

Recent Proposals by the Administration Hint at Areas of Focus for Upcoming Drug Pricing Plan /

President Trump is expected to announce a drug pricing plan in the coming weeks; signals from the White House indicate potential alignment around several priority policies.

President Trump and his administration continue to keep drug prices on its list of domestic priorities. Indeed, in recent months, the administration has taken several opportunities to communicate its support for a range of policies through the President's FY19 budget request, the White House Council of Economic Advisers (CEA) report on drug pricing, and the annual Economic Report of the President, which is produced by the Chairman of the CEA.

In the coming weeks, the Trump administration is slated to announce a drug pricing plan. While the specifics of the plan are uncertain at this time, the areas of alignment across the White House reports lend insight into the policies that may see further action. Potential areas of focus may include:

FDA Reforms. The administration has consistently pointed to certain FDA reforms as a potential avenue to increase drug pricing competition. Namely, the President's budget sought FDA reforms that would ease the ability of generics to enter the market and incentivize more competition among drug and biologic manufacturers.

Part B Drug Reforms. Across the President's budget, CEA report, and White House economic report, the administration has signaled a strong interest in increasing the competition and management under the Part B drug benefit. The focus has largely been on two types of policy mechanisms: (1) revising the Part B drug payment methodology; or (2) allowing an intermediary or other entity to negotiate and manage Part B costs.



The first set of proposals would directly impact unit prices of Part B drugs, while the second set of policies would seek to increase competitiveness within certain drug classes.

The proposed payment modifications supported by the administration would include requiring all manufacturers to report average sales price (ASP) data, revising the WAC-based payment rate, and establishing a limit on ASP-based payment increases tied to a measure of inflation. The Medicare Payment Advisory Commission (MedPAC) has made similar recommendations to Congress in the past.

The administration has also expressed support for policies that would allow a third party to manage Part B costs. The President's budget included language to authorize the HHS Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B. This proposal followed public comments by CMS Administrator Seema Verma that the Center for Medicare & Medicaid Innovation (CMMI) is exploring a pilot to move a subset of drugs from Part B into Part D. Secretary Azar has also stated that Part B could benefit from third-party negotiations of prices, akin to pharmacy benefit managers' function in the Part D program.

Part D Rebate Pass Through. Reflecting the growing focus on the role of rebates in Part D, the administration's reports all include a proposal requiring plans to share manufacturer discounts with Medicare beneficiaries at the point of sale. The President's budget specifically proposes to require Part D plans to pass on at least one-third of total rebates and price concessions to beneficiaries at the point of sale. CMS is currently reviewing public responses to its Request for Information on pass-through rebates in Part D, which will inform the administration's next steps on this issue.

Medicaid Flexibility in Administering Drug Benefits. The three White House reports include a proposal to establish a new Medicaid demonstration to test state-driven negotiations in up to five participating states. Specifically, the demonstration would waive the statutory minimum Medicaid drug rebate and allow states to establish a closed formulary. A pending MA waiver and a potential AZ waiver similarly seek a closed formulary approach, a flexibility that has not been approved to date.

The drug pricing plan announcement and any associated HHS notice or Request for Information may not prompt immediate policy change but may provide a roadmap of priorities that will be subject to further legislative or regulatory action. While the administration has signaled alignment around the four policy areas outlined above, each



raise critical policy design and operational questions for stakeholders that will need to be addressed.

Avalere is closely monitoring the administrative and legislative activity on drug pricing. For more information, [connect with us](#).

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