To Address Drug Affordability, Grab the Low-hanging Fruit

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With COVID-19 dominating the news, it is easy to forget that up until a year ago, the US public’s top domestic priorities for Congress were improving the affordability of health care and prescription drugs. But the need for action has only increased during the pandemic as millions of people in the US lost employer-sponsored insurance, states incurred massive expenses, and prescription drug prices continued their upward march.

Notwithstanding the new balance of power in the US Senate, making big strides in addressing drug costs at the federal level remains challenging. Many potentially useful measures are under consideration in Congress, including repeal of the Medicaid rebate cap. But despite signs that Congress recognizes drug costs as a priority, federal reforms that significantly ease costs face steep odds. None of the political barriers to far-reaching reform that surfaced during the Trump administration have vanished, and the prevailing partisanship and Democrats’ razor-thin Senate majority limit the range of realistic possibilities. Therefore, it is likely that states will continue to be the major players in prescription drug affordability reforms.

States have been highly energetic in passing a range of laws aimed at drug prices, from price transparency requirements to drug affordability boards. Among the most promising policy options not yet widely adopted is legislation regulating excessive or unsupported price increases (UPIs). Laws addressing UPIs impose a tax or penalty when a drug’s price increases by more than a specified percentage (such as the rate of general inflation) over a defined period. Companies are given the opportunity to justify large price increases—for example, by presenting new evidence about the drug’s clinical value or by showing that an ingredient became more expensive. If they cannot, most of the revenue generated from the disallowable portion of the price increase is taxed.

The underlying logic of UPI laws is that because drug companies are essentially free to set the base or launch price for a new drug at whatever the market will bear, base prices represent a fair return on companies’ investment in research and development. Therefore, they should not increase much over time in real terms, absent some extenuating circumstance.

Proposals addressing UPIs vary in which drugs are covered by the price-increase cap, with some specifying drugs with annual costs over a particular threshold, and others relying on work by the Institute for Clinical and Economic Research for identifying drugs with large price increases that are unsupported by new evidence of clinical value. Because of the difficulty of obtaining information about net prices of drugs after discounts and rebates, the UPI laws typically reference a drug’s wholesale acquisition cost, which approximates the drug’s list price. State proposals apply to units of product sold, dispensed, or delivered in the state.

The UPI concept has found expression in both federal and state bills, as well as in then-candidate Biden’s health care proposals. Bills in both the House and the Senate in 2019-2020 proposed to penalize drug manufacturers when the average manufacturer’s price for a Medicare-covered drug increased by more than the rate of inflation, requiring them to pay rebates to Medicare equal to the excessive portion of the increase.

In Massachusetts, Gov Charlie Baker has spearheaded legislation to limit annual price increases for drugs with average annual costs of $50,000 or more to inflation plus 2%. Increases above the limit are subject to a tax penalty of 80% on the excess portion. Originally introduced in 2019, the proposal is included in Baker’s fiscal year 2022 budget proposal, which awaits legislative action. Interest in, and arguments in favor of, UPI proposals have been strong enough that the National Academy for State Health Policy has created model legislation. Washington, Hawaii, Maine, and Connecticut introduced UPI legislation in the opening weeks of 2021 and more states are expected to follow.

What makes UPI laws such an appealing approach? First, large price increases continue to be a major driver of prescription drug costs. In 2020, list prices for more than 860 drugs rose by approximately 5% on average (compared with a 1.4% increase in the Consumer Price Index for 2020). In January 2021, at the height of the COVID-19 pandemic, drug makers hiked the price of 832 oral medications by an average of 4.6%—the largest number of January increases in years. More than half these drugs also had their price increased in 2020 and 2019, resulting in cumulative increases as high
as 20% to 30%. Increases in the price of widely used, existing drugs—not market entry of new drugs—are the primary driver of the rising cost of brand-name drugs and are common even among generic drugs. Between 2007 and 2018, list prices rose 159% (an average annual increase of 9.1%) even after rebates and discounts given to some purchasers, the cumulative increase was 60% (4.5% annually). An analysis of existing policy analogues to UPI laws in federal drug purchasing programs found they had a significant price-constraining effect over time.

Second, UPI laws avoid the thorny conceptual problem of how to evaluate the reasonableness of launch prices. What constitutes a fair base price for a drug has many possible answers and even proponents of price regulation have not reached consensus. The UPI laws continue to let the market decide what a reasonable launch price is and simply assert that if a company wishes to raise that price over time it must offer a justification.

Third, UPI laws are likely to hold up to legal challenges. Because the conduct that violates the law can be specified very clearly, it is hard for drug companies to argue the statute is unconstitutionally vague. To minimize the potential for patent preemption challenges (claiming that when states regulate the price of on-patent drugs, they unlawfully interfere with the federal patent scheme), states can impose a tax that is substantial but not 100%. After all, states tax many patented goods, and here only a portion of the price increase is being taxed. The most serious legal threat is a challenge based on the dormant commerce clause doctrine, which bars states from regulating in ways that place undue burdens on interstate commerce. State price regulations that may apply to transactions wholly outside the state often attract such claims—and the challengers sometimes prevail. But states can design UPI laws to focus on in-state transactions.

In addition, UPI laws are appealing because they are a policy win-win: either they succeed in deterring large price increases or they generate revenue for the state when enforced against violators. Some companies may decide to simply pay the tax rather than limit price increases—the likelihood of this depends on, among other things, the amount of the tax—but the tax revenue can be used to offer relief to consumers with high out-of-pocket drug expenses.

The UPI laws will not solve a key drug affordability issue: drug makers’ ability to launch new drugs at whatever price the market will bear, virtually without fear of coverage denials. Addressing that problem will require companion legislation—for example, state or federal legislation providing for international reference pricing, prohibiting price gouging, or empowering Medicare to negotiate prices and deny coverage if a deal cannot be reached. Indeed, companion legislation may become a necessity if drug companies respond to UPI laws by raising launch prices for new drugs.

But in the US, the battle against drug overpricing is more likely to be fought with a thousand arrows than a single bullet. A UPI law is an especially valuable one for states to have in their quiver.

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Correction: This article was corrected on March 1, 2020, to add the Conflict of Interest Disclosure appearing last for Dr Mello.

Conflict of Interest Disclosures: Dr Mello reported receiving grants from Arnold Ventures for projects on policies to address prescription drug costs; receiving consulting fees from the National Academy for State Health Policy for writing reports assessing the legality of prescription drug price regulation proposals; serving as an advisor to CVS Caremark on its value-based formulary product but has not received fees from the company; and receiving personal fees from law firms for expert witness testimony in support of plaintiff drug companies and pharmacies alleging anticompetitive pricing practices. Ms Riley reported receiving grants from Arnold Ventures for projects relating to state policies for improving prescription drug affordability.

Note: Source references are available through embedded hyperlinks in the article text online.

Previous Publication: This article was previously published in JAMA Health Forum at jamahealthforum.com.


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