Issue Brief

ASHP Analysis of the Administration's Drug Pricing Blueprint

On May 11, President Donald Trump unveiled the outline of his "American Patients First" blueprint (the "Blueprint") to address high drug prices. The Blueprint identifies four key challenges that underpin drug pricing: 1) high list prices, 2) overpayments due to lack of negotiation, 3) high out-of-pocket costs, and 4) "foreign free-riding," which is the term used in the Blueprint to refer to the fact that some other countries pay substantially less for drugs than Americans.

I. What Is the Administration Proposing, and When Will We See Changes?

In response to these challenges, the Administration proposes to focus on improving competition and negotiation, incentivizing lower list prices, and lowering out-of-pocket costs. **The Blueprint does not contain any proposals for direct negotiation of drug prices by Medicare and Medicaid with manufacturers, and it does not target the prices of drugs directly beyond suggesting incentives to induce manufacturers to decrease prices voluntarily**. Instead, the Blueprint options are largely centered on reducing the consumer burden of drug pricing. Some of the proposals can be implemented directly by the U.S. Department of Health & Human Services (HHS) and its subagencies, but others are still under consideration and will be the subject of requests for public comment and stakeholder feedback (known as requests for information [RFIs]). **It is important to note that because all of the proposals require regulatory action, which is time-consuming and requires notice and comment in most (if not all) cases, we are unlikely to see immediate action on most of these proposals**. By some estimates, it may be several years before the proposals can be fully vetted and implemented in a way that reduces prices for consumers.

The Blueprint includes dozens of policy proposals that will impact every stakeholder in the drug-pricing supply chain, from manufacturers to patients. The Blueprint contains thumbnail sketches of policy options rather than detailed proposals. The details of how a policy is implemented can fundamentally alter the impact of that policy; thus ASHP's support of drug-pricing policy proposals will be determined on a case-by-case basis and will be contingent on the actual implementation process for those proposals. ASHP plans to carefully monitor, and assertively and comprehensively address, proposals as federal agencies and Congress consider them.

II. ASHP's Stance on the Blueprint's Policy Proposals

In general, ASHP is pleased to see proposals focused on increasing generic competition, reducing patient cost-sharing, and improving transparency. However, we are deeply concerned by the Administration's targeting of the 340B Drug Pricing Program for further cuts, as well as its suggested expansion of site-neutral payment provisions. Below, we highlight the most promising provisions for members and their patients, and we identify the provisions that may be detrimental to members and their patients.

A. Promising Proposals

A number of the Blueprint's policy proposals align with ASHP's policies on drug pricing. In particular, we believe ASHP can be supportive of the following initiatives:

- Reducing Patent Gaming: Specifically, the Blueprint notes that Risk Evaluation and Mitigation Strategies (REMS) should not be used to prevent generic competition. This assessment is in line with the CREATES Act, which ASHP supports. Ideally, we would hope to see additional proposals that incentivize generic competition, particularly for drugs that are currently in shortage or have been in shortage in previous years. Because the policies in the Blueprint are in outline form, ASHP believes there will be an opportunity to advocate for more robust versions of some of these policies.

- Improving Biosimilar Access: The Blueprint notes that the U.S. Food and Drug Administration (FDA) is seeking feedback on how to improve access to, and development of, biosimilars. Although no concrete proposal is included, ASHP would likely support efforts to improve clinician and patient education regarding biosimilars, to update *The Purple Book*, and to incentivize interchangeability.

- Experimenting with Value-Based Purchasing in Federal Programs: ASHP's support for this policy will hinge on how the policy is implemented. In general, we support efforts to innovate around purchasing, particularly when it reduces out-of-pocket costs for patients. However, we have opposed large-scale demonstrations that fundamentally change purchasing without sufficient stakeholder input or notice, such as the Part B payment demonstration that was proposed, and subsequently withdrawn, under the previous administration.

- Allowing More Substitution in Medicare Part D: The Blueprint includes this provision as a longer-term goal and it is in line with ASHP's policy on substitution. Again, this is a policy where our support will depend on how it is implemented, and ASHP would expect to see pharmacists leading all decisions regarding substitution for Medicare Part D beneficiaries before we could support it.

- Requiring Manufacturer List Prices in Advertising: As ASHP has advocated for increased pricing transparency, this provision merits further exploration. However, list prices can mean little in the abstract for patients who know their insurers will cover part of the cost. Therefore, although this provision may create public relations headaches for manufacturers of high-priced products, it is unclear whether the provision would change consumer behavior.

- Removing the Gag Clause in Part D: Pharmacists are currently prohibited from telling Medicare Part D beneficiaries when they could pay less for a drug by paying out-of-pocket rather than through insurance. ASHP would support a change that allows pharmacists to assist patients in finding the lowest-cost option available to them.

- Updating Medicare's Dashboard to Increase Transparency, and Increasing Communication to Part D Beneficiaries: The Blueprint contains several suggestions for increasing pricing and coverage transparency for beneficiaries. Because ASHP supports measures that provide beneficiaries with greater clarity and control around their drug expenditures, we are generally supportive of this type of change.

B. Areas of Concern

The Blueprint includes a number of undefined references to wholesale changes to federal programs, and these are generally our areas of concern.

- Reforms to the 340B Drug Discount Program: ASHP is particularly troubled by the Administration's insistence that the 340B drug-discount program contributes to high drug prices. ASHP strongly opposed the recent Centers for Medicare & Medicaid Services (CMS) cuts to the 340B program, and we will continue to oppose efforts to undercut a program that benefits patients. The Blueprint does not detail how it proposes to change the program, but it notes that with the growth of the program the "additional billions of dollars in discounted sales and the cross-subsidization necessary may have created additional pressure on manufacturer list price." It raises some broad questions about how to approach program authority, program eligibility, and duplicate discounts, but it does not suggest specific programmatic changes. ASHP will be carefully monitoring CMS and Congress for activity on the 340B program. We anticipate the next major rulemaking that could include changes to the 340B program is the Hospital Outpatient Prospective Payment System proposed rule, which is due out this summer.

- Requiring Site Neutrality in Payment: The Blueprint asks a number of open-ended questions regarding whether the payment differential between Medicare Part A and Part B drugs benefits patients and whether there is a way to shift patients between settings. Given the heavy investment in ambulatory care models and facilities, ASHP is concerned that, depending how changes are made, this type of policy modification could adversely impact ASHP members. Currently there is no actual proposal for change, but the inclusion of this issue in the Blueprint suggests that the Administration is interested in taking action on this issue.

- Reforms to Rebates in Medicaid and Medicare: This is another area where the Blueprint asks some questions but does not provide any policy prescriptions. However, because changes to rebates could have wide-ranging impact, we are noting this as an area of concern. Should the rebate changes be designed to provide benefit to patients in the form of reduced out-of-pocket costs, or to remove barriers such as retroactive direct and indirect remuneration, ASHP may be supportive. However, if the changes damage patient choice through, for example, changes to Part D formulary standards that would require only one covered drug per category or class rather than two, then ASHP may be less supportive. As with many of the proposals in the Blueprint, much will depend on the proposal details and implementation plan.

- Merging Part B Drugs into Part D: The Blueprint notes that the President's Budget (which is generally not adopted by Congress) requests authority to move some Medicare Part B drugs to

Medicare Part D. The Blueprint then raises questions about which types/classes of drugs should be included and how moving Part B drugs into Part D would impact out-of-pocket costs for patients without Part D or Part B supplemental benefits. It further asks whether Part D should be allowed to negotiate prices for some Part B drugs. Although these proposals are speculative, ASHP will request member feedback on how shifting drugs from Part B to Part D might impact practice and patients. We are concerned that there are financial and operational considerations that need to be brought to the Administration's attention.

C. Next Steps

Addressing rising drug prices remains a top priority for ASHP, and we applaud the Administration for taking concrete steps on this issue. ASHP will continue to engage fully with agencies and Congress to push for pricing reforms and to ensure that the provisions outlined in the Blueprint are implemented in a way that protects and benefits patients. In addition to our individual efforts, ASHP is also a member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition consisting of physicians, consumers, payers, hospitals, health systems, and patient advocacy groups.

In tandem with the Blueprint, HHS has released a Request for Information soliciting ideas for reducing drug costs. ASHP will submit comments reinforcing the necessity of engaging pharmacists in these efforts and offering suggestions on how best to accomplish that aim.