

White House Swings for Fences with FY 2019 Drug Pricing Proposals

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In February 2018 the White House and its advisers released the President's Budget, a Council of Economic Advisers report and the Economic Report of the President. Together these documents provide a framework to address prescription drug pricing and outline a multi-faceted approach that the administration believes can reduce spending on prescription drugs in the United States while continuing to encourage growth and innovation.

Helpful Resources:

- [The Council of Economic Advisers report](#)
- [The Economic Report of the President](#)
- [The President's FY 2019 Budget](#)



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Since the run-up to the 2016 presidential election, Donald Trump has stated his interest in controlling and lowering the high cost of prescription drugs. Until recently his administration had released limited details on possible ways to do so.

Three documents recently released by the White House and its advisers provide a framework outlining a multi-faceted approach that the administration believes can reduce spending on prescription drugs in the United States while continuing to encourage growth and innovation.

One of my greatest priorities is to reduce the price of prescription drugs. In many other countries, these drugs cost far less than what we pay in the United States. That is why I have directed my administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down.

President Trump, [2018 State of the Union](#)

On February 8, 2018, the White House Council of Economic Advisers (CEA) released a white paper outlining, at a high level, a number of policy alternatives aimed at reducing the price of prescription drugs in the United States. The White House followed the CEA report with its proposed FY 2019 budget that adopted many of the CEA policy proposals. This was quickly followed by the Economic Report of the President that included all of the CEA policy proposals.

Together, these documents underscore the administration's position that prices paid by Americans for many drugs are too high, particularly when those drugs are purchased through and used by beneficiaries of government programs. The reports place blame for increased prices on a combination of flawed public program reimbursement regulations that inhibit healthy price competition coupled with aggressive rate setting in other countries that drives manufacturers to charge disproportionately high prices within the US market.

According to the reports, reforms to public drug payment policies must consider two simultaneous goals: lowering prices and encouraging innovation. While these goals may seem inconsistent, the administration believes they can be achieved simultaneously through a comprehensive series of policy reforms aimed at establishing policies that encourage rational domestic pricing while reducing "free-riding" abroad.

Federal Payment Policy Suggestions

Medicaid

Reforms proposed to the Medicaid program include changes to the "Medicaid Best Price" program that seek to eliminate artificially high private sector prices. According to the report, the current program encourages artificially high prices in the private sector, particularly where a large share of a drug's market is enrolled in Medicaid. In these cases, inflating prices in the private sector will have little impact on sales, because of low utilization in that sector, but can increase post-rebate prices from Medicaid. Similarly, manufacturers cannot offer discounted prices to low-income private sector patients without jeopardizing the Medicaid "Best Price."

The administration's recommendations would also allow manufacturers to determine their "Best Price" retroactively after a patient has received treatment and clinical data on the drug's impact is available. This policy would encourage price competition among manufacturers, incentivize better patient adherence to therapy and ensure that state Medicaid programs are paying for effective treatments.

The administration also proposed a limited demonstration that would allow up to five Medicaid programs to create more competitive drug formularies and then negotiate pricing with drug manufacturers.

Medicare

Under Medicare, the administration recommends disconnecting physician payment from drug payment by eliminating the current Average Sales Price (ASP) + 6 percent payment methodology and moving most Part B drugs into Part D. This policy is said to encourage price competition by replacing the administratively set prices currently used in Part B with negotiated rates that are more market-based.

The administration also believes that because Part B payment rates are based on selling prices of drugs, and because drugs with limited or no sales data for which no ASP-based rate is reported may be priced by the Medicare Administrative Contractors using the Average Wholesale Price (AWP) as a benchmark, some drug makers may try to delay sales for which an ASP is required to be reported in order to extend payment under the more generous AWP benchmark. By cutting payments for newer drugs and for drugs with limited ASP reporting without ASP-based rates published, the administration believes it can encourage better and faster price reporting and avoid artificial price inflation.

Medicare Part D

The reports criticize the Part D program on a number of fronts for artificially raising prices, and support policy changes that would allow Part D plans to better negotiate prices, lower co-payments for certain drugs and encourage the use of less expensive generic equivalents.

First, the reports criticize the government's requirement that Part D plans cover at least two drugs in a therapeutic class and category. In situations where only two drugs in a category or class are marketed, plans have limited ability to negotiate pricing. By eliminating this requirement and allowing plans to select which drug to cover, plans will have greater ability to negotiate lower prices with manufacturers.

The report also calls the Part D program to task for prohibiting formulary tier-based cost sharing for low-income subsidy (LIS) enrollees. For this group of enrollees, cost sharing is based on income and not on formulary placement. Studies have shown that a larger proportion of LIS enrollees have higher drug costs than non-LIS enrollees, possibly due to the use of higher cost drugs by LIS enrollees. By applying formulary tier-based cost sharing to all Part D enrollees, both LIS enrollees and their physicians may be more likely to make low-cost, high-value prescribing decisions.

The program is also criticized for encouraging the use of expensive branded drugs by patients in the "donut-hole" in an effort to more quickly reach the catastrophic coverage phase of the program. Requiring Part D plans to better manage costs throughout the entire Part D benefit will reduce costs and encourage more rational prescribing decisions.

340B Drug Discount Program

The administration also asserts that the current design of the 340B program encourages increased spending in two key areas.

First, the administration believes that the program has expanded far beyond its original intention, and that many facilities that are currently eligible for the program should not be. Under the administration's proposal, facilities that do not serve vulnerable populations and that do not provide substantial amounts of charity care would not have the ability to purchase drugs under 340B.

Next, the administration believes that facilities should be required to use money earned from the 340B program to benefit low-income, vulnerable populations, and not simply as the facility sees fit. By making this change, the administration believes it can rein in program growth and reduce 340B spending.

In the 2018 Outpatient Prospective Payment System Final Rule, CMS finalized reductions to payments for drugs purchased under 340B to ASP -22.5 percent.

Policy Suggestions to Encourage Competition

FDA

The reports indicate that the US Food and Drug Administration (FDA) can also contribute to reforms by reducing the costs associated with entering the drug market and encouraging price competition among innovators.

By expanding the generic drug approval process to allow expedited review for second or third products in a class (as opposed to just first generics), or second or third products for a given indication for which there are no generics, manufacturers would be more likely to enter the generics market sooner, thus allowing the overall system to lower costs faster.

Additionally, the administration calls on FDA to streamline the process for approving biosimilars. A biosimilar approval process that is easier to understand and less expensive to adhere to will encourage more development of less expensive alternative therapies.

Pharmacy Benefit Managers

Pharmacy Benefit Managers (PBMs) are called out by the administration as well. The administration believes the market itself creates artificially high prices and results in excessive profits to the PBMs. The administration asserts that policies that open the PBM market to more companies would encourage price competition, thus further reducing prices paid by providers.

International Changes

Because of government price controls outside the United States, the US market is responsible for a disproportionate share of profits made by pharmaceutical manufacturers. Manufacturers underwrite their financial return on investments worldwide with sales to US patients at higher prices. The administration criticizes overseas government price controls that limit prices paid for drugs in those countries to marginally more than the cost of manufacturing the drugs. This so-called “free riding” puts a disproportionate financial burden on US patients, who are asked to

Domestic Contribution to Global Profits



Figure 1: Americans contribute more than 70% of patented biopharmaceutical profits

foot a larger portion of the bill for innovation and drug development. The administration aims to better understand this disparity and to seek changes that will encourage all countries to share in the cost of innovation.

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As noted, these reports propose a comprehensive framework of policies intended to address increasing drug prices. A clearer assessment of this framework will emerge as policy details are drafted in the legislation and regulations that will be necessary to implement these concepts. Nonetheless, it is clear that the administration is attempting to create a broad plan that the administration believes will encourage competition while lowering prices paid for drugs.

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