Insight

Prescription Drug Price Controls and State-Level Policymaking

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Executive Summary

- Over the past several years, federal lawmakers have debated policies that penalize manufacturers for drug price increases and tie U.S. drug prices to international reference prices, but with federal action stymied thus far, a number of states are considering similar policies.
- These policies would not solve the issue of high drug prices, but they do threaten innovation and access to therapies.
- While the impact of a small number of states implementing these policies is modest, policymakers should not underestimate the effect that widespread adoption might have on both access and innovation.

Introduction

Federal lawmakers have been debating policy initiatives aimed at constraining prescription drug prices for several years. Of particular focus have been proposals to implement penalties for price increases deemed excessive and international reference pricing—recent examples include the International Price Index (IPI), Average International Market (AIM) price, and Most Favored Nation (MFN) price. While the Trump Administration initiated a rulemaking aimed at implementing the MFN price regime (which is currently on hold) and the reconciliation bill currently under consideration includes changes to Medicaid's inflation-related manufacturer rebates, the federal government has not implemented any significant action restricting drug prices.

These progressive "solutions" are largely counterproductive, as the analysis below shows. As patients and politicians become increasingly focused on the issue of drug prices, however, policies aimed at constraining prescription drug prices have gained new support among populist conservatives and have begun to take root in state legislatures. Organizations such as the National Academy for State Health Policy (NASHP), among others, have been pushing sample legislation aimed at moving states to implement these anti-market policies. While the impact of one or two states adopting these measures would likely be modest, the strategy of implementing nationwide policy on a state-by-state basis is a threat to effective policymaking and a well-functioning prescription drug market.

The concern is not theoretical. State legislatures increasingly are introducing legislation advancing these poorly considered policies. In North Dakota, legislation has been introduced that would set a maximum price for a drug sold in the state as the lowest price available in the Canadian provinces of Alberta, Ontario, and Quebec. North Dakota is also considering legislation aimed at importing drugs directly from Canada—another Trump Administration initiative that is unlikely to provide any real benefit to American consumers. Oklahoma, Rhode Island, Hawaii, and Maine are among the states considering similar proposals. Hawaii and Maine are also considering proposals to tax or penalize manufacturers for price increases deemed excessive, as are Washington State and Massachusetts.

In many cases, support for these types of solutions is borne out of either genuine or willful economic ignorance. These policies might lower drug prices in some instances, but they also risk curtailing innovation and access.

Penalizing Price Increases

Many progressives have sought in recent years to limit pharmaceutical companies' ability to increase prices for existing drugs, arguing that these price increases are unjustified. One of the initiatives that is gaining traction in states is penalizing manufacturers for increasing prices by imposing taxes or penalties on revenue from price increases. In NASHP's sample legislation, the penalty for an "unsupported price increase" is set at 80 percent of the difference between the revenue generated by sales of the drug and the revenue that would have been generated if the manufacturer had kept the price unchanged, with an allowance for increases relative to inflation.

The sample legislation defines an unsupported price increase as "an increase in price for a Prescription Drug for which there was no, or inadequate, new clinical evidence to support the price increase." In order to determine if this is the case, the legislation would defer to the Institute for Clinical and Economic Review's (ICER) annual Unsupported Price Increase Report.

As those who seek to curtail drug prices need to assess the value of a medication to determine if the price is reasonable, they are increasingly leaning on third-party entities such as ICER to make determinations on value. This reliance on third parties may seem reasonable, but these valuations necessarily require judgments about the value of a year of life—or fraction thereof—or the quality of that year. Ultimately, decisions about value that have traditionally been made by patients and their doctors would be turned over to bureaucrats and academics. This type of evaluation system is typical of many countries with lower drug prices, where politicians have been willing to forego access to innovative treatments for their populations in order to limit health care costs. This issue is in some ways secondary, however, when it comes to price increase restrictions.

The primary flaw in efforts to restrict price increases to no more than the rate of inflation is that they do not work in the long run. Instead, policies that limit the ability of a company to increase prices over time simply result in increases in the initial list price of medications when they first come to market. A manufacturer's ability to adjust the price of an existing drug in a specific state may be limited, but if enough states adopt policies like this it will simply lead to higher launch prices nationwide.

International Reference Pricing

International reference pricing schemes appeal to the understandable frustration that many Americans feel because of the higher prices they pay for medications compared to patients in other countries. Particularly in states bordering Canada, frustration that a particular treatment might be substantially cheaper just a few miles north is unsurprising. While the implications of importing Canadian prices in an individual state are certainly less significant and harder to quantify than similar proposals at the federal level, the American Action Forum (AAF) has examined the three most recent variants of this concept at the federal level. The IPI, AIM and MFN would—to varying degrees—all result in restricted access to treatments, reduced innovation, and cost-shifting. [1],[2],[3]

The International Price Index

The Trump Administration's 2018 IPI proposal would have been limited in application to drugs purchased through Medicare Part B. Under current law, Part B reimburses physicians for the drugs they dispense at the

average sales price of the drug nationwide, plus a 6 percent add-on payment to cover physician costs and services. The IPI would have consisted of 16 countries deemed economically comparable to the United States, and Part B payments for drugs would have been set at 126 percent of the average price in IPI countries.

AAF research found in 2019 that the IPI would pose significant challenges to timely access to new medications for American patients. Within the countries considered for inclusion in the IPI, between 2011 and 2018 only 48 percent of all new medicines and 57.1 percent of new cancer medications were available, and it took patients in those countries an average of 16 months and 17.8 months, respectively, to achieve that access. Over the same period, 89 percent of all new medicines and 96 percent of all new cancer medications were available to U.S. patients within 3 months. More significantly, the IPI would have reduced future innovation. Just using the IPI price for Part B drugs would have reduced pharmaceutical industry revenue over 10 years by roughly the equivalent of the cost of developing 30 new medications. While drug developers would be unlikely to make up this lost revenue exclusively through reduced innovation, there is no doubt the IPI would have reduced the number of new therapies available to patients in the United States and around the world in future years. Additionally, because the IPI would only have applied to drugs purchased by Medicare through Part B, manufacturers would most likely have increased prices for other payers, in particular private health insurance plans, to recoup some of the lost revenue.

The Average International Market Price

A much broader and more damaging international reference pricing scheme—the AIM price—was included as part of the "Elijah E. Cummings Lower Drug Costs Now Act" (H.R. 3), introduced by Speaker Pelosi in the 116th Congress. The AIM price would have been based on a volume-weighted average price for specific drugs in Australia, Canada, France, Germany, Japan, and the United Kingdom. Manufacturers would have then been limited in what they could charge for the drug in question to no more than 120 percent of the AIM price. Unlike IPI, the AIM price would have been applied to the entire U.S. market, encompassing both private and public payers. Further, while the AIM would not have applied to all drugs, it would have covered many of the most commonly used treatments and was designed to expand to more drugs with each passing year, effectively leading to application to most drugs in relatively short order. As a result, the negative impacts projected under the IPI proposal on both the access and innovation would have been exponentially greater under AIM—though cost-shifting would not have been a substantial issue given the application to the entire market.

The Most Favored Nation Price

The MFN is a modified version of the IPI. The Trump Administration attempted to implement the MFN through rulemaking at the end of 2020, but the initiative was caught up in legal challenges and is also now subject to review by the Biden Administration. Instead of having Medicare pay 126 percent of the average price of the index for Part B drugs as with the IPI, the MFN would have mandated that Medicare pay no more for treatments than the lowest price, after adjusting for volume and differences in national gross domestic product, that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development that has a comparable per-capita gross domestic product.

AAF research previously estimated the potential impact of the MFN on innovation, using data on international drug prices from a 2018 report from the Health and Human Services Assistant Secretary of Planning and Evaluation (ASPE), released as part of the IPI proposal. Using total spending data available in the Centers for Medicare and Medicaid Services Drug Spending Dashboard for Part B drugs, as well as the U.S.-international price ratios found in the ASPE report for 26 different drugs, the research found that revenues for these same 26 drugs would be reduced by an estimated 64.1 percent if reimbursement were limited to the lowest price

available in any of the other countries. Total spending by Medicare Part B on those 26 drugs in 2018 was $19.9 billion; paying the lowest price for each would reduce total revenue by $12.8 billion. For comparison, under the original IPI proposal these drugs would have seen a 30 percent reduction in reimbursement, or a $6 billion reduction in total revenue. In other words, the impact of the MFN on manufacturer revenue was estimated to be twice that of the IPI impact, assuming no changes in utilization from 2018.

State-level Policies

The impact of one state, or even a handful of states, restricting drug prices to no more than the lowest price in Canada would have nowhere near the same impact on innovation that similar policies would have if applied nationwide. The same is likely true for penalties on increasing drug prices.

These attempts to "free-ride" would lead to cost-shifting to other states and payers, however. One can also anticipate other states following suit to avoid this cost-shifting, even in the absence of a concerted effort to press states to adopt these policies. As more states adopt these policies, the negative impacts on innovation would expand.

Another risk is that states would effectively restrict their residents' access to medications, as manufacturers could end or restrict access to certain medications as these price limitations are applied. Some of the state proposals have sought to curtail this risk by forbidding manufacturers from restricting access to medications in the state, but the legality of a state requiring a company to sell a product within that state is suspect at best.

Conclusion

Patients and policymakers are increasingly frustrated about the price disparity for pharmaceutical treatments between the United States and many other seemingly similar countries. This frustration is understandable, but debate on the issue often ignores the very real impact that other countries' price restrictions have had on their citizens' access to innovative therapies. Additionally, many of the policy solutions being advocated to bring U.S. prices in line with other countries' are punitive in nature, aimed more at punishing pharmaceutical companies for high prices than at meaningfully addressing health care costs. The problem with seeking to punish drug companies for high prices is that in most cases the effects of these policies will ultimately negatively impact American patients most of all.

[1] https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/

[2] https://www.americanactionforum.org/testimony/testimony-on-the-lower-drug-costs-now-act-h-r-3/

[3] https://www.americanactionforum.org/insight/the-impact-of-a-most-favored-nation-drug-price-rulemaking-on-innovation/