



# State Policies to Address Prescription Drug Prices

By Thomas Huelskoetter | May 31, 2018

Over the past few years, high and rising prescription drug prices have generated significant controversy. Large, bipartisan majorities of the public support increased government action to reduce drug prices.<sup>1</sup>

However, little action has been taken at the federal level to reduce prices. Despite President Donald Trump's repeated promises during the campaign to crack down on high drug prices, his administration has only recently begun to develop a policy response.<sup>2</sup> And unfortunately, the president has abandoned the more ambitious proposals he supported during the campaign, such as Medicare price negotiation, in favor of more modest and pharma-friendly proposals. Perhaps as a result, President Trump's recent drug pricing speech was followed immediately by a notable rise in pharmaceutical industry stocks.<sup>3</sup>

Yet in spite of this federal inaction, several states have taken steps to address prescription drug prices over the past couple years. Many of these reforms fall into three major categories: improving price transparency; increasing state negotiating power; and cracking down on price gouging.

The experiences of these states demonstrate potential promising paths forward for other states, which have the opportunity to take a leadership role in reducing drug prices for patients.

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## Improving price transparency

Although greater transparency by itself is not enough to bring down prescription drug prices, laws that ensure meaningful transparency are still an important and achievable goal. In addition to providing tools to publicly shame prescription drug manufacturers who implement egregious price increases, it can help advocates and policymakers lay the groundwork for more ambitious reforms in the future.

The transparency bills that states have considered vary in their strength and utility. Two strong examples of transparency legislation were signed into law in 2017 by Nevada and California. The Nevada law focuses specifically on insulin, requiring insulin manufacturers to justify price increases above a certain threshold. It also requires manufacturers to annually report information including insulin profits, production costs, and marketing spending.<sup>4</sup> It increases transparency on pharmacy benefit managers (PBMs), which negotiate prescription drug prices on behalf of large employers and insurers, by requiring them to disclose data on the rebates they negotiate with insulin manufacturers. In addition, it requires patient advocacy groups to publicly disclose their donations, including donations from pharmaceutical companies.

Meanwhile, the California law requires drug manufacturers to provide advanced notice if an upcoming price hike would have the effect of increasing a drug's list price by 16 percent or more over the course of two years.<sup>5</sup> The law also requires health insurers to report annual data showing what percentage of their premium increases are attributable to rising prescription drug prices.

Following California's example, Oregon enacted a transparency law in 2018.<sup>6</sup> While a California-style proposal to mandate advanced notification of price increases was dropped from the final bill, the Oregon law does require drug manufacturers who raise a drug's cost by more than 10 percent annually to report information such as profits, research and development costs, marketing spending, and data on total sales for the drug.<sup>7</sup>

Some other state transparency laws have been more limited. In 2016, Vermont became the first state to act on transparency for price increases, passing a law that "requires the state to identify up to 15 drugs that account for significant state spending and which have seen price increases of either 50 percent over five years or 15 percent over one year." The law requires the relevant manufacturers to justify these price increases.<sup>8</sup> Since 2016, however, some Vermont legislators have expressed frustration that the law did not go far enough in ensuring access to meaningful data on specific drugs; the price justifications submitted by drug manufacturers were largely protected by confidentiality rules and thus inaccessible even to the legislators themselves.<sup>9</sup>

Furthermore, legislators in some states have proposed transparency laws that focus only on PBMs.<sup>10</sup> Although more transparency for PBMs and the rebates they negotiate with pharmaceutical companies would be a positive step forward, it is not a substitute for greater transparency on pharmaceutical companies. Given that pharmaceutical companies are largely able to set their own prices for their monopoly products, bringing down drug costs will ultimately require legislation that directly addresses these underlying list prices.

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## Increasing state negotiating power

Recently, policymakers and advocates in Maryland proposed ambitious legislation to tackle high drug prices directly. Inspired by Maryland's historical all-payer rate setting system for hospitals and model legislation from the National Academy for State Health Policy, the legislation would establish a Drug Cost Commission that would be empowered to set payment rates for certain prescription drugs. This commission would perform a similar role to the state's Health Services Cost Review Commission, which manages hospital payment rates.<sup>11</sup>

As introduced, the Drug Cost Commission would have tracked prescription drug prices and closely monitored the most expensive drugs. For drugs that exceeded a certain price, the commission could have launched a formal review with additional disclosure requirements on drug manufacturers, who would have to justify their price. In cases where this review found the price to be excessive, the commission could then have established a maximum payment rate for the drug, which would have applied to commercial plans as well as Maryland's Medicaid program and state employee plans—and which would apply up through the supply chain.<sup>12</sup> This would have functioned as an upper limit, preventing these payers from paying a higher price for the drug than the commission's maximum rate.

However, this rate-setting authority was dropped from later versions of the bill, which pared down the commission's role to focus on reviewing drug pricing data and releasing an annual report on pricing trends with policy recommendations to address prices.<sup>13</sup> This compromise version of the bill passed the state's House of Delegates, but the state Senate did not pass it before the end of the most recent legislative session.<sup>14</sup>

While many states have focused on legislative efforts, Massachusetts' approach centers around a proposed Medicaid waiver amendment from the federal government. The state's proposal would amend its existing Section 1115 waiver to enable the Massachusetts Medicaid program to adopt a commercial-style formulary, or list of covered and noncovered drugs, in addition to the traditional rebate program that helps control Medicaid drug spending.<sup>15</sup> Importantly, the state hopes to be able to use comparative effectiveness data on a drug's clinical benefit relative to other treatments as one of its criteria for inclusion or exclusion on the formulary. Given the vulnerability and significant health care needs of the Medicaid population, it will be important for state and federal policymakers to ensure that this formulary is not too restrictive and that there is a robust and adequate appeals process.

In its justification for this proposal, the state has emphasized not only the budgetary strain of rising prescription drug prices but also concern over federal efforts to relax approval standards at the Food and Drug Administration (FDA), which approves new drugs.<sup>16</sup> For example, the 21st Century Cures Act, enacted in 2016, expanded the types of data that the FDA could consider when reviewing whether a drug is safe and effective, including the use of less rigorous surrogate endpoints in place of more traditional proof of clinical effectiveness.<sup>17</sup>

Notably, Massachusetts' waiver request specifically references 21st Century Cures and argues that, "Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints."<sup>18</sup> As a result, Massachusetts argues that its Medicaid program should have more authority to "exercise discretion about whether these drugs should be covered without being fully clinically proven."<sup>19</sup> For these drugs, the state proposes to establish an additional review process with the University of Massachusetts Medical School to further study the evidence and ensure that covered drugs are proven to be clinically effective before the state pays high prices for them.

Unfortunately, Massachusetts' waiver request also contains a proposal to reduce the state's Medicaid expansion eligibility from 138 percent of the federal poverty level (FPL) to 100 percent of FPL.<sup>20</sup> These beneficiaries would be shifted to marketplace coverage, which would likely lead to them having access to fewer benefits and paying higher costs. However, the waiver request's specific proposal on drug pricing remains a promising approach if it includes the protections mentioned above to protect beneficiaries' access to treatment.

Furthermore, there is currently uncertainty as to whether the federal government will approve Massachusetts' waiver request.<sup>21</sup> The state's waiver proposal is similar but distinct from a Trump administration proposal to test Medicaid formularies in up to five states.<sup>22</sup> The Massachusetts formulary system would complement the existing Medicaid rebate program; the state would negotiate additional savings in addition to the standard rebates. On the other hand, the Trump administration proposal would require the demonstration states to opt out of the current drug rebate program entirely and use formularies instead. The latter approach is significantly flawed, as there would be no guarantee that these states could maintain the same level of savings that they currently receive under the rebates, raising the possibility that state Medicaid drug spending could actually increase under the proposal.

### Medicaid Drug Rebate Program<sup>23</sup>

State Medicaid payment for prescription drugs is complex, and includes the Medicaid Drug Rebate Program. This program ensures that, as a condition of Medicaid covering all of a manufacturer's drugs, state Medicaid programs receive rebates based on the discounts that manufacturers negotiate in the commercial market. Most states have supplemental rebate agreements in addition to this federal requirement.

Meanwhile, New York implemented a drug spending cap within its Medicaid program in 2017 as part of the state's fiscal year 2018 budget.<sup>24</sup> In years when the state is on track to trigger the cap, state Medicaid officials must identify the prescription drugs most responsible for driving higher spending and attempt to negotiate additional rebates with drug manufacturers in order to try to bring spending back under the cap. To add to the state's leverage in these negotiations, state officials can require manufacturers to confidentially disclose to them information such as average profits, research and development spending, marketing spending, and average rebates. Furthermore, drug manufacturers who refuse to agree to additional rebates may have their drugs referred to the state Medicaid Drug Utilization Review Board, which will conduct a value assessment and recommend a target rebate amount. If the manufacturers do not agree to sufficient rebates after the value assessment, the state Medicaid program can subject all of their drugs to penalties. These potential penalties include formulary-style actions, such as the state requiring prior authorization for the drugs or recommending that the state's Medicaid managed care organizations drop coverage for the drugs—within certain guidelines to maintain beneficiaries' access to care.<sup>25</sup>

New York is currently on track to trigger the cap in 2018 for the first time, and the state has begun the process of reviewing high-priced drugs and negotiating additional rebates.<sup>26</sup>

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## Addressing price gouging

The widespread pharmaceutical industry practice of annually hiking prices on existing drugs far in excess of the rate of inflation has increasingly become a major source of concern for patients and policymakers.

In 2017, Maryland responded to this issue by passing a law that empowered the state's attorney general to crack down on excessive price increases on generic drugs.<sup>27</sup> Under the law, the attorney general would have the authority to sue drug manufacturers who raise the prices of qualifying generic drugs to "unconscionable" levels.<sup>28</sup> If the state court decided to impose penalties, it could require the price to be lowered to a previous level; order that rebates be provided to those who paid the price; or impose fines on the manufacturers.

Recently, a panel of the 4th U.S. Circuit Court of Appeals ruled 2-1 that this law violates the U.S. Constitution's dormant commerce clause.<sup>29</sup> Maryland Attorney General Brian Frosh has requested an en banc review of this decision by the full 4th Circuit.<sup>30</sup> Despite this current uncertainty, other states are continuing to explore price gouging laws, given their potential to curb excessive price increases. For example, the Illinois House of Representatives recently passed a similar price gouging bill in April 2018.<sup>31</sup>

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## Other proposals

States have explored several other types of reforms in addition to the three categories detailed above. Most recently, the governor of Vermont signed legislation to legalize the importation of prescription drugs from Canada, making Vermont the first state to enact such a law.<sup>32</sup> Under the new law, Vermont's Agency of Human Services must design an implementation proposal for the drug importation program and submit this plan to the federal government for approval by July 2019.

Other examples include ballot initiatives in California in 2016 and Ohio in 2017 that would have capped the drug prices paid by state agencies, including Medicaid, at the level paid by the U.S. Department of Veterans Affairs.<sup>33</sup> Both ballot initiatives were defeated after heavy lobbying from the pharmaceutical industry, which spent at least \$60 million opposing the Ohio initiative and more than \$109 million opposing the California initiative.<sup>34</sup>

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## Conclusion

Across the country, states are beginning to take action on a variety of reforms to address prescription drug prices; the reforms detailed in this issue brief are just a few examples. Policymakers in other states should carefully monitor these reforms and adapt the most effective proposals for their own states.

Taking action on drug prices is never easy. Most of the legislation reviewed here has been aggressively challenged in court by the well-funded pharmaceutical industry, which also spent heavily on lobbying to defeat them legislatively.<sup>35</sup> But with the public demanding policy solutions and the federal government taking little action, it's time for state policymakers to take the lead and work to reduce rising drug prices for their residents.

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