

## Ensure Access to Affordable and Essential Medications

### Reforms Needed to Reduce Drug Costs, Improve Transparency, and Eliminate Harmful Protocols

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#### **Background**

It is too often the case that patients are denied access to the most appropriate prescription drugs or treatments, as prescribed by their physicians, due to excessive costs and bureaucratic protocols. This can and often does put patients' health at risk and creates financial burdens that can be catastrophic. Patients can be left feeling helpless and without recourse. Unless much-needed reforms are made to the health care system to protect patients in these circumstances, patients will continue to suffer. Congress has taken note of several egregious practices that are harming patients and efforts are underway legislatively to make some important changes in the following areas:

**Reform Step Therapy Protocols:** "Step Therapy" is a type of prior authorization used by some insurance companies to determine if they will cover a prescribed procedure, service, or medication. "Step therapy" requires patients to first "try and fail" certain treatments (often lower cost) before being allowed access to other, potentially more appropriate treatments. The requirement to first "try and fail" can harm patients, undercut the physician-patient decision-making process, and create burden. Physicians do not currently have ready access to accurate patient benefit and formulary information, as there is no capability making this information available through EHRs. This lack of transparency makes it difficult to determine what treatments are preferred by a particular payer at the point of care.

ACP policy supports efforts to reduce the barriers to care associated with step therapy protocols as well as the administrative burdens imposed on physicians who must adhere to these protocols when treating patients. Furthermore, cost should only be a determinant when safety and efficacy are equal among two comparable drug choices and ACP strongly opposes overly restrictive drug formularies that impose substantial economic barriers to enrollees obtaining needed medications, particularly for low-income enrollees.

**Address Prescription Drug Costs:** 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."

The ACP has a long-standing policy of advocating for the ability of Medicare Part D to negotiate drug prices and rebates directly with pharmaceutical manufacturers as a way to lower costs within the program. Although employer and self-insured plans are able to negotiate and use their bargaining power to lower the price of drugs, Medicare and Medicaid programs are directed by statutes that can impede their ability to obtain the best prices. Medicare Part D pays on average more than other federal health programs: 73 percent more than Medicaid and 80 percent more than the Veterans Health Administration. ACP believes that seniors can get a better deal on their drug costs if Medicare were allowed to negotiate prices.

**Increase Transparency in Prescription Drug Pricing:** For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development cost and innovation and is well regulated by market forces. Price spikes for drugs already on the market have made many stakeholders wary, especially because many of these new therapies

treat small populations, with little supporting data that overall health care costs are reduced. In 2018, a number of drug manufacturers announced they would not raise prices on drugs, noting the public concern about increasing drug prices. However, these decisions created a false sense of confidence that the issue was being addressed and in late 2018, most of these companies reneged on these announcements and raised the prices of their products.

ACP outlined its support for increasing transparency in the pricing, cost, and comparative value of all pharmaceutical products in our 2016 policy paper, "[Stemming the Escalating Cost of Prescription Drugs](#)." We also support broad efforts by federal regulators to ensure that information about a drug's effectiveness and safety, and about alternative treatments, is clearly disclosed to patients.

### **Congressional Environment**

Legislation has been introduced in both the House and Senate to address burdens imposed by step therapy protocols. The Safe Step Act (H.R. 2279/S. 2546), as introduced in the House by Rep. Raul Ruiz (D-CA) and in the Senate by Sen. Lisa Murkowski (R-AK), would require health insurers to provide an exceptions process for any medication step therapy protocol based on clinical decision-making, medical necessity, and other patient needs. ACP supports this legislation.

The House Energy and Commerce, Ways and Means, Education and Labor Committees as well as the Senate HELP Committee are all examining the related issues of the cost and transparency of prescription drugs and are working to develop consensus on legislation to address these issues. Several legislative proposals, with differing elements, have already been put forth and are working their way through the committee process. ACP has weighed in with the committees on the various individual proposals.

### **Request of Congress**

- Cosponsor and pass the Safe Step Act (H.R. 2279/S. 2546), which would ensure patient access to appropriate treatments based on clinical decision-making and medical necessity, not arbitrary step therapy protocols.
- Cosponsor and pass legislation to reduce prescription drug costs such as 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.
- Cosponsor and pass legislation to address transparency in prescription drug pricing such as the Prescription Drug STAR Act (H.R. 2113), which would require 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.