

Client Alert

May 15, 2018

Key Points

- The administration's drug pricing Blueprint combines proposals that are already under way with new initiatives that may or may not be adopted.
- Many of the more dramatic proposals would require federal rulemaking or even legislation to be implemented on a broad scale.
- Stakeholders have the opportunity to provide feedback on the proposals by responding to a Request for Information, due by mid-July.



Trump Administration Drug Pricing Blueprint: Overview and Analysis

Introduction

On Friday, May 11, President Donald Trump introduced his administration's plan to address rising prescription drug prices: [American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs](#). He and Health & Human Services (HHS) Secretary Alex Azar identified key challenges facing the prescription drug market, including high list prices, limited negotiation tools, rising out-of-pocket costs, and foreign governments taking advantage of American pharmaceutical investment and innovation. This Alert describes the potential path forward for the various initiatives in the Blueprint, and it summarizes the key proposals. An addendum also identifies proposals for immediate action likely to require enactment of legislation for implementation.

Drug Pricing Plan: The Path Forward

The Blueprint combines new proposals with previously announced initiatives, some of which are already under way. The administration has the authority to advance some portions of the Blueprint through regulatory action, as noted in further detail below; other components might require congressional action, such as making significant changes to Medicaid drug coverage and empowering the Food and Drug Administration (FDA) to require disclosure of list prices in direct-to-consumer advertising. Given the tight congressional calendar and looming midterm elections, prospects for proposals that require legislation appear unlikely before November. However, a post-election, "lame duck" session of Congress could provide greater opportunity to advance these initiatives.

In other areas, the administration has more latitude to act on its own, through demonstration authority, rulemaking or other subregulatory policy development. For example, the Centers for Medicare and Medicaid Services (CMS) could provide Part D plans with greater flexibility to modify their formulary or

benefit design midyear in response to drug price increases. FDA plans to issue guidance that would expedite generic versions of drugs and biosimilars.

In public remarks on May 14, HHS Secretary Azar highlighted several specific activities planned for the near term. He indicated that CMS will be sending a letter to all Medicare Part D plan sponsors this week directing them to eliminate the “gag clauses” that prevent pharmacists from advising their patients of the most affordable options to purchase drugs. CMS also updated its drug-pricing dashboard today to increase the information available to consumers regarding increases in drug prices. In addition, Secretary Azar noted that HHS will begin work immediately to develop a new set of incentives on drug list prices, and CMS will be issuing a request for proposal “in short order” for an alternative system for purchasing Medicare Part B drugs through a Competitive Acquisition Program.

The administration is seeking feedback from stakeholders on a wide range of potential actions, providing opportunities to inform the administration’s thinking on how it can improve transparency and competition in the prescription drug market. A corresponding [Request for Information \(RFI\)](#) will be published in the Federal Register on May 16, and comments will be due by mid-July.

Below we have highlighted key aspects of the proposal across several programmatic areas, including opportunities to provide input.

Drug Pricing Plan: Key Highlights

Medicare

The President’s FY 2019 Budget proposed a number of policies impacting drug spending in Medicare, including making changes to Part D plan formulary standards and protected classes; excluding manufacturer discounts when calculating out-of-pocket costs for beneficiaries in the so-called “donut hole”; and giving the HHS Secretary the authority to move certain Part B drugs into Part D.

The administration’s new Blueprint proposes a number of additional actions related to Medicare, many of which would strengthen the negotiating power of Part D prescription drug plans. The Blueprint proposes, for instance, to allow Part D plans to adjust formulary or benefit design during the benefit year to respond to price increases for sole-source generic drugs. This change could be implemented in next year’s rulemaking for the Prescription Drug Benefit and Medicare Advantage Programs. The Blueprint further proposes to allow high-cost drugs in Part D to be priced or covered differently based on their indication. It is uncertain whether CMS can implement this policy without congressional action.

Regarding physician-administered drugs, the Blueprint proposes that HHS prepare a report identifying opportunities to achieve savings by moving particular drugs or classes of drugs from Part B to Part D. CMS may need additional legislative authority to make this change, particularly if the program were to extend beyond a demonstration basis. Secretary Azar further emphasized in comments to reporters, “Moving the reimbursement of physician-administered drugs from Part B to Medicare Part D has the best promise of constraining the costs of very high priced medicines.”

In announcing the Blueprint, President Trump highlighted a specific proposal to block Part D pharmacy “gag clauses,” which prohibit pharmacists from telling patients when they could pay less out-of-pocket by not using insurance. Secretary Azar also mentioned this policy at a subsequent White House Press Briefing, suggesting that it is a top priority. With the goal of reducing list prices, the Blueprint also proposes to update CMS’ drug-spending dashboard to improve the transparency of Medicare and Medicaid prices and “hold drug makers accountable for their price increases.”

As stakeholders review the aforementioned Medicare policies, there will be additional questions regarding implementation and potential savings to the system. The Blueprint specifically seeks input regarding other Medicare proposals, including those related to value-based arrangements, long-term financing models and site neutrality across Part B drugs, as well as across drugs administered in both inpatient and outpatient settings.

Medicaid

The President’s FY 2019 Budget proposed to clarify how drugs are classified for Medicaid rebate purposes, clarify the Medicaid definition of “brand drug” and establish a new five-state Medicaid demonstration to apply private-sector practices to reduce drug prices. The new Blueprint further proposes to “develop proposals” related to the Affordable Care Act’s (ACA) maximum rebate provision, which potentially could increase manufacturers’ rebate obligations and/or impose new conditions for coverage under the Medicaid program.

The ACA previously limited the maximum federal rebate owed by a manufacturer for brand and generic drugs to 100 percent of the Average Manufacturer Price. The administration cites the risk of excessive price increases and cost-shifting by manufacturers as potential justifications for lifting the cap on rebates. The Blueprint also seeks input from stakeholders regarding a range of other potential initiatives to avoid underpricing of generic drugs, promote value-based and indication-based pricing and payment arrangements, and advance long-term financing models for high-cost drugs.

Most of these proposals likely would require that Congress amend the Medicaid statute. In addition, legislative and regulatory action may be required at the state level to align existing Medicaid program rules with new federal requirements. Particularly with respect to new payment and financing models, the Center for Medicare and Medicaid Innovation (CMMI) could play a leading role in advancing these objectives, and it represents an important target for engagement.

340B

The Blueprint contains a number of proposed changes to the 340B Drug Pricing Program, which generally requires drug manufacturers to provide covered outpatient drugs at reduced prices to eligible health care providers—also known as “covered entities”—that serve vulnerable patient populations.

In its Fact Sheet, released simultaneously with the Blueprint, the administration indicated that some hospitals receiving 340B discounts “do not provide meaningful levels of charity care to low-income and vulnerable patients, ultimately pushing up drug prices for patients with private health insurance.” As part

of its planned reforms, the administration is proposing to require hospitals paid under Medicare Part B to provide at least 1 percent of their patient costs in charity care in order to remain eligible for the 340B discount.

In the Blueprint, the administration invited public comment on a number of issues related to the 340B program, including how the growth of the 340B drug discount program has affected list prices. The most significant of these are proposals to change the definition of “patient” under the 340B program or to change the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (also known as “child sites”). Additionally, the administration is seeking comment on whether the current mechanisms for identifying and preventing duplicate 340B discounts and Medicaid drug rebates for the same drugs are sufficient, and on ideas on ways to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market.

FDA Initiatives

Several aspects of the Blueprint feature proposals for FDA to facilitate drug industry competition and transparency. Some of the FDA-related initiatives leverage the agency’s existing Drug Competition Action Plan. For example, FDA will issue guidance addressing mechanisms that can be misused to delay or hinder the development of generic versions of a drug, such as shared system risk evaluation and mitigation strategies (REMS), and will release new policies to facilitate the development of biosimilars, including interchangeable biosimilars, under a forthcoming Biosimilar Action Plan. The Blueprint further directs FDA to evaluate issues relating to access to reference product samples.

One of the more notable proposals in the Blueprint would direct FDA to evaluate the mandatory inclusion of list prices in manufacturers’ direct-to-consumer advertising. This proposal raises a number of questions, including whether FDA has statutory authority to require this information. Finally, the Blueprint seeks input on whether Medicare and Medicaid should be able to adjust payment rates for various indications of a drug, and whether changes are required to the National Drug Code numbering system as used by CMS for price reporting.

Trade

According to the new Blueprint, the U.S. Trade Representative (USTR) will prioritize addressing unfair intellectual property and market access policies in trade agreements, so as to ensure that U.S. trading partners “contribute their fair share to innovation.” The USTR has often criticized foreign countries’ intellectual property policies, including through its annual Special 301 Report. For instance, in the just-released 2018 Special 301 Report, the USTR highlighted its Intellectual Property Rights (IPR) concerns with respect to Chile, Colombia, El Salvador, India and Malaysia for issuing, or threatening to issue, compulsory licenses on patented pharmaceuticals. These are used to drive down the cost of innovative drugs in these countries, either through allowing foreign companies to break existing patents in order to avoid paying patent licensing fees or using the threat of compulsory licenses to negotiate a very low price for the patented products. These tactics, according to the Blueprint, have resulted in U.S. consumers “subsidizing” the overseas low prices because they are being forced to pay higher prices here in the United States.

Pharmaceutical pricing has been a key focus of trade agreement negotiations in recent years. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), to which all WTO states are signatories, contains a number of provisions bearing directly on pharmaceuticals, including requirements to establish robust patent protection in all WTO member countries. Also, although it does not refer to the practice by name, the TRIPS Agreement does allow compulsory licensing under certain specific conditions in order to “strike a balance between promoting access to existing drugs and promoting research and development of new drugs,” according to a WTO factsheet. More direct pharmaceutical pricing obligations were subsequently added in the U.S.-Korea Free Trade Agreement, as well as in the initial draft of the Trans-Pacific Partnership Agreement.

Trade association response to the new Blueprint has thus far been mixed. Following President Trump’s announcement, BIO President and CEO Jim Greenwood issued a statement warning that, while the company “look[s] forward to working with the administration on solutions that help provide all patients access to prescription drugs with out-of-pocket costs they can afford,” they “have concerns that some of the ideas proposed today could, if adopted, hurt patient access to the medicines they need.” Nonprofit organizations have also complained about the Blueprint, arguing that compulsory licensing and the lack of patent protection is not the reason that U.S. drug prices are so high.

In sum, there appears to be little support for the Blueprint’s rationale for linking IPR and drug prices, and legitimate concern for the administration’s proposed responses to these issues.

Proposals for Immediate Action Likely to Require Legislation

The following immediate actions proposed in the administration’s drug pricing plan are likely to require enactment of legislation for implementation. Page numbers correspond to the relevant sections of the Blueprint.

- providing plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes (p. 24)
- evaluating options to allow high-cost drugs to be priced or covered differently in Part D based on their indication (p. 24)
- taking steps to leverage the authority created by the Competitive Acquisition Program for Part B Drugs & Biologicals (pp. 24-25)
- developing and implementing proposals related to the ACA’s Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100 percent of the Average Manufacturer Price (p. 25)
- requiring the inclusion of list prices in prescription drug direct-to-consumer advertising (p. 25)
- adopting legislative solutions to address the unfair disparity between the drug prices in America and other developed countries (p. 25).

Further proposals for which HHS is soliciting stakeholder feedback through the RFI process and other avenues also may require legislative action, depending on the scope of those initiatives.

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