



Insight

Understanding the Biden Administration's Drug Pricing Plan

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Executive Summary

- The Department of Health and Human Services released the administration's Comprehensive Plan for Addressing High Drug Prices in response to President Biden's executive order that identified a lack of industry competition as a key driver of high drug prices.
- The plan outlines support for several Democratic drug pricing proposals and suggests complementary administrative actions; of note, the plan supports direct federal negotiation of drug prices, a cap on out-of-pocket spending for Medicare Part D beneficiaries, updates to the approval and market entry process of generics and biosimilars, and funding for a new agency at the National Institutes of Health.
- The ultimate impact of the plan is difficult to predict, given the uncertainty of ongoing congressional negotiations over the various drug pricing proposals on which it is based.

Introduction

On July 9, 2021, President Biden issued Executive Order 14036 "[Promoting Competition in the American Economy](#)" that blamed monopolistic market behavior for rising drug prices and directed the Department of Health and Human Services (HHS) to devise a plan to improve pharmaceutical supply chains and address the high price of prescription drugs. On September 9, 2021, HHS released the [Comprehensive Plan for Addressing High Drug Prices](#), which aims to make drug prices more affordable and equitable, improve and promote competition in the prescription drug market, and foster scientific innovation.

The plan embraces several key proposals from Democratic drug pricing legislation and highlights administrative measures across various departments and agencies that would support the legislative changes. While the plan points to policies from a variety of Democratic drug pricing bills, it does not provide specific details about the impacts of such policies or the tools required to implement such administrative actions. Compared to other drug pricing proposals previously touted among Democrats, the plan notably leaves out support for the idea of international reference pricing used in [H.R.3](#), or the use of "[march-in rights](#)" to lower drug prices, and provides little insight into the administration's stance on the "[rebate rule](#)," which was delayed until 2026 as a pay-for in the Senate's August [infrastructure bill](#). Additionally, the plan does not include any projected costs or savings. The ultimate impact of the plan is difficult to predict, given its non-binding nature and the uncertainty of ongoing congressional negotiations over the various drug pricing proposals. In short, the plan will almost certainly evolve as negotiations on the Hill continue.

Legislative Actions

Drug Price Negotiation

The administration's plan supports progressive legislation that would allow the federal government to directly

negotiate prices for drugs covered by Medicare. The plan endorses directing the HHS secretary to negotiate “fair prices” directly with drug manufacturers on behalf of Medicare Parts B and D. Of note, the proposal follows Speaker Pelosi’s lead and supports extending these lower costs to patients with private health insurance plans if plan sponsors choose to participate. The administration states that this could result in hundreds of billions of dollars in savings for the federal government, yet it lacks details about the negotiations and fails to define what constitutes a “fair price.”

Research has shown that allowing Medicare to negotiate drug prices will result in less money for drug research and development and ultimately slow pharmaceutical innovation. According to the Congressional Budget Office’s analysis of H.R. 3, a drug pricing bill that included a negotiation proposal similar to that in the administration’s plan, direct federal price negotiations for Medicare drugs would eliminate jobs and lead to at least 60 fewer new treatments over the next 30 years.[1] Additionally, the American Action Forum’s (AAF) [Christopher Holt](#) and [Douglas Holtz-Eakin](#) have both discussed the consequences of the government’s limited drug-price negotiating powers, such as reduced incentives for manufacturers and decreased access to medications for beneficiaries. Under legislation like H.R. 3, direct price negotiations act effectively like government price-setting, as drug manufacturers that do not comply with the government-established prices face extreme tax penalties. The likely outcome, supported by evidence in other countries that dictate prices, is fewer innovative therapies for consumers in the future.[2]

Medicare Part D Reform

The administration’s plan supports restructuring Medicare Part D to slow the growth of Part D drug spending and ensure beneficiary access to affordable medications. The plan supports an out-of-pocket (OOP) spending cap for beneficiaries and a reduction in cost-sharing for beneficiaries through increased liability of Part D plans and drug manufacturers, coupled with decreased Medicare liability in the catastrophic phase. Consistent with the rest of the plan, the support for Medicare Part D reform is quite broad and leaves out any reference to specific monetary values for OOP caps or cut-offs for shifts in liability.

The administration’s proposed Medicare Part D redesign is similar in concept to past proposals from AAF and the bipartisan Prescription Drug Pricing Reduction Act of 2019 ([S. 2543](#)), which AAF’s Tara O’Neill Hayes describes in detail [here](#) and [here](#). From a broad perspective, realigning incentives and increasing insurer liability would put downward pressure on prescription drug prices and will reduce financial risk for beneficiaries and taxpayers. Even small differences in Part D reforms, such as the value of the OOP cap or the split in liability between drug manufacturers and insurers, can lead to great differences in impact, however, including how much beneficiaries and the government save and the amount of downward pressure on drug prices.

Slowing Price Increases Relative to Inflation

The administration’s plan calls on Congress to address situations in which manufacturers increase drug prices faster than the rate of inflation, but it leaves the details up to congressional negotiation. Democrats have historically favored penalizing manufacturers for drug price increases through fines or taxes and have included such penalties in several recent drug pricing proposals. AAF’s Christopher Holt explains the consequences of such measures [here](#), highlighting the resulting increases in the launch price of medications and the eventual costs to consumers.

Improving Market Competition Through Biosimilars and Generics

To improve market competition and promote the use of lower-cost options such as biosimilars and generics, the plan expresses support for updates to Medicare and provider payment structures. According to the plan, offering a single Medicare payment for both the reference biologic and its biosimilars, rather than the separate calculations that currently exist under Medicare Part B, would encourage competition and ultimately drive down the average sale price for both drug options. The plan also supports updating provider payments to increase incentives for prescribing biosimilars and generics rather than higher-cost alternatives.

Enhancing the Regulatory Environment

The administration's drug pricing plan supports increasing industry competition by reducing regulatory barriers. Examples include prohibiting "pay for delay" agreements and preventing brand manufacturers from using the regulatory process to limit the approval and entry process of biosimilars and generics.

"Pay for delay" agreements allow drug manufacturers to pay potential biosimilar or generic competitors in return for their delayed market entry,^[3] which the administration's plan estimates costs consumers up to \$36 billion annually. Additionally, the 180-day exclusivity period for the first-to-file generic drug does not begin until after the delay due to "pay for delay" agreements, which further slows market entry of lower-cost alternatives and prevents competition.^[4]

The plan includes claims that prohibiting "pay for delay" agreements and amending the exclusivity period would allow lower-cost alternative drugs to come to market sooner, therefore increasing supply and competition.

Administrative Actions

Medicare Part B

The administration's plan proposes testing "small-scale mandatory models" through the Center for Medicare and Medicaid Services (CMS) Innovation Center to link payments for drugs covered by Medicare Part B to improvements in patient affordability and health outcomes, and reductions in overall costs and health disparities. The plan proposes offering provider incentives to prescribe "high-value therapies," but fails to provide a tool for the clinical valuation of drugs or any concrete details on the models.

Other models mentioned in the plan related to Medicare Part B include an option for bundled payments for drugs and related drug administration services, and an option for shared savings between the government and providers who prescribe biosimilars, generics, or other high-value options. All of the models, however, are similarly lacking in detail.

Medicare Part D

The administration's plan supports the continued testing of the impacts of the voluntary Part D Senior Savings model, which currently provides an increased choice of plans to offer beneficiaries predictable costs for formulary insulins and proposes expanding the model to include additional drug classes. The plan also proposes testing models through the CMS Innovation Center to provide additional cost-sharing to low-income subsidy beneficiaries of Medicare Part D that use biosimilars or generics.

Additionally, the plan proposes demonstrations through the CMS Innovation Center on total cost of care models within both Medicare Parts B and D to examine the effects of coordinated care and bundled payments on drug

utilization, patient outcomes, and total spending.

Drug Price Transparency

The administration's plan includes claims that increased data collection from insurers and pharmacy benefit managers (PBMs), implemented through provisions from the [Consolidated Appropriations Act, 2021](#), will improve transparency surrounding drug prices, rebates, and OOP spending for beneficiaries. The original legislation requires group health plans, health insurance issuers in the individual and group markets, and issuers of Marketplace plans or their PBMs to annually report data about prescription drugs and medical costs to the Departments of HHS, Labor, and the Treasury, which will publish a biannual report to Congress with the findings. Data collection is expected to begin in 2022.

Biosimilar and Generic Competition

The administration's plan calls on the Federal Trade Commission and the Food and Drug Administration (FDA) to identify and address any efforts that impede biosimilar and generic competition. The plan also highlights ongoing measures within the FDA that promote the approval and market entry of lower-cost drug options, including the Biosimilars Action Plan from 2018 for biosimilars and the Drug Competition Action Plan for generic drugs. The FDA is updating previous guidelines on the use of biosimilars to account for modernized technologies and is exploring the use of labeling carve-outs and provisions in the [CREATES Act](#) to increase supply of biosimilars and generics in the drug market and increase access to product samples.

The plan also proposes educational initiatives in medical, nursing, and pharmacy schools to better inform health care providers and patients about the cost savings associated with biosimilars and generic drugs.

Drug Importation for States and Tribes

In the Competition executive order, President Biden called on the FDA to work with states and Indian tribes to develop importation programs for prescription drugs. The plan highlights the FDA's role in answering this call through Section 804 Importation Programs that would provide reduced-cost prescription drugs from Canada that do not increase public health or safety risk. The FDA is currently working with states and Indian tribes on these programs and has invited others to join, though none of the approved programs have started so it is too early to evaluate the effects of importation on prescription drug prices.^[5] Neither the [final rule](#) nor the [FDA's final regulatory impact analysis](#) provided any estimate of expected savings.

Innovation and Research

The administration's plan proposes the creation of a new agency at the National Institutes for Health called the Advanced Research Projects Agency for Health that would specifically focus research on chronic conditions such as cancer, diabetes, and Alzheimer's. The goal of the new research agency would be to promote biopharmaceutical innovation; the agency would be modeled on existing agencies such as the Defense Advanced Research Projects Agency and the Biomedical Advanced Research and Development Authority that contributed significantly to the accelerated development and distribution of COVID-19 vaccines through public-private collaboration.^[6] ^[7]

Conclusion

The Comprehensive Plan for Addressing High Drug Prices provides insight into the Biden Administration’s stance on drug pricing, but “comprehensive” is an overstatement. Though the plan includes several measures to lower the cost of prescription drugs, it primarily relies on direct government negotiation that would significantly hinder pharmaceutical research and development. Given that the plan lacks concrete tools for implementation, and with various drug pricing legislation still under negotiation, the actual impacts of the plan remain unclear.

[1] <https://www.cbo.gov/system/files/2021-08/57010-New-Drug-Development.pdf>

[2] <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/Pelosi-Plan-Comparison-of-Availability-of-Medicines-092319.pdf>

[3] <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>

[4] <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#howlongexclusivity>

[5] <https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/#:~:text=Several%20states%2C%20including%20Florida%2C%20Vermont%2C%20Colorado%2C%20Ma>

[6] <https://homelandprepnews.com/stories/50578-barda-darpa-support-astrazeneca-through-phase-1-trial-of-covid-19-therapeutic/>

[7] <https://crsreports.congress.gov/product/pdf/IN/IN11560>