

Prescription Drug Prices: Problems, Solutions, and What States Can Do

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BACKGROUND

The price of prescription drugs has increasingly been a topic of public concern over the last several years. A 2018 Kaiser poll showed that 80% of Americans believe drug prices are unreasonable, and a significant majority think that Congress and the President are not doing enough about the problem.¹ Additional attention to the issue has been driven by media coverage of particularly riveting examples, including the case of Martin Shkreli, who raised the price of a patented drug 5,000% overnight; the \$94,500 launch price of the first effective treatment for Hepatitis C; and the recent dramatic price increases for Epi-pens and insulin, two commonly used drugs that have been on the market for decades.

While all these examples illustrate a pricing problem, there are actually several different dynamics at work in each case, spanning business practices, health policy, and clinical implications.² At the root of the issue in each case, however, is the so-called “list price” of the drug that is set by the manufacturer. While that price can become dramatically skewed through the distribution chain because of discounts, rebates, and insurance coverage, the list price is always at the center of those calculations, and has a direct relationship to the price paid by many consumers. Consequently, the single most impactful action policymakers can take on the issue

of drug costs is to address the underlying list price itself.

Even when a more direct solution isn't feasible, however, there are interventions that can be effective in mitigating the impact of high prices on certain parties. Depending on the situation they are most urgently looking to address, policymakers at the state level should also consider the merits of different proposals that shift the burden of cost away from consumers and on to other entities, including employers, health care providers, or the state itself.

THE TYPES OF PRESCRIPTION DRUG PRICING PROBLEMS

★ **High and increasing prices for drugs that are old and commonly used but effective.** There are several reasons that common, long-available drugs can be expensive or suddenly spike in price. Sometimes, as in the case of shortages, a mismatch between supply and demand can prompt a significant price hike. More often, however, pharmaceutical companies increase prices simply because it is profitable.³ There are many loopholes that allow drug manufacturers to monopolize the market for certain drugs: gaming of special programs designed to incentivize the development of treatments for rare disease, “pay-for-delay” tactics to prevent competitors

entering the market, and other forms of patent abuse.

- ★ **Expensive drugs that are ineffective or have cheaper alternatives.** A consequence of having an insurance system that protects most consumers from understanding the cost of the drugs prescribed to them is that it's difficult to assign responsibility for determining the best balance of price and effectiveness. Patients don't have the medical knowledge necessary to understand clinical differences between products, and many doctors and pharmacists don't view it as their responsibility to consider price when distributing a prescription to the patient. This means that even when a drug may offer a very limited benefit or when an equally effective and less costly option is available, patients may not be aware they have a choice, allowing pharmaceutical companies to maintain or raise prices without concern about the usual impact of competition.
- ★ **Extremely high prices for new and effective treatments.** Periodically, new drugs come to market that have the potential to dramatically improve treatment options for a given disease, as in the case of CAR T-cell therapies

1 <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals/>

2 <https://ldi.upenn.edu/healthpolicysense/what%E2%80%99s-story-drug-prices>

3 <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-drug-prices-20181008-story.html>

for some forms of cancer or the introduction of the breakthrough treatment for Hepatitis C. In these cases, manufacturers have an argument to make that the drugs are genuinely “worth” a high price because of the positive impact they have on patients’ lives, especially if they treat a rare disease. In these cases, policymakers must ask themselves what a truly fair and reasonable price is - considering cost-effectiveness analysis as well as the personal impact on patients and families. They must also reckon with the reality that even a cost-effective drug, if needed by a large population, could break the budget of a public payer like Medicaid or state correctional systems - a problem states grappled with after the introduction of the effective Hepatitis C treatment. Failure to address this issue in advance of new breakthroughs targeting some of our most devastating diseases like cancer, Alzheimer’s, and ALS could again result in treatments being rationed among patients even more explicitly than they are today - an outcome that all policymakers should agree is unacceptable.

STATE OPTIONS

Many of the most impactful policy interventions related to drug prices are outside the purview of state influence, including reforming the drug approval and patenting processes. There are actions states can take, however, to achieve different goals: addressing underlying prices, controlling state spending on drugs, and providing relief to consumers.

Ways States Can Address Underlying Prices

- ★ **Creating new transparency laws in the hopes that public pressure will impact drug pricing:** One aspect that makes understanding drug pricing so challenging is that the use of discounts and rebates mean that the prices listed for drugs don’t have a clear relationship to what different stakeholders actually pay for them. One way states can begin to make progress on this issue is by creating new laws requiring manufacturers to report to the state about the list price for certain drugs, the rebates purchasers receive, and/or information about their development costs and profits. While these laws don’t include any authority to lower the price of a drug directly, their goal is to provide state government new data to inform regulation efforts, and in some cases to provide the public with insights that may inspire them to put additional pressure on drug companies to reform their practices.



State to Watch: California

In October 2017, California passed legislation requiring manufacturers to provide 60 days notice to health plans if they plan to increase a drug’s price by more than 16% over two years, and to give a justification for the increase. This type of legislation is particularly impactful in a large and populous state like California which represents a significant share of pharmaceutical companies’

domestic business. A little less than a year into implementation, some supporters and journalists have attributed cancelled price increases to the law,⁴ although it’s difficult to discern what other factors may have influenced the companies’ decisions.

- ★ **Instituting legal and/or financial penalties for price gouging:** Some states have gone a step further by introducing legislation that would penalize drug companies for increases that meet the state’s definition of “price gouging,” although the first of these bills to pass, in Maryland, is currently being challenged in court. It’s possible that legislation more specifically written in regard to the scope of the law could avoid similar litigation, but policymakers should be cautious about the long term outlook for this category of legislation before pursuing it.



State to Watch: Maryland

In May 2017, bipartisan majorities in the General Assembly voted to adopt first-in-the-nation legislation prohibiting a manufacturer or wholesale distributor from engaging in price gouging in the sale of certain drugs.⁵ The law authorizes the attorney general to file suit against manufacturers that unjustly raise the price of needed medications that have no competitors above a certain threshold. The law went into effect in October 2017 but was struck down in April 2018 by a federal appeals court. Maryland’s attorney general has petitioned the U.S. Supreme Court in an effort to overturn the lower court’s ruling.⁶

4 <http://www.latimes.com/business/la-fi-drug-prices-20180710-story.html>

5 <http://mgaleg.maryland.gov/webmga/frm.Main.aspx?pid=billpage&stab=03&cid=HB0631&tab=subject3&cys=2017rs>

6 <http://www.baltimoresun.com/news/maryland/politics/bs-md-frosh-drugs-20181019-story.html>



Providers and Payers Innovating to Control Costs

In addition to state government-led efforts, there are ways that health care providers and insurance companies can creatively attempt to address high prices. One of the most innovative approaches is the example of Civica Rx - a new non-profit generic drug manufacturer formed in 2018 by a coalition of health systems across several states. The initiative, which is also supported by private foundations, will focus on manufacturing alternatives to 14 generic drugs often used in hospitals, with the dual goals of lowering costs and providing a more predictable supply.⁷ The company hopes to have drugs on the market as soon as early 2019.

Ways States Can Control Their Own Spending On Drugs

- ★ **Requesting additional authority from the federal government to exclude low-value drugs from coverage under state Medicaid programs:** State Medicaid programs currently have special access to the Medicaid drug rebate program - an arrangement in which pharmaceutical companies provide a special discount on pharmaceuticals

in exchange for having most of their products covered in the Medicaid program.⁸ States also negotiate additional discounts with manufacturers, but under current Medicaid rules they are prohibited from excluding any drugs from their Medicaid formularies - even if they are shown to be ineffective or prohibitively costly. Massachusetts applied for a waiver of those federal rules in order to be able to exercise the same authority over their Medicaid drug programs that private health plans utilize, but the Centers for Medicare and Medicaid Services (CMS) rejected the proposal on the basis that the state would be violating the terms of the rebate program.⁹ CMS has instead indicated it may be willing to allow states to utilize closed formularies if they opt-out of the drug rebate program, but to date no state has pursued that option, likely because of the significant risk that it would end up making drugs more, rather than less, expensive.¹⁰



State to Watch: New York

New York has taken one of the most aggressive approaches to controlling costs in its Medicaid program possible without federal approval. In its budget for state fiscal year 2018, New York implemented a cap on Medicaid prescription drug spending. If the Department of Health projects that spending on drugs will exceed the cap, a

process is triggered to prompt the commissioner to negotiate supplemental rebates for certain drugs identified as contributing to the increase. If the commissioner and the company cannot reach an agreement about an extra rebate, the state's Drug Utilization Review Board is called upon to identify an appropriate rebate amount, and if the manufacturer declines to comply, the state can institute utilization management tools to restrict the use of the drug.¹¹

- ★ **Utilizing outcomes-based contracting tools:** In the absence of waiver approval to exclude specific drugs from their formularies, many states are exploring outcomes-based contracting tools in an attempt to control costs in their Medicaid programs. This type of contracting involves creating voluntary arrangements in which there are financial penalties or rewards tied to a drug's actual performance in the covered population. While far from a panacea for underlying problems,¹² these types of contracts may have potential to lower state spending when applied effectively.



State to Watch: Oklahoma

In June 2018, CMS gave Oklahoma approval to begin negotiating with drug companies to enter into voluntary agreements under which price the state pays for a given drug can be tied to the value it provides

7 <https://intermountainhealthcare.org/news/2018/09/not-for-profit-generic-drug-company-officially-established-named-civica-rx/>
 8 <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>
 9 <http://www.wbur.org/commonhealth/2018/06/27/trump-administration-rejects-massachusetts-plan-to-curb-medicaid-drug-prices>
 10 <https://ccf.georgetown.edu/2018/07/16/trump-administration-encourages-states-to-look-for-waivers-to-opt-out-of-medicaid-drug-rebate-program/>
 11 <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap>
 12 <https://morningconsult.com/opinions/outcomes-based-drug-contracts-not-move-us-closer-value/>



for patients. In most cases, this would likely take the form of an additional rebate paid to the state by the drug company if its product fails to achieve agreed-upon outcomes. In its first use of this new authority, however, Oklahoma agreed to pay a manufacturer less for a schizophrenia medication the longer a patient took it - the idea being that by aligning incentives under the arrangement, there is potential for everyone to benefit: the drug company still makes a profit because the patient continues to use its product, the state derives a financial benefit from encouraging patients to adhere to their medication over time, and the patient maintains a stable and effective treatment regimen.¹³ The evidence base for these types of arrangements is still unclear, so other states interested in trying innovative approaches to purchasing should keep an eye on the models tested, and what the University of Oklahoma's eventual analysis tells us about their effectiveness.

WAYS STATES CAN HELP CONTROL COSTS FOR CONSUMERS

- ★ **Regulating Pharmacy Benefit Managers:** Pharmacy Benefit Managers (PBMs) act as third-party administrators for the prescription drug portions of health insurance plans. The majority of the market is dominated by just a few large PBMs, each of which manages the pharmacy benefits for tens of millions of people enrolled in different health plans across

the country. They decide how formularies and management tools should be structured and use the massive bargaining power they have to negotiate rebates and discounts on drugs for the health plan. In theory, those discounts should make prescriptions more affordable for patients, too, but because of the way incentives are structured for PBMs, they are primarily accountable to the health insurers they contract with and their own shareholders, not consumers. States can create new regulations for PBMs that prevent them from implementing business practices that harm consumers or payers, like employers and the government, and require them to ensure that the special deals they negotiate for health plans benefit individuals and families as well.



State to Watch: Ohio

In recent years, several states including West Virginia, Kentucky, and Arkansas have discovered that PBMs contracting with Medicaid plans in their states were charging the program a significantly higher price for prescriptions than they were paying pharmacies to fill them - a practice known as “spread pricing.” While West Virginia responded by prohibiting the use of PBMs in their Medicaid program entirely, Ohio is taking a slightly different approach to the same problem, by requiring Medicaid plans to develop new contracts that use a pass-through pricing model in which the state would be billed the

same amount paid to the pharmacy for filling the prescription, plus an administrative fee.¹⁴ The new policy will go into effect January 1, 2019, and is projected to save the state \$16 million.¹⁵

- ★ **Exerting pressure on the federal government to allow the importation of prescription drugs:** The price of drugs in other developed nations are often dramatically lower than those paid by American consumers, likely due to the lack of centralized drug procurement and coverage decisions in the United States. Under current federal law, however, the importation or re-importation of prescription drugs from other countries is illegal, even for personal purposes. Since 2006, the Secretary of the United States Department of Health and Human Services (HHS) has had the authority to permit the importation of drugs from Canada under specific circumstances, but no Secretary has exercised that right. States are increasingly interested in how they can exert pressure on HHS to allow them to create drug importation programs that would offer lower cost options to patients, employers, and state health plans.



State to Watch: Vermont

The National Academy of State Policy has developed model legislation on importation designed to fit clearly within the constraints of what the federal executive branch is authorized to allow. In 2018,

13 <https://www.reuters.com/article/us-health-usa-medicaid/oklahoma-medicaid-tests-new-tactic-to-curb-u-s-drug-costs-idUSKCN1L81L6>

14 https://www.cleveland.com/open/index.ssf/2018/08/ohio_medicaid_to_end_contracts.html

15 <https://www.policymed.com/2018/09/ohio-cracking-down-on-pbm-contracts.html>



Vermont became the first state to pass a bill based on that approach, which establishes a state-based infrastructure prepared to import drugs from Canada on a wholesale basis, and directs the state's Agency for Human Services to formally request approval of the program from the federal Secretary of Health and Human Services, Alex Azar.¹⁶ Secretary Azar's comments about the safety and effectiveness of importation have been mixed,¹⁷ so it is unclear how, and if, he will respond to such a direct appeal from a state government.

CONCLUSION

Addressing drug prices can be a daunting task for state leaders, both because of the complexity of the issue and the powerful interests involved. When exploring options to address drug prices, state lawmakers should keep in mind that many of these approaches will affect pharmaceutical companies' profits, and may prompt legal action from the well funded and staffed industry. Legislators

shouldn't be dissuaded by the possibility of legal action, but should keep in mind that once their proposals are passed and enacted, it will ultimately be up to their Attorneys General to defend against legal challenges. Early input about the legal arguments on both sides of the issue can help legislators to weigh the pros and cons of various approaches in terms of the time spent in litigation, and can also be useful in drafting legislation that can withstand legal challenges.

Finally, state elected leaders should consider how they can utilize individual and collective action to put pressure on the federal government to take more aggressive action on drug prices. Although it may be indirect, state leaders can make a meaningful difference for their constituents by encouraging members of their Congressional delegation and the executive branch to address pricing through changes to the Medicare program, the drug approval and patenting process, and Federal Trade Commission action to promote competition.

The drug pricing problem is a complicated one and a comprehensive solution doesn't appear to be on the immediate horizon, but by utilizing a multi-pronged approach, state policymakers have the power to influence prices, control costs for state government, and provide relief to their constituents.

FURTHER RESOURCES:

[The Drug Pricing Lab](#) at Memorial Sloan Kettering - for tutorials and resources to understand the drug pricing problem.

The National Academy of Health Policy's [Center for State Rx Drug Pricing](#) - for tracking of current state bills, model legislation, and policy and legal resources for lawmakers.

Pew's Drug Spending Research Initiative - [for additional ideas](#) about how states can creatively address drug prices broadly, or in targeted programs.

Harvard University's [Program on Regulation, Therapeutics, and Law](#) - for technical assistance and research resources.

¹⁶ <https://nashp.org/how-vermont-will-implement-its-groundbreaking-drug-importation-law/>

¹⁷ <https://www.healthleadersmedia.com/finance/azar-drug-importation-may-not-be-gimmick-after-all>