

## DRUG PRICING AND TRANSPARENCY

### AAFP Position

The AAFP has long supported legislation to ensure the availability of effective, safe, and affordable prescription medications. The AAFP is a member of the Campaign for Sustainable Rx Pricing (CSRxP), a nonpartisan coalition of nonprofit medical associations, insurers, and hospitals committed to pushing back against drug price increases by striking a balance between drug innovation and affordability. As a member of CSRxP, the AAFP is working with stakeholders to promote transparency and stronger regulatory enforcement to lower the cost of prescription drugs. The AAFP also supports the availability of affordable generic medications as a cost-effective substitute for many brand-name prescription medications.

### Drug Pricing in the United States

Americans spend more on prescription drugs than any other country in the world, accounting for approximately 17 percent of all health care spending.<sup>1</sup> Unlike other nations where government plays a role in setting prices, drug prices in the United States are largely set by pharmaceutical companies. The high cost of prescription drugs is one of the top health care concerns facing Americans today, yet there is little consensus on strategies to best address this health care priority.<sup>2</sup>

Most insurance plans, including employer-based coverage, Medicare Part D, and Medicaid, include some form of prescription drug coverage, with various levels of cost sharing for specific drugs. Drug manufacturers, insurance providers, pharmacy benefit managers (PBMs), and providers all play a role in setting the price of medications.

### *Exclusivity and Generics*

The Food and Drug Administration (FDA) allows new drugs a period of exclusivity. This period applies to various drugs upon FDA approval and prohibits copycat generic drugs from entering the market for a specified length of time. Groups opposed to this model argue these “patent monopolies” allow drug manufacturers to charge a premium for these medications, knowing that they can delay competing with a cheaper alternative.

At the same time, policymakers and manufacturers have long advocated for accelerated development of generic medication alternatives to cut drug costs. Today, approximately 90 percent of all prescriptions filled in the United States are for generic drugs identical in dosage form, composition, safety, and strength to their brand-name counterparts. Generic drugs, while often different in shape and color than the original, tend to be cheaper than their brand name counterparts. Generics allowed for \$1.67 trillion in savings over the past decade alone and cost, on average, 80-85 percent less than their brand-name equivalents.<sup>3</sup>

<sup>1</sup> Avorn, J., Kesselheim, A.S., and Sarpatwari, A. “The High Cost of Prescription Drugs in the United States.” *JAMA*. Web.

<sup>2</sup> Palosky, C. “Prescription Drug Costs Remain Atop the Public’s National Health Care Agenda, Well Ahead of Affordable Care Act Revisions and Repeal.” *Kaiser Family Foundation*. Web.

<sup>3</sup> Gottlieb, S. “FDA Working to Lift Barriers to Generic Drug Competition.” FDA. Web.

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## Current Legislation

While Congress has long debated measures to address the high cost of prescription drugs, many states have also introduced legislation to lower the cost of prescription medication.

### *Drug Importation*

Many states, including [Colorado](#), [Utah](#), and [Vermont](#), are considering bills to allow individuals within the United States to purchase and import drugs from Canada or other nations where prescription drug prices can be a fraction of those found in the U.S. Personal importation of drugs from foreign nations is currently illegal under US law, and groups opposed to importation, including drug manufacturers, argue that these drugs would not be subject to the FDA's rigorous safety standards. Any state looking to import drugs from abroad would also need federal approval from the Department of Health and Human Services prior to establishing an importation program.

### *Negotiated Pricing and Price Controls*

Some patient advocacy groups have long supported a more direct role for government in the drug pricing debate. Today, drug manufacturers are required to offer significant discounts on the drugs paid by Medicaid, while the Veterans Health Administration can directly negotiate with drug manufacturers to secure even larger discounts. Furthermore, AAFP is supportive of [legislation](#) that would allow Medicare Part D to negotiate prices with drug manufacturers to lower costs for seniors.

Efforts in several states, most notably [California's Prop 61](#) and Ohio's [Issue 2](#), have sought to tie drug prices paid by state agencies to those paid by the VA, which is required by federal law to offer prescription drugs approximately 24 percent below that of the drug's list price. Both ballot measures faced fierce opposition from drug manufacturers and were ultimately rejected by voters. Recently, [Maryland](#) passed a law that prohibits generic medication price gouging.

### *Pharmacy Benefit Managers*

Pharmacy Benefit Managers (PBMs) act as middlemen between drug manufacturers and insurers and are often able to negotiate lower rates for prescription drugs for patients. PBMs have been criticized for adopting a more vertically integrated business model in which they distribute drugs to their own in-house pharmacies. As a result, states have been increasingly likely to regulate PBMs as part of their efforts to lower prescription drug prices. Several states, including [Pennsylvania](#), [Texas](#), and [Nevada](#) have passed legislation requiring PBMs to register prior to operating within that state, while others, including [Connecticut](#), [Georgia](#), and [North Carolina](#), have banned PBMs from inserting "gag clauses" into their pharmacy contracts prohibiting pharmacists from recommending cheaper prescription drugs when they're available.

### *Drug Cost/Price Hike Transparency*

Pending legislation in 30 states, including [Nebraska](#) and [Massachusetts](#), would require drug companies to publicly disclose whenever the year-over-year price increase of a drug exceeds a certain percentage. This legislation would also require companies to justify any significant price hikes and have that information made public.

In 2017, California passed [legislation](#) that would require drug manufacturers to justify any price increases that exceed 16 percent or more over two years. Nevada's governor signed into [law](#) a bill that places stricter limits and disclosure requirements on drug manufacturers and PBMs that produce and distribute diabetes treatment products, including insulin. These bills have been heavily opposed by drug manufacturers and are currently being argued in court.