for the cost of the drug. Along with the higher costs absorbed by the

beneficiary, adherence rates tend to be lower among Medicare beneficiaries who are in the donut hole and may not have the financial resources to pay for their medications. This is in stark contrast to the very reason DIR fees targeting manufacturer rebates were created — so that savings could be passed on to the beneficiary.

Pharmacies are not alone in their concern. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited those fees as contributing to increased drug costs, which, in turn, increased beneficiary out-of-pocket spending and Medicare spending overall. Although CMS stopped short of prohibiting the fees, the public concern expressed by CMS is a rare occurrence. Additionally, questions remain as to whether Part D plan sponsors have the authority to assess these fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Part D statute or corresponding CMS regulations.

ASHP's policy is as follows:

> *To advocate that payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,*
>
> *To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.*[1]

DRUG IMPORTATION

A number of bills introduced in the Senate, S. 61, the "Safe and Affordable Drugs from Canada Act of 2019," and S. 97, the "Affordable and Safe Prescription Drug Importation Act," would allow for importation of prescription drugs by individuals, wholesalers, or pharmacies. ASHP does *not* support these bills, as they put patients at unnecessary risk. ASHP policy is as follows:

> *To advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further,*
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> *To urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.*[2]

[1] ASHP Policy 1814, *Direct and Indirect Remuneration Fees*
[2] ASHP Policy 0413, *Importation of Pharmaceuticals*.

We urge the committee to carefully consider how any bill that includes an importation policy could negatively affect a drug's pedigree and potentially allow adulterated and/or counterfeit drugs into the supply chain. Importation is in direct conflict with the Drug Supply Chain Security Act passed by Congress in November 2013, which sought to better track and trace drugs through the supply chain.

THE FEDERAL 340B PROGRAM

For 25 years, the federal 340B program has allowed safety-net hospitals "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This program has been essential to expanding access to lifesaving prescription drugs and comprehensive healthcare services to low-income and uninsured individuals, at no cost to the federal government. The federal 340B program is not causing high drug prices. The program accounts for less than 5 percent of annual drug purchases in the United States while safety-net providers give 30 percent of the care. Given the increasingly high cost of pharmaceuticals, the federal 340B program provides critical support to the entities eligible to participate in the program.

The federal 340B program enables these hospitals to serve their communities by providing vital uncompensated care such as:

- Free or lower cost medications to patients.
- Programs to increase medication adherence.
- Caring for more patients.
- Screenings and preventive care services.

The federal 340B program is under threat, especially as a result of a recent change in Medicare payment policy that reduces payment from Average Sales Price plus 6 percent to Average Sales Price minus 22.5 percent. Cuts of this magnitude undermine the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities.

CONCLUSION

ASHP thanks the Senate Committee on Finance for holding its hearings on this important topic, and we look forward to learning more about the causes and potential solutions to this issue. Additionally, ASHP

remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

Again, ASHP thanks the committee for its work on this public health crisis. As the committee continues its work, we encourage you to view ASHP as a resource on this critical issue. Please contact me with any questions at 301-664-8692 or at kthompson@ashp.org.

Sincerely,

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