Full Senate Committee on Health, Education, Labor, and Pensions

Hearing on: "The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II"

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Statement for the Record
Submitted by ASHP

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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Senate Committee on Health, Education, Labor, and Pensions (HELP) hearing on "The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 44,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 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.

While we have always placed high importance on safe and effective use of medications, their proper use becomes even more important as the price of drugs continues to increase. Proper medication adherence is essential when high-cost drugs and biologics can cost hundreds of thousands of dollars per course of treatment.

Pharmacists are the medication experts on the interprofessional patient-care team. Pharmacists have extensive education and training specifically on optimizing the use of medications and decreasing patient costs by focusing on safe and appropriate medication use. Pharmacists provide such services as

comprehensive medication therapy management; initiating and modifying drug therapy and ordering laboratory tests; medication reconciliation, discharge planning, chronic care management, and transitions of care to name only a few.

While many private payers and state Medicaid programs are increasingly turning to pharmacists to reduce the cost of care, the federal Medicare statute does not explicitly recognize pharmacists or cover the services that they provide. These services can have significant impact where patients lack adequate medical care such as in federally designated Medically Underserved Areas (MUAs). For this reason, ASHP strongly supports S.109, the "Pharmacy and Medically Underserved Areas Enhancement Act," a bipartisan bill that will improve patient care and health outcomes, and will ultimately reduce costs under Medicare Part B. The legislation was introduced in January by Senators Chuck Grassley (R-IA), Bob Casey (D-PA), Susan Collins (R-ME), and Sherrod Brown (D-OH). S. 109 currently has 45 bipartisan co-sponsors, and a similar version in the 114th Congress had 51 bipartisan co-sponsors.

The bill would allow Medicare patients in MUAs to better use the services of pharmacists subject to individual state scopes of practice. Pharmacists, especially those in medically underserved communities, are often the most accessible healthcare professional and are an obvious solution to the current shortage in primary-care providers. ASHP recognizes the support by many of the members of this committee and urges passage of S. 109 in this Congress.

ASHP is also 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 has been participating in a series of stakeholder meetings with key members of Congress to explore legislative solutions to the problem. We are encouraged that the Senate HELP Committee is continuing the work it began on June 13, 2017, when the committee first convened on this topic.

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. ASHP is eager to learn more about why these price spikes are occurring and to explore potential policy options and market-based solutions that may exist to prevent or minimize the likelihood of this occurring in the future. In this statement, we address four important issues as they relate to drug pricing: competition, Risk Evaluation and Mitigation Strategies (REMS), Direct and Indirect Remuneration (DIR Fees), and importation of prescription drugs.

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. 124,

the “Preserve Access to Affordable Generics Act” of 2017, and S. 297, the “Increasing Competition in Pharmaceuticals Act” of 2017. Both bills would potentially increase competition by either prohibiting companies from engaging in “pay-to-delay” tactics to stifle generic entry or expediting reviews of a generic drug where there are currently no generic alternatives.

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. For this reason, we support bills such as S. 974, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017.” 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. In addition, we urge the committee to ask the pharmaceutical industry, represented here today by the Pharmaceutical Research and Manufacturers of America (PhRMA), the extent to which they are aware of this practice and their policy position on the issue.

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. In general, it was originally a way for CMS to account for manufacturer rebates.

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 dispensing covered Part D drugs. 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. For these reasons, we support S. 413, the "Improving Transparency and Accuracy in Medicare Part D Spending Act," which would eliminate the ability of Part D plan sponsors to retroactively reduce payment to pharmacies under the Part D program.

DRUG IMPORTATION

A number of bills introduced in the Senate, including two before the committee — S. 92, the "Safe and Affordable Drugs from Canada Act of 2017," and S. 469, the "Affordable and Safe Prescription Drug

Importation Act" of 2017, 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.*[1]

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.

Conclusion

ASHP thanks the Senate HELP Committee for continuing 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.

[1] ASHP Policy 0413, *Importation of Pharmaceuticals*.