

Blog Post

Derailing the Gravy Train - Trump Unveils Plan to Reduce Drug Prices

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Throughout his presidential campaign, President Trump championed the need to allow the government to negotiate drug prices on behalf of the Medicare program. However, that third rail for pharmaceutical companies was not included as part of the President's recently released blueprint for lowering drug prices. Instead, the plan takes aim at the entire supply chain that lies between drug manufacturers and patients, including health insurers, distributors, pharmacy benefit managers and even foreign governments.

The Trump administration's "[American Patients First](#)" plan lays out four "key strategies for reform." These strategies involve two phases. In the first phase, the President may direct the US Department of Health and Human Services (HHS) to issue guidance geared toward accomplishing these strategies. The second phase involves further analysis of the complexities of the system and submitting proposed rules for feedback. The following summary condenses the almost 40-page plan into the most salient points since not all of the ideas are fully fleshed out.

Key Strategies for Reform

1. *Increased Competition.* President Trump seeks to improve competition by, among other things, directing the Food and Drug Administration (the

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FDA) to issue guidance that streamlines the Risk Evaluations and Mitigation Strategies that have been previously used by manufacturers to delay or block competition from generic products entering the market. Further, the FDA will issue new policies to improve the availability, competitiveness and adoption of biosimilars as affordable alternatives to branded biologics.

2. *Better Negotiation.* President Trump seeks to improve negotiation by directing the Centers for Medicare and Medicaid Services (CMS) to develop demonstration projects that encourage value-based care and lower drug prices. They seek to align these models for drugs with CMS's previously stated goal of rewarding value over volume. While there is no suggestion that CMS negotiate directly with manufacturers to lower drug prices, President Trump has instead recommended, among other things, permitting sponsors of Part D plans to adjust formularies or benefit designs to address price increases, and giving flexibility to sponsors to manage high cost drugs. Further, consistent with the concept behind President Trump's "America First" tariff policy, his "American Patients First" drug price reduction policy seeks to work in conjunction with the Department of Commerce, the US Trade Representative and the US Intellectual Property Enforcement Coordinator to address the disparity in drug prices between the United States and other developed countries. While no specific actions have been set forth in this regard, the goal is clear: to eliminate "free-riding [by other countries] off of American investment in innovation."

3. *Incentives for Lower List Prices* President Trump hopes that transparency will encourage lowering prices, and he may direct the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising, as well as direct CMS to make drug prices more transparent. Also, President Trump proposed a five part plan in his FY2019 budget designed to modernize the Medicare Part D

program and incorporate incentives for plans to negotiate with manufacturers.

4. *Lowering Out-of-Pocket Costs.* To accomplish this, the Trump administration seeks to finalize Medicare Outpatient Prospective Payment System rules to reduce beneficiary out-of-pocket spending for 340B drugs administered in certain hospitals. Also, the Trump administration will seek comments on policy approaches for applying some manufacturer rebates and pharmacy price concessions at the point of sale. Finally, his five-part plan in his FY 2019 budget, that is referenced above, is also designed to eliminate cost-sharing on generic drugs for low-income beneficiaries and require plan sponsors to apply a substantial portion of rebates at the point of sale.

From all appearances, this blueprint is just the first step in a long process. Stay tuned as things continue to develop.

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