

Lowering Drug Prices

2020
BUDGET
FACT
SHEET



PUTTING- AMERICAN PATIENTS FIRST: LOWERING LIST PRICES, REDUCING OUT-OF-POCKET COSTS, AND IMPROVING NEGOTIATION AND COMPETITION

The President has consistently emphasized the need to reduce the price of prescription drugs. American 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 Administration's comprehensive drug pricing strategy addresses the problem of high drug prices, provides greater and more affordable access to lifesaving medical products, and ensures the United States remains the leader in biomedical innovation. Consistent with the Trump Administration's *Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs*, the 2020 Budget proposes strategies targeted at increasing competition, encouraging better negotiation, incentivizing lower list prices, and lowering out-of-pocket costs for beneficiaries.

Modernize the Medicare Part D Drug Benefit. Misaligned incentives in the Part D benefit design help drive increased drug spending by promoting use 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 to improve plans' ability to deliver affordable drug coverage for seniors and reduce their out of pocket costs. This 3-part proposal gives plan sponsors more incentives to manage benefits, 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.

- *Eliminate cost-sharing on generic drugs and biosimilars for low-income beneficiaries.* Current law specifies the cost-sharing amounts for more than 13 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 eliminating all cost sharing for generics, including biosimilars.
- *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 manufacturer discounts on brand name drugs are counted towards the calculation of out-of-pocket costs while generic drugs do not have required discounts that could be similarly applied.. 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 and treats brand and generic drugs the same when calculating out-of-pocket costs.
- *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.

- *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. The Secretary would not use this authority when it limits beneficiaries' access to the drug or increases beneficiary cost-sharing. Beneficiary cost-sharing for any drugs shifted from Part B to Part D may be counted toward the Medicare Advantage out-of-pocket limit for plans that have a combined Part D benefit, as it would have if the drug was covered under Part B.
- *Improve manufacturers' reporting of average sales prices (ASP) 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 submit required data on time. 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 drug manufacturers to report ASP data for Part B drugs and provide the Secretary with the authority to apply civil monetary penalties to manufacturers who do not report required data.
- *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 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. Reducing the WAC add-on from 6 percent to 3 percent would better reflect the discounts that ultimately are included when payment shifts to use of ASP data.
- *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.
- *Eliminate Pass-Through Payments for Drugs, Biologicals, and Biosimilars.* The Medicare Outpatient Prospective Payment System (OPPS) currently pays for a newly approved drug, biologic, or biosimilar at

ASP plus 6 percent for three years when the cost exceeds a certain threshold. These payments are known as “pass-through payments.” This proposal removes transitional pass-through payment for drugs, biologicals, and biosimilars from the OPPS. Eliminating pass-through payment for drugs, biologicals, and biosimilars will lower patient out-of-pocket costs by making them eligible for the reduced 340B payment level.

- *Reduce Average Sales Price-Based Payments When the Primary Patent Expires to Increase Competition and Reduce Gaming.* When a drug is about to go off patent, manufacturers often pay generic and biosimilar competitors to delay release of generic or biosimilar drugs, extending the time during which those drugs do not have competition. This proposal reduces payment for innovator drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action post-primary patent expiration or market exclusivity period expiration, whichever date is earliest. Once a competitor is commercially available, CMS will pay for both innovator and competitor drugs at ASP plus 6 percent. These changes will create a financial disincentive to anti-competitive behavior.

Eliminate the Medicaid Rebate Cap. One factor contributing to the increase in Medicaid drug spending is a statutory cap on manufacturer drug rebates at 100 percent of a drug’s average manufacturer price. Once this cap is reached, manufacturers can increase a drug’s price without increasing the associated Medicaid rebate, allowing manufacturers to set excessive prices outside of Medicaid. The Budget calls for eliminating this cap, ensuring manufacturers pay rebates covering all price increases for a drug.

Test Innovative Medicaid Drug Coverage and Financing Reforms. To test options for modernizing Medicaid drug coverage and financing, the Budget calls for new statutory demonstration authority allowing up to 5 state Medicaid programs, to test a closed formulary under which they negotiate prices directly with manufacturers. The proposal includes exempting prices negotiated under the demonstration from Best Price reporting, facilitating price negotiation between states and manufacturers. Participating states will be required to develop an appeals process for beneficiaries to access drugs outside the formulary based on medical necessity.

Improve Program Integrity in Medicaid Drug Benefits. The Budget closes loopholes manufacturers use to avoid paying their full rebate obligations, and calls for other changes to ensure appropriate payments. Among these proposals, the Budget closes a gap in HHS enforcement authority, enabling HHS to impose fines when manufacturers misclassify drugs for Medicaid drug rebate purposes, and eliminates a loophole allowing manufacturers to lower their rebate obligations on an original drug when they introduce an authorized generic. Further, the Budget revises Medicaid’s Federal Upper Limit (FUL) to reflect only true generic drug prices, ensuring it is not improperly inflated.

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 is re-proposing to end this type of anticompetitive behavior. 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.

Amend the 180-Day Forfeiture Provision Addressing Failure to Obtain Tentative Approval. Currently, first applicants with a deficient application for a generic drug before FDA can avoid forfeiting their 180-day exclusivity by claiming the failure is caused by a change in or a review of the requirements for approval imposed after the date on which the application is filed. This legislative proposal closes this loophole by

limiting it to instances where the change in the requirements for approval was the only reason the applicant failed to obtain tentative approval.

Codify FDA's Approach to Determining New Chemical Entity Exclusivity. This Budget codifies a narrow definition to avoid awarding exclusivity to products that do not represent a true innovation. Under the proposal, five-year new chemical entity exclusivity will apply only to drugs with significant changes to their chemical structure compared to current drugs.

Provide FDA Enhanced Authority to Address Abuse of the Petition Process. Sham citizen petitions, which are requests to FDA with the intent to delay approval of new generic drugs, do not promote generic drug competition. This proposal provides FDA with greater flexibility to summarily deny these petitions, and eliminate the mandatory 150-day response timeframe for these petitions, which FDA believes is unnecessary because all generic drug applications have goal dates under law and language is no longer needed to prevent delay of approval.

Encourage Biosimilar Development. Biosimilars must meet the same monograph standards issued by the U.S. Pharmacopeia as other non-biologic products, which include standards for strength, quality, packaging and labeling. This requirement can impede biosimilar innovation and competition. This proposal amends the Public Health Service Act so that biological products do not have to meet separate standards that were designed specifically for drugs. This change will make it easier for biosimilars to enter the market and increase competition, which is essential to reducing costs for biologic products.

Improve 340B Program Integrity. The Budget proposes to improve 340B Program integrity and ensure that the benefits of the program are used to help low-income and uninsured patients. 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.