

Leadership Day, May 14-15, 2019

The High Cost of Prescription Drugs

Senators and House members should cosponsor and pass legislation to establish greater transparency in drug pricing, prohibit anti-competitive industry practices that create barriers to generics coming to market, take into account value in payment and coverage for prescriptions, and provide authority to the federal government to negotiate drug discounts under the Medicare Part D program, as described below in the “What is ACP Asking of Congress” section.

What’s it all about?

The cost of prescription drugs continues to rise, which greatly impacts access to life-saving treatments for patients who are unable to afford high out-of-pocket costs. Studies show that millions of Americans face the difficult choice of filling their prescriptions or paying for necessities such as food or housing. Patients may resort to cutting back or skipping doses of their medicines to save money, which can lead to more serious health complications. A [report](#) by the Senate’s Homeland Security and Governmental Affairs Committee found that “the prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017. On average, prices for these drugs increased 12 percent every year for the last five years—approximately ten times higher than the average annual rate of inflation.” According to a recent [report](#) published in *JAMA Internal Medicine*, the cost of the four most popular types of insulin, a life-saving treatment for diabetes, has tripled over the last decade and out-of-pocket costs have doubled. By 2016, the average price of insulin increased to \$450 per month and costs continue to rise. As a result, one in four people with diabetes report cutting back or skipping life-saving doses, which can be dire. If steps are not taken now to address the problem of rising and unsustainable drug pricing, both by the federal government and manufacturers alike, the very life-saving benefit these drugs were designed to provide could be lost to many.

What’s the current status?

In 2019, the House Committees on Oversight and Reform, Ways and Means, and Energy and Commerce, along with the Senate Finance Committee have held multiple hearings to examine policy solutions to lower the costs of prescription drugs. These hearings have examined testimony from patients whose prescribed medications remain unaffordable, experts in the field of medicine and academics who offer their expertise on lowering drug costs, and drug manufacturers being asked to justify the pricing of their products and why some remain unaffordable to those who need them. Bipartisan consensus has emerged in Congress on the need to lower drug prices, but not on a comprehensive set of reforms on how to get there. Still, many bills have been introduced in the 116th Congress addressing various aspects of prescription drug pricing, which is encouraging.

Addressing the cost of prescription drugs has also been a priority for President Trump and his administration. In May of 2018, the administration offered a blueprint to lower drug prices that identified four key strategies for reform including: improved competition, better negotiation, incentives for lower prices, and lower out-of-pocket costs. The administration has also issued a series of proposed regulations through the Department of Health and Human Services that provide additional strategies for lowering drug prices. These include, changes to Medicare Part D to lower prescription drug cost for beneficiaries, requiring the disclosure of list prices of all drugs covered under Medicare and Medicaid that are marketed through direct-to-consumer (DTC) advertisements, implementing a new International Pricing Index Payment Model designed to align drug prices in the United States with those of similar economies in other nations, and lowering out-of-pocket cost for patients using drugs with high rebates.

Why and how should Congress address this issue?

The rising cost of prescription drugs is of top concern to constituents from both political parties. It also strains the budgets of Medicare, Medicaid, and other payers, forcing trade-offs as more dollars need to be allocated to support

excessively priced medication at the expense of reduced benefits for other needed services, higher premiums, and higher taxes. Congress should focus on promoting competition in the pharmaceutical industry, increasing transparency in the pricing and costs associated with the development of drugs, implementing reforms to Medicare to lower out-of-pocket costs for seniors, and increasing the value of drugs in the marketplace. ACP supports the following bills that have been introduced in the 116th Congress:

- **The *Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 1209)***, which would amend the law to remove incentives for drug manufacturers to file excessive patents to keep generic drugs off the market, and would lift legal barriers that delay generic entry into the market.
- **The *Prescription Drug STAR Act (H.R. 2113)***, which would require manufacturers to publicly justify large price increases for existing drugs and high launch prices for new drugs, and would require the Secretary of HHS to publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs) on a public website, so consumers, employers, and other payers can understand and compare the discounts PBMs receive. It would also require all drug manufacturers to submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under part B. The bill has been approved by the House Ways and Means Committee and is pending action on the House floor.
- **The *Medicare Prescription Drug Price Negotiation Act of 2019 (H.R. 275/S. 62)***, which allows the Secretary of Health and Human Services to negotiate covered Part D drug prices on behalf of Medicare beneficiaries.
- **The *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/S. 340)***, which would improve patient access to alternative low-cost prescription drugs and biological products by preventing prescription drug manufacturers from misusing the FDA's Risk Evaluation and Mitigation Strategies (REMS) process to make it difficult for competing generics to be brought to the market. ACP [signed](#) a letter of support for this legislation. It has been approved by the House Energy and Commerce Committee and is awaiting action on the House floor.

What is ACP asking of Congress?

ACP published a position paper entitled "[Stemming the Escalating Cost of Prescription Drugs.](#)" Congress should increase its efforts to develop and pass policy reforms, consistent with ACP's paper, to increase transparency and accountability in drug pricing. We urge:

Senators to cosponsor and pass in the Senate the *Reforming Evergreening and Manipulation that Extends Drug Years, REMEDY Act (S. 1209)*, which would aid in the approval of more generic drug applications by the FDA and therefore improve patient access to those medications. Representatives should introduce the companion version in the U.S. House.

Representatives to cosponsor and pass the *Prescription Drug STAR Act (H.R. 2113)*, which takes important steps to promoting drug pricing transparency by requiring manufacturers to justify and explain price spikes on their drugs as well as reveal the price and quantity of the drug free samples that they give to clinicians, among other things. Senators should introduce the companion version in the Senate.

Representatives and senators to cosponsor and pass the *Medicare Prescription Drug Price Negotiation Act of 2019 (H.R. 275/S. 62)*, which would help to reduce drug prices by allowing the federal government to negotiate lower drug prices on behalf of Medicare beneficiaries.

Representatives and senators to cosponsor and pass the *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, (H.R. 965/S. 340)*, which would help prevent egregious practices by manufacturers that keep generic drugs from coming to the market.

Representatives and senators to cosponsor and pass the *Fair Accountability and Innovative Research (FAIR) Drug Pricing Act (H.R. 2296/S. 1391)*, which would require drug companies to disclose and provide more information about imminent drug-price increases, including data about research and development costs.

Who can I contact to learn more?

advocacy@acponline.org; Digital version of this issue brief can be found at: <https://www.acpservices.org/leadership-day/policy-priority-issues>