VIEWPOINT

HEALTH POLICY

Paying for Prescription Drugs in the New Administration

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In a national survey in January 2020 involving 1011 participants, the second-ranked domestic priority for members of both the Democratic and Republican parties was lowering the cost of medications, just behind access to affordable health care.[1] This was not surprising. In 2019, a Kaiser Family Foundation poll found that 62% of people in the US were taking at least 1 prescription drug, and the total per capita expenditure for prescription drugs in the US in 2018 ($1228) was more than twice the average per capita expenditure for other Organisation for Economic Co-operation and Development countries ($562) (**Figure**).[2] The Trump administration often stated that lowering high drug costs was one of its highest policy priorities, but its statements and executive orders were not meaningfully implemented or were unlikely to have a substantial effect. In a survey from 2019 involving 1440 US adults, 24% reported having difficulty affording their medications.[3]

The increase in drug spending is driven primarily by brand-name drugs, which account for approximately 80% of drug expenditures. Unlike many developed nations, the US does not have a rigorous and independent mechanism to assess the benefits of new products in relation to their prices. By contrast, many peer countries use the findings of health technology assessment organizations to inform drug pricing and coverage decisions. Further, in the US, the payer landscape is highly fragmented for several reasons. Multiple private payors and different agencies within the federal government pay markedly different prices for the same drugs; required coverage of specific drugs and drug classes limits the bargaining power of Medicare and Medicaid. Although the US Medicare program represents more beneficiaries and drug expenditures than many countries, current law prohibits Medicare from directly negotiating drug prices with manufacturers (the federal government negotiates the prices of nearly all other products it purchases).

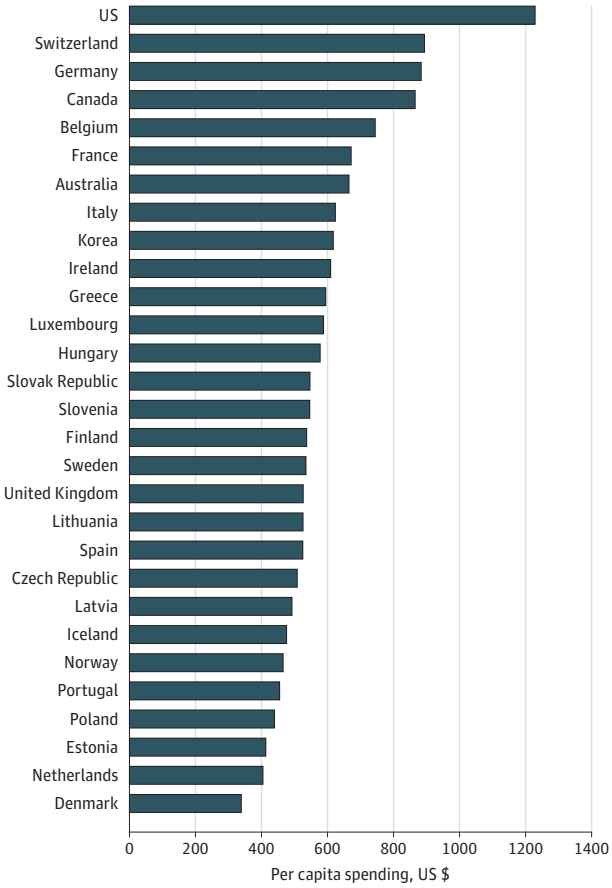
The Biden administration has stated its goal to repeal the prohibition on Medicare negotiation of Part D drug prices, establish an independent commission to recommend reasonable prices for high-cost drugs based on their value and prices paid in other countries, and limit drug price increases to the rate of inflation. Price increase limitation has garnered bipartisan support in Congress and was supported by the Trump administration; 6 states (New York, Massachusetts, Maine, Maryland, New Hampshire, and Ohio) have already enacted legislation to create drug affordability review boards.

The new administration can already begin implementing some of these objectives through existing authority and will quickly need to decide whether to adopt, modify, or reverse last-minute regulations promulgated by the Trump administration. These regulations would set drug payment in Medicare Part B at the lowest price paid in similar countries; in Medicare Part D, the regulations would prevent Part D plans from negotiating confidential rebates with manufacturers, as is now the case, and would instead encourage negotiation of price reductions and point-of-sale discounts. Both the Congressional Budget Office[4] and the Centers for Medicare & Medicaid Services' Office of the Actuary[5] estimated that such a rebate rule would increase premiums and federal spending by the Medicare program (overall by $170 billion over 10 years), but reduce out-of-pocket costs for some Medicare beneficiaries. New leadership in Washington, DC, could use the same statutory authority that the Trump administration relied on to create a new payment model for Medicare that would require drugmakers to provide rebates on price increases that exceed inflation, as is currently required by Medicaid and the Department of Veterans Affairs, and pass on some of these savings to patients.

The Biden administration could also plan to establish a Drug Affordability Commission to review the clinical benefits of high-cost drugs and publish voluntary recommendations for negotiated prices. Such a body, which might build on work by the independent nonprofit Institute for Clinical and Economic Review, would parallel the important role that health technology assessment organizations play in other countries, such as Canada, Germany, and the United Kingdom. The Biden administration has called for a public health insurance plan that would be made available to all US residents, the so-called "public option." Such a plan that paid for drugs with discounts similar to those currently in place in Medicaid could reduce net drug expenditures by approximately 49% compared with net drug costs currently paid by commercial insurers. A public plan that took a more limited approach similar to Medicare Part D could reduce net drug costs by an estimated 9% to 15%.[6]

Congressional action would be needed for broader drug pricing reforms, and a blueprint for this already exists. In December 2019, the House of Representatives passed the Elijah E. Cummings Lower Drug Costs Now Act, which gave the government the authority to negotiate the prices of certain drugs, set a price limit of 120% of the average price in 6 comparable countries, and limited annual price increases on branded drugs to the rate of inflation. In the Senate, Senators Chuck Grassley (R-Iowa) and Ron Wyden (D-Oregon) introduced the bipartisan Prescription Drug Pricing Reduction Act, which did not include a negotiation provision but was similar in other ways to the Cummings bill. This Act would also limit drug price increases in Medicare, restructure the design of the outpatient Medicare drug benefit to cap beneficiary costs, shift more responsibility for costs from the government to the insurers implementing the benefit, and increase the level of discounts in Medicaid. The Congressional Budget Office estimated that these House and Senate bills would save approximately $490 billion and $95 billion, respectively, over 10 years, but neither bill has been enacted.[7,8]

Figure. Per Capita Spending on Prescription Drugs in Organisation for Economic Co-operation and Development Countries in 2018



The new Congress and administration could reintroduce these bills in their entirety or support the writing of new legislation. Because relying on other countries' price negotiations is inefficient and could result in unintended consequences in the US and abroad, the government could support an independent health technology assessment organization to determine a fair value for costly new drugs. Even if its determinations are not initially used to define what government pays, having an evidence-based independent voice in the marketplace would be a useful guide for payors in the public and private sectors, and could be used to inform programs to educate physicians about more affordable prescribing.

While more robust negotiation would help bring about fairer prices for brand-name drugs, the new administration will also need to address the market for generics and biosimilar products. Brand-name manufacturers have used a variety of approaches to limit generic competition that go well beyond the original intent of their patent protections, leading to billions of dollars in excess spending. One often-used strategy is for companies to build a thicket of patents covering different formulations and uses of a given product that generic or biosimilar manufacturers then have to address, often in protracted litigation. The Biden administration can prevent excessive delays in generic and biosimilar competition by reforming the process for obtaining patents, protecting real innovation while making it easier to challenge patents that cover trivial changes or were improperly granted, and prohibiting anticompetitive rebate agreements that prevent biosimilar introduction and uptake.

The greatest challenge in enacting these changes will be the political strength of the pharmaceutical industry lobby, one of the largest in Washington, DC, which will charge that any drug pricing reform will reduce innovation. But transformative drug innovation often emerges in large part from publicly funded research and development, as the recent evolution of coronavirus disease 2019 treatments and vaccines has shown. In addition, less than one-third of new drugs approved in the past decade were rated as providing high clinical value compared with existing alternatives, although this rarely leads to lower prices.[9] The ability of manufacturers to set high prices for marginal new products may actually reduce the pressure for them to develop medications that truly add clinical value. More data-driven policies on drug pricing need not reduce prices equally across the board; pricing based on a product's actual clinical benefits could still lead to substantial manufacturer revenue and thus offer a strong incentive for research and development.

Medications are a ubiquitous and crucial part of medical practice. However, the unaffordability of prescription drugs contributes to negative outcomes for patients and places substantial strain on health care systems. The new administration and Congress have before them a variety of practical policy options that could make it possible to deploy this important component of health care more rationally and affordably, while protecting the discovery of truly useful new treatments.

ARTICLE INFORMATION

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