

# Lower the Price of Drugs by Reforming Payments

2019  
BUDGET  
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## Rethinking Drug Pricing to Put American Patients First: An American Budget

The President has consistently emphasized the need to reduce the price of prescription drugs. Many drugs are too expensive for Americans, and too many patients continue to be priced out of the medicines they need. In many other countries, these drugs cost far less than in the United States. While American innovators bring life-saving pharmaceutical products to the world, the government and consumers purchase drugs through a system that prevents, rather than fosters price competition through an inefficient, opaque maze of segmented channels and a poorly understood network of pricing schemes. The goal of the Administration's comprehensive strategy is to address the problem of high drug prices, provide greater access to medical products, and ensure that the United States remains the world leader in biomedical innovation.

The Administration has already taken a number of significant administrative steps to reduce drug costs. This includes the Food and Drug Administration's (FDA) approval of the highest total number of generic drugs (1,027) in any year in the agency's history. The Administration has also implemented changes in Medicare payment to lower the costs seniors pay for certain drugs in the hospital outpatient setting. This Medicare payment change will save seniors an estimated \$320 million on drug copayments in calendar year 2018 alone. For 2019, the Budget proposes new strategies to address high drug prices and increase access to innovative products by rationalizing the current incentive structure, fostering greater competition, and leveraging leadership in innovation in the international market to ensure we put American consumers first.

**Modernize the Medicare Part D Drug Benefit.** Misaligned incentives in the Part D benefit design help drive increased drug spending by rewarding drug pricing and price concession strategies that encourage plans to provide preferred formulary placement and to promote utilization of high cost drugs when lower cost options are available. This results in higher spending for both beneficiaries and the government. The Budget modernizes the Part D drug benefit, based upon 12 years of program experience, to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter.

This 5-part proposal gives plan sponsors more tools and incentives to manage benefits. It provides beneficiaries with better protection against catastrophic costs and encourages use of lower-cost drug alternatives. It also addresses the unintended consequences of current plan design that result in plans shifting substantial drug costs to Medicare and beneficiaries.

- *Increase Medicare Part D plan formulary flexibility.* This proposal enhances Part D plans' negotiation power with manufacturers by allowing for additional flexibilities in formulary management. It changes Part D plan formulary standards to require a minimum of one drug per category or class rather than two. It also expands plans' ability to use utilization management tools.
- *Eliminate cost-sharing on generic drugs for low-income beneficiaries.* Current law specifies the cost-sharing amounts for more than 12 million low-income subsidy (LIS) enrollees at different income levels. Current cost-sharing requirements provide insufficient incentive for these beneficiaries to choose low-cost generics. As a result, their use of generics is lower than for non-LIS beneficiaries. The Budget would encourage the use of higher value products among low-income subsidy enrollees by reducing cost sharing for generics, including biosimilars, to zero.

- *Require Medicare Part D plans to apply a substantial portion of rebates at the point of sale.* This proposal works to lower beneficiary costs at the pharmacy counter by requiring plans to share at the point of sale at least one-third of rebates that plans receive from drug manufacturers. Requiring plans to apply a portion of their negotiated discounts to the point of sale will decrease plan sponsor and pharmacy benefit manager (PBM) preference for the inclusion of high-priced drugs with generous rebates on formularies.
- *Exclude manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Medicare Part D coverage gap.* Generally, only cost sharing the beneficiary pays out-of-pocket counts toward determining whether the individual has reached the out of pocket threshold where catastrophic coverage begins. However, required discounts paid by manufacturers on brand-name drugs are also counted. This current-law requirement, along with Medicare's coverage of 80 percent of costs above the out-of-pocket threshold for catastrophic coverage (discussed further below), provides poor incentives for plans to encourage use of generics. The Budget excludes manufacturer discounts from the calculation of true out-of-pocket costs to correct this misaligned incentive.
- *Establish a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase.* This proposal eliminates beneficiary cost sharing above the catastrophic coverage threshold and increases Part D plan sponsors' responsibility for these costs to 80 percent, with Medicare covering the remaining 20 percent. This will provide beneficiaries with better protection against high drug costs and encourage plans to better manage spending throughout the entirety of the benefit.

**Modify Medicare Part B Drug Payment.** The Budget modifies payment for Medicare Part B drugs to discourage manufacturers from increasing prices faster than inflation and improve payment accuracy. The Budget also modifies hospitals' payment for drugs acquired through the 340B drug discount program to ensure hospitals that benefit from the 340B drug program provide at least a minimum level of charity care.

- *Address abusive drug pricing by manufacturers by establishing an inflation limit for reimbursement of Medicare Part B drugs.* Medicare pays most Part B drugs based on 106 percent of the average sales price (ASP). Currently, there is no limit on how much the payment rate for a drug can increase over time. The Budget would place a limit on increases in Medicare's payment rate for a Part B drug based on inflation as measured by the consumer price index.
- *Reduce Wholesale Acquisition Cost (WAC)-Based Payment.* The Budget would reduce payments on drugs for which ASP data isn't available, to better approximate the discounts that would be incorporated into average sales prices. For the first two to three quarters a new drug is on the market, it is generally paid at 106 percent of WAC, a price that does not reflect any available discounts. Reducing the WAC add-on from 6 to 3 percent would better reflect the discounts that ultimately are included when payment shifts to use of ASP data.
- *Improve manufacturers' reporting of average sales prices to set accurate payment rates.* The Centers for Medicare & Medicaid Services (CMS) relies on manufacturers to submit ASP data to calculate payment rates for Part B drugs. Manufacturers that do not have a Medicaid drug rebate agreement are not required to submit ASP data. In addition, some manufacturers fail to timely submit required data timely. The Department of Health & Human Services Office of Inspector General found that in 2012, at least one-third of the more than 200 manufacturers of Part B drugs did not submit ASPs for some of their products in the third quarter of 2012, despite being required to do so. Additionally, at least 45 manufacturers were not required to report ASPs for 443 national drug codes in the third quarter. In that quarter, only about half of those manufacturers voluntarily reported data. When payment rates are based on incomplete data, Medicare's payment rate does not accurately reflect price concessions and other factors that would ensure accurate payment. To address these issues, the Budget would

require all Part B drug manufacturers to report ASP data and provide the Secretary with the authority to apply penalties to manufacturers who do not report required data.

- *Authorize the HHS Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B.* This proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D where there are savings to be gained through increased price competition.
- *Modify payment for drugs hospitals purchase through the 340B discount program and require a minimum level of charity care for hospitals to receive a payment adjustment related to uncompensated care.* Under a regulation that went into effect CY 2018, hospital payment for 340B drugs is reduced to reflect the average discount 340B hospitals receive. Statute requires the savings from this payment modification to be redistributed among the payment rates for other hospital services. Under this proposal, the savings from 340B hospitals that provide uncompensated care equaling at least one percent of their patient care costs are redistributed to hospitals based on their share of aggregate uncompensated care. Hospitals not meeting that threshold are not eligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Fund.

**Test Innovative Medicaid Drug Coverage and Financing Reforms.** The Budget calls for new Medicaid demonstration authority for up to five States to test drug coverage and financing reforms that build on private sector best practices. Participating States would determine their own drug formularies, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly with manufacturers. HHS and participating States would rigorously evaluate these demonstrations, which would provide States with new tools to control drug costs and tailor drug coverage decisions to State needs.

**Prevent Manufacturer Gaming of the Medicaid Drug Rebate Program.** The Budget calls for a legislative change to clarify the Medicaid definition of brand drugs, which would address inappropriate interpretations leading manufacturers to classify certain brand and over-the-counter drugs as generics for Medicaid rebate purposes, reducing rebate amounts owed.

**Speed Development of More Affordable Generics to Spur Competition.** Today, a generic manufacturer that has been awarded 180-day exclusivity for being the first generic to file can “park” their application with FDA indefinitely, preventing additional generic manufacturer from entering the market. The Administration’s proposal would end this type of anticompetitive behavior. The Budget gives FDA greater ability to bring generics to market faster by incentivizing more competition among generic manufacturers. The Budget proposes to ensure that first-to-file generic applicants who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period. FDA has found that the appearance of a second generic drug greatly reduces the average generic price to nearly half the brand name price.<sup>1</sup> The Budget proposal will spur greater competition and help lower drug prices for American patients.

**Address price disparities in the international market.** The Administration is updating a study from 2004 to analyze drug prices paid in countries that are a part of the Organization for Economic Co-operation and Development. HHS, working in conjunction with the Department of Commerce and the U.S. Trade Representative, would develop the knowledge base to understand the unfair disparity between the drug prices in America and other developed countries. This Administration is committed to making the appropriate regulatory changes and seeking legislative solutions to put American patients first.

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<sup>1</sup> <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>

**Improve 340B Program Integrity.** The FY 2019 Budget proposes to improve 340B Program integrity and ensure that the benefits of the program are used to help low-income and uninsured patients rather than subsidize providers or cross-subsidize the care they provide. This proposal includes broad regulatory authority for the 340B Drug Pricing Program to set enforceable standards of program participation and requires all covered entities to report on use of program savings.