Price Controls by Another Name
How Drug “Affordability” Boards Harm Consumers

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Momentum is building in many states to establish prescription drug “affordability” boards with the power to impose upper payment limits on drugs that are deemed unreasonably expensive. But as economic theory, as well as historical experience shows, such policies, like other forms of government price controls, produce shortages, economic inefficiencies, and, ironically, threaten patients’ access to low-cost medicines. More specifically, drug “affordability” boards can disrupt the generic drug market, which has generated nearly $2 trillion in savings over the last decade, undermine pharmaceutical competition, and drive consumers to more expensive alternatives. Policymakers seeking to lower drug costs for American consumers should instead prioritize reforming the anti-competitive pharmacy benefit managers and ensuring that health plans are not preferring higher-priced brand drugs over generics and biosimilars.

Introduction

In response to continued concerns over rising prescription drug costs in the U.S.,1 several states have created drug “affordability” boards charged with overseeing pharmaceutical pricing trends and imposing, contingent on legislative approval, payment caps when price increases exceed certain thresholds.2 Maryland and Maine have already enacted legislation establishing such boards, and momentum is building for similar initiatives throughout the country.3

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2 Legislation setting up prescription drug affordability review boards is being considered in at least 10 states with variations around mandates to curb excess costs. In most cases, the review boards will allow the states to set pricing caps for certain higher-cost drugs.
3 Maryland’s Prescription Drug Affordability Board Act went into effect on July 1, 2019. A similar law in Maine was implemented in September 2019.

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Allowing bureaucratic agencies to set prices for medicines will not address the affordability challenges patients face. Instead, as this report shows, this misguided approach could undermine pharmaceutical competition and limit consumers’ access to medicines.

This report identifies and discusses the consequences of recent policies aiming to establish prescription drug “affordability” boards as a way to reduce drug costs by specifically focusing on the short- and long-term consequences on drug access and innovation.

The report also offers recommendations to help address the issue more efficiently without hampering innovation or reducing access to innovative drugs.

How Drug Affordability Boards Work

So far, two states, Maryland and Maine, have enacted legislation to create prescription drug “affordability” boards. Several more states, including Illinois, Nevada, Oregon, Massachusetts, Missouri, Minnesota, and New Jersey, are weighing similar measures.4

Maryland and Maine enacted their laws last year, establishing state agencies to review the costs of drugs and take action against those whose price increases exceed a certain threshold.5 Upper payment limits on some drugs in Maryland may take effect as early as January 2022, while Maine’s board is expected to begin setting annual spending targets for drugs purchased by state and local governments in 2021.

While both states take slightly different approaches, Maryland's statute is particularly illustrative as a potential template for other jurisdictions.

Maryland’s Board, composed of five members appointed by the state’s political leaders, is tasked with reviewing prescription drugs that meet any of the following general criteria:6

- New brand name prescription drugs that enter the market at $30,000 or more per year or course of treatment;

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- Existing brand name medications that increase in price by $3,000 or more per
  year or course of treatment;
- Existing generic medications which increase in price by 200% or more per year
  or course of treatment; and
- Any prescription drug that creates affordability challenges to the Maryland health
  care system, including patients.

Once a drug is identified for cost review, the Board will seek input from the “Prescription
Drug Stakeholder Council,” which is tasked to offer stakeholder input to guide the
Board’s decision-making.7

As part of its cost review, the Board is authorized to consider a wide range of factors,
including the wholesale acquisition cost (WAC) for the drug, the discounts the
manufacturer offers, the prices of other medicines in the same therapeutic class, the
cost to health plans, the impact on patient access resulting from the cost relative to
insurance benefits, the dollar value of patient access programs supported by the
manufacturer, the relative financial impacts to health, medical and social services, and
the average patient co-pay or cost-sharing.8

If the Board determines that pricing for a prescription drug presents an affordability
challenge, the Board may set an upper payment limit on how much state and local
governments pay for the drug. What the Board proposes will then be submitted to the
Maryland General Assembly’s Legislative Policy Commission for approval. The Board
will also monitor the availability of any drugs that are subject to upper payment limits. If
a shortage develops, the Board can remove its upper payment limit.

Most of the recent legislation proposed in other states is modeled after the draft
legislation released by the National Academy for State Health Policy.9 In
Massachusetts, for example, drug manufacturers would be required to report key pricing
information such as research and development (R&D) costs so that the state’s Health
Policy Commission can create pricing caps,10 while in Oregon, the proposed Drug Cost

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7 The Council consists of members from various backgrounds and associations, including representatives
of pharmacists, biotechnology companies, physicians, and hospitals; a labor union representative;
representatives of brand name and generic drug corporations; and a representative of pharmacy benefit
managers (PBMs).
8 Michelle L. Caton, “Maryland’s Prescription Drug Affordability Board Bill Set to Take Effect,” The
affordability-board-bill-set-to-take-effect.
Rate-Setting-Model-Act.pdf.
10 Kyle Blankenship, “Pharma Maryland, Massachusetts statehouses press drug-pricing bills as feds
founder,” FiercePharma, April, 12, 2019, https://www.fiercepharma.com/pharma/maryland-
Review Commission would determine the excess costs associated with prescription drugs and establish maximum prices.\textsuperscript{11}

While specific variations exist around their mandates to curb excess costs, in most cases, the proposed boards will allow the states to set pricing caps for certain higher-cost drugs. Such provisions, however, call into question how effective affordability boards will be at reducing costs, and whether such boards threaten innovation and access to certain cutting-edge drugs.

**Why Drug Price Regulation Doesn’t Work**

Prescription drug affordability boards are merely a recent incarnation of an old idea: relying on the government, rather than the competitive marketplace, to set the price of goods.

Government price controls have never delivered on the lofty promises of their political advocates. Imposing an artificial price ceiling on a good invariably leads to shortages in the short-run and decreased innovation in the long-run as suppliers seek better opportunities in other sectors of the economy.

When the Nixon administration instituted industrial price caps in the early 1970s, for example, production dropped and shortages quickly developed for many consumer goods.\textsuperscript{12} In the words of former Treasury Secretary George Schultz, price controls meant "low prices for food, but nothing to buy."\textsuperscript{13} In many cities, including New York City, Washington, DC, San Francisco, and Los Angeles, another type of price control -- rent control -- perpetuates a shortage of rental units, undermines landlords’ incentives to invest in rental properties, and creates a host of related economic distortions.\textsuperscript{14}

Although drug price regulation manifests differently, price controls in the pharmaceutical market show similar harmful effects. A recent study by the American Consumer Institute specifically shows that government-imposed price ceilings consistently reduce pharmaceutical innovation, retard the development of new therapies, and impair


patients’ access to life-saving drugs. By artificially suppressing drug prices, “affordability” boards could have a similar effect, reducing incentives for pharmaceutical R&D and delaying the development of novel medicines, thus resulting in fewer treatment options for patients.

To encourage the development of new medicines despite these enormous costs and the slim chances of success (only about 1 in 10 drugs that reach clinical trials ultimately get FDA approval), pharmaceutical companies must feel confident that their investments will generate an adequate return. A 2016 study by the National Bureau of Economic Research (NBER) estimated that, counting post-approval expenses, average R&D costs for new drugs and biologics reached $2.8 billion. The same study also showed that total capitalized development expenses increased (after adjusting for inflation) at an annual rate of 8.5% from 2003 to 2013, resulting in an overall increase of 145 percent over a decade.

Price controls, which are often unpredictable and can substantially reduce revenues, deter R&D spending and delay the discovery of novel treatments. A 2005 NBER working paper, for example, showed that government-imposed pharmaceutical price cuts of 40 to 45 percent would lead to a 50 to 60 percent decline in the number of new compounds progressing from laboratory testing to human trials.

Research focusing on the effects of pharmaceutical price controls is extensive, with findings showing that these types of policies are likely to reduce innovation because of both lower expected revenues and a higher cost of capital. More specifically, several empirical studies found that while drug plans and consumers benefit from lower prices in the short term, price controls would be expected to reduce R&D. While in theory, regulated prices could lead to lower costs per use and therefore greater use, extensive empirical evidence shows that price regulation would have a number of

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adverse consequences\textsuperscript{19} that mitigate or outweigh this effect, including reduced R&D, and delays in the launch of new drugs even after they have already been discovered.

Take the example of several European countries, where government panels already set prices for drugs, the availability of cutting-edge medicines is far more limited than in the U.S., where free market forces are the dominant factor in regulating prices. Of all new medicines launched worldwide between 2011 and 2018, the U.S. has access to nearly 90 percent of them.\textsuperscript{20} By contrast, other developed countries had access to only 47 percent of new drugs, on average.\textsuperscript{21} Even when new drugs are ultimately introduced in foreign countries, patients must typically wait more than a year longer than in the U.S.

Empowering bureaucratic “affordability” boards to set drug prices invites similar results, thereby hurting American patients by limiting their access to lifesaving drugs and treatments.

\textbf{Consumer Benefits from Generic Drug Competition}

In 1984, Congress passed the Hatch-Waxman Act\textsuperscript{22} which streamlined the regulatory pathway to bring generic drugs to market, less than 20 percent of prescriptions were for generic drugs. The FDA has since approved more than 16,000 generic applications, and in 2018 generics accounted for 90 percent of dispensed prescriptions in the U.S. but were responsible for only 22 percent of total drug spending.

Increasing competition from generic drugs by allowing lower-cost versions of brand drugs to compete both with the originator drug and with other generic versions greatly reduces spending on prescription drugs. Once a brand drug’s period of market exclusivity ends, generic versions enter the market at substantially lower prices than the originator drug, leading prices to drop as more generic manufacturers vie for market share. According to research by the IMS Institute for Healthcare Informatics, “generics that entered the market between 2002 and 2014 reduced the price of medicines by 51% in the first year and 57% in the second year following loss of exclusivity.”\textsuperscript{23}

\textsuperscript{21} Ibid.
\textsuperscript{23} “Price Declines After Branded Medicines Lose Exclusivity in the U.S.,” IMS Institute for Healthcare Informatics, 2015, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-
The FDA estimates that, counting only generic drugs approved in 2017, American consumers save $16 billion per year.\textsuperscript{24} Additionally, recent research by the Association for Accessible Medicines and IQVIA found that generic medicines generated $293 billion in savings for patients and taxpayers in 2018, and nearly $2 trillion over the last decade.\textsuperscript{25} The average copayment for a generic prescription -- just $5.63 -- is almost one-seventh of the average copay for a brand-name drug, and about 93% of generic copays are under $20.\textsuperscript{26}

Over the last few years, generic drug prices have been in historic decline\textsuperscript{27} and very few generics have seen significant price increases recently. This is emphasized by a 2016 report by the U.S. Department of Health and Human Services: “Our review of evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation.”\textsuperscript{28}

Yet, it is paramount to note that price control drug policies can have indirect effects on competition, including generics.\textsuperscript{29} Specifically, price controls tend to undermine competition such that countries with heavier regulation have less competition from generic and over the counter drugs, which thrive as cheaper alternatives in countries that permit freer pricing of branded prescription drugs.

How Drug Affordability Boards Threaten Consumer Welfare

Drug affordability boards could inadvertently undermine generic drug competition, harm lower-priced generic competitors, and drive patients to more expensive alternatives. Maryland’s Prescription Drug Affordability Board, for example, is empowered to medicines-lose-exclusivity-in-the-us.pdf?la=en&hash=642B9A40F3F176CE93E8E9F791EE2BE4975C8580.


\textsuperscript{26} Ibid.

\textsuperscript{27} Valerie DeBenedette, “Prices for Generic Drugs Fall by About 9%; Third Decrease in Three Years,” Drug Topics, April 11, 2019, https://www.drugtopics.com/article/prices-generic-drugs-fall-about-9-third-decrease-three-years.


establish upper payment limits on generic drugs that, after adjusting for inflation, have a wholesale acquisition cost of $100 or more for a 30-day supply or that increased in price by 200 percent or more during the preceding 12-month period.\textsuperscript{30}

Under this criterion, the Board could target, ironically, the lowest-cost generics, the very medicines delivering significant savings to American consumers. Increasing the price of an inexpensive generic by 200 percent, from $1 to $3, for example, is unlikely to create affordability challenges for most patients, but such an action could trigger a review by a prescription drug affordability board and potential price controls, creating uncertainty for generic manufacturers, discouraging generic competition, and ultimately reducing low-cost alternatives for patients.

Like Maryland, other similar pending state legislations fail to account for the fact that a generic drug may increase its price by a large percentage amount and still be a fraction of the price of the originator drug. An analysis by the Government Accountability Office, for example, cites the price of hydrocortisone, an anti-inflammatory drug, rising from $0.16 per 20 mg tablet in 2012 to $0.41 per tablet in 2013, an increase of 160 percent.\textsuperscript{31} Due to the low cost of most generic medicines, small price changes can result in significant percentage increases.

In addition, a 2018 study published in Health Affairs finds that just 4.4 percent of generic drugs at least doubled in price in 2013, showing that significant price hikes are not a pervasive concern in the generic market.\textsuperscript{32} Corroborating the Government Accountability Office’s analysis, the study also finds that almost all large percentage price increases affected products that were initially low- or medium- price medications and not among the most widely used generics.

By creating an avenue for bureaucratic control over generic drug pricing, Maryland’s and other similar pending state laws threaten to reduce competition in the generic market, drive up prices, and potentially force patients to rely on higher-priced brand drugs.


A Better Way Forward

A one-size-fits-all approach is unlikely to be the answer to a nuanced problem such as drug costs; but as this report suggests, so are price regulation policies that propose creating “affordability” boards.

Given the complexity of this issue, clearly, no single solution will suffice. Yet, some solutions show more promise, and when implemented together they can have a meaningful cumulative effect on drug pricing.

One such solution is making sure generics are substituted on government plans when possible. Currently, Medicare Part D formularies, for example, exclude first generics almost 40 percent of the time. By not recognizing the immense value generics and biosimilars offer to patients and the health care system, health plans are making them unavailable to patients, which increases patient costs.

As such, 1) creating a new specialty tier reserved for biosimilars and specialty generics with lower cost-sharing for patients that would allow for differentiation between specialty brands, generics, and biosimilars, and 2) ensuring that generic drugs and biosimilars are placed on the tiers where they were originally meant to be, would incentivize competition based on list price and encourage patients to switch to lower-cost generics.

Another promising policy solution would be reforming the pharmacy benefit manager (PBM) industry and increasing transparency in the supply chain, which would render more beneficial changes for the millions of patients who are unable to afford their medicine than the misguided proposals to create drug “affordability” boards.

Few consumers, if any, understand the breakdown of what factors into pricing a drug. On top of that, drugs change hands several times before they get to the patient. In particular, commercial payers, wholesalers and PBMs potentially play a large role in determining the price of a drug, but their influence is unknown.

Historically, PBMs were established to process prescription medication claims for insurers and plan sponsors, such as private employers or government health programs. But PBMs have evolved into powerful entities helping to fuel the rising cost of drugs in the U.S. Exploiting the lack of transparency in their transactions with pharmacies,

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insurers, payers, and consumers, PBMs leverage their position as “middlemen” to extract profits and stifle market competition.

PBMs derive much of their revenue from rebates, or discounts drug manufacturers provide to PBMs in exchange for the PBM including the manufacturer’s drug in its formulary, the menu of drugs covered in a plan. To secure deeper rebates from manufacturers, PBMs sometimes agree to place formulary restrictions on competitors’ products, limiting price competition and potentially depriving patients of the most effective clinical treatment. Since plan sponsors rarely know the details of the contracts between PBMs and manufacturers, the PBM typically pockets a large portion of these rebates.

Another source of PBM revenue is a practice known as “spread pricing,” where the PBM reimburses the pharmacy one price for a prescription and charges the plan sponsor a higher price for the same transaction. As intermediaries between pharmacies and plan sponsors, PBMs negotiate separate contracts with each entity, preventing the other from knowing the pricing details of the other’s contract. In addition, PBMs’ contracts with pharmacies commonly contain gag clauses prohibiting pharmacists from informing patients of this price difference, even when paying out-of-pocket for a prescription would be cheaper than paying through their drug plan. These “clawbacks” generate substantial profits for PBMs at consumers’ expense.

It has been estimated that PBMs fail to pass about $120 billion in rebates back to consumers each year, and retain another $30 billion in additional out-of-pocket costs.35 Meanwhile, the market leader, Express Scripts, reported an increase in net income from $2.0 billion in 2014 to $3.4 billion in 2016 — a 70% increase in just two years. By contrast, data from the Bureau of Economic Analysis indicates that across all industries, after-tax corporate profits did not increase over that period.36

PBMs’ concentrated market structure also raises anti-competitive concerns.37 The three largest PBMs Express Scripts, CVS Health and OptumRx, control about three-quarters of the market, allowing firms to maximize their negotiating leverage.

Realigning PBMs’ incentives and creating greater transparency to prevent abuses would do much to lower drug costs for Americans. A survey conducted by the American Consumer Institute in 2019 found that 86 percent of Republicans, 79 percent of Democrats, and 91 percent of independents agree that policymakers should act to ensure that drug maker rebates paid to PBMs are passed through to consumers,

36 See Bureau of Economic Analysis data: https://www.bea.gov/national/pdf/SNTables.pdf.
insurers and hospitals to help lower prices.\textsuperscript{38} Legislative proposals focusing on increasing transparency would mandate the public release of information about the components of the price of a drug, and would grant patients access to information that allows them to pay the lowest price for drugs in terms of personal out-of-pocket costs.

**Conclusion**

Economic theory, as well as historical experience, show that price regulation is inefficient, creates shortages, and ultimately endangers patients’ access to lifesaving treatments.

This report highlights the significant negative effects that numerous enacted and proposed state legislation creating drug “affordability” boards would have on consumer welfare, both short- and long-term.

Per the evidence provided here, we do not recommend creating “affordability” boards as an effective solution to America’s escalating drug prices. As such, with potential bureaucratic interference, pharmaceutical innovators may cut back on R&D investments and reduce access to drugs in regulated markets. Additionally, the thriving generic drug industry, which has delivered nearly $2 trillion in savings to the U.S. economy in the last decade, could be threatened by price regulations triggered by insignificant price increases on low-cost products.

Identifying which policies heighten price competition while better promoting innovation and granting patients access to cutting-edge drugs is important to increasing consumer welfare and transparency in the drug supply chain.

Some important recommendations follows from this report: ensuring that generics and biosimilars are covered immediately upon launch and that they are placed on correct tiers, and reforming PBMs’ practices while promoting a competitive environment, policymakers could do much to increase affordability of drugs in the U.S. without triggering the negative consequences associated with arbitrary price controls.