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Tara Sklar

Christopher Robertson
Boston University School of Law

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Affordability Boards — The States' New Fix for Drug Pricing

Tara Sklar, J.D., M.P.H., and Christopher Robertson, J.D., Ph.D.

On April 8, 2019, Maryland's General Assembly passed a law creating a prescription-drug affordability board to help the state regulate drug prices. This policy, which took effect on July 1, 2019, requires drug manufacturers to justify high prices or price spikes for both patented and generic drugs. If the board rejects a manufacturer's explanation for a pricing decision, it can, with the approval of the state legislature, set a lower price for the drug.

This approach represents a more direct attack on prescription-drug prices than the wave of 45 cost-control bills passed by 28 states in 2018. Such efforts focused largely on regulating and licensing pharmacy benefit managers and prohibiting them from keeping pharmacists from informing patients about lower-priced options.[1] Similarly, California's drug-transparency law, which went into effect in 2018, was hailed as one of the most transformative pieces of health legislation in the country. But that law requires drug makers only to provide notice before they raise prices above certain thresholds; it doesn't directly regulate prices.

The Maryland law, and the model law on which it is based, go further by permitting payment limits. Such a mechanism is uncommon in the United States, although precedents exist, including policies permitting state boards to cap the cost of electricity, car-insurance premiums, and hospital rates — domains in which policymakers have found that competition alone may not protect the public from extremely high prices. From a global perspective, many countries limit how much they pay for prescription drugs by negotiating prices and implementing national formularies and price ceilings.[2]

Maryland's law was originally intended to apply to all payers, including commercial plans, but it was amended just before passage to apply only to health plans that serve employees of the state government and of county and city governments. Although this change dramatically narrows the scope of the law, it helped limit political opposition and may improve the law's prospects in the courts.

Maryland has attempted to regulate drug prices before. In 2017, the state passed the Anti–Price-Gouging Act to prohibit unconscionable price increases, but the federal Fourth Circuit Court of Appeals struck down the law as unconstitutional on the grounds that it interfered with interstate commerce, which is the exclusive domain of the federal government.[3] In early 2019, the U.S. Su-

preme Court refused to hear the state's appeal, thus sealing the law's fate. Unlike the price-gouging legislation, the new Maryland law doesn't regulate commerce — it simply allows the state to decide how it spends its own money. State lawmakers thus avoided the legal problems that plagued the prior bill.

We believe that the new law is a harbinger of what's to come in drug-pricing legislation. During the 2019 legislative session, eight additional states introduced bills that would create drug-cost commissions. Legislation is pending in half these states, failed in three states, and recently passed in Maine. Maine's affordability board act was part of a four-bill prescription-drug–reform package and is less detailed in its approach than the Maryland law. Like Maryland, Maine limits its board's scope to state, county, and local government health plans.

The Maryland law and other state bills call for a cost review only when prices or price increases for certain drugs exceed specified thresholds. They create boards or commissions of five to nine people who would range from elected officials to members of the public and establish larger advisory or stakeholder councils composed of patient representatives, payers, providers, and pharmaceutical manufacturers.

Most state bills trigger board review for patented drugs when drugs enter the market with a wholesale acquisition cost of at least $30,000 per year or treatment course or undergo a price hike of at least 10%, $10,000, or $3,000 within 1 year, depending on the state. For generic medications, board review is generally triggered when a drug costs $3,000 or more per year or has increased in price by 25% or $300 for a 30-day supply within a 1-year period. Maryland is one of a minority of states that use lower thresholds.

There is an important third trigger for review that the Maryland law and most state bills include, which functions as a catch-all. Beyond the specified price triggers, a board can review any prescription drug when it determines that the drug creates affordability challenges for the state health care system and patients.

The pending state bills generally grant affordability boards broad authority to establish new reimbursement levels for reviewed drugs after determining that a given price or price increase is justifiable using information provided by the manufacturer, including information on research and development costs and prices elsewhere. Maryland's law, however, takes a more conservative approach. Maryland's board reports its determinations to the state's legislative policy committee, and the committee then has 45 days to approve the board's proposed reimbursement rate. If it doesn't approve the rate, the board then submits its proposal to the governor and state attorney general. Maryland's board cannot set a payment limit without approval of the legislative policy committee or the governor and state attorney general.[4] Drug manufactures are required to accept the price set by the board in order to sell the drug in question to state, county, and local government plans operating in Maryland.

Similarly, Maine's board isn't authorized to set spending caps; rather, it provides recommendations on spending targets for drugs to the joint standing committee of the legislature. These limited powers call into question how effective affordability boards will be at reducing costs, even for public payers. They also reflect a concern among some state legislators — which the drug industry has reinforced — that such boards may ultimately reduce access to certain cutting-edge drugs. Maryland also limits its board's authority to regulate the prices of drugs that are in short supply, which therefore preserves access to essential medications, regardless of cost.

Such provisions reflect the fact that Maryland has relatively little bargaining power; companies could simply walk away from the market, rather than set a precedent for other payers by selling certain drugs at prices below current levels. States may need to act collectively to simultaneously drive down prices and ensure access to drugs. The current consolidated state of the pharmaceutical industry, in which many drug makers face little or no direct competition, exploits the fragmentation of the states.

Still, we believe that such efforts by state legislators represent laudable experiments to address a recognized problem. State drug-pricing reform efforts are building on each other; many of the bills proposing drug-cost review boards also incorporate elements from price-transparency laws. For example, under Maryland's law and the bills introduced in other states, drug manufacturers have the opportunity to explain prices or price increases as part of the review process. Price-transparency laws have thus far withstood legal challenges from the drug industry claiming

that they interfere with interstate commerce and violate the First and Fourteenth Amendments.[5] California's law has reportedly had some success, as drug companies have decided to rescind or reduce previously announced price increases for health plans in that state. Establishing affordability boards may be a natural next step that more states take to exert a stronger influence over price spikes and still survive legal challenges.

An audio interview with Prof. Sklar is available at NEJM.org

The challenge facing any state-level effort will be to achieve the kind of scale necessary to affect an industry that manufactures more than 4 billion prescriptions' worth of drugs each year for the United States alone. These new approaches are unlikely to be a substitute for a federal solution that alters the fundamental market factors responsible for driving up drug prices.

Disclosure forms provided by the authors are available at NEJM.org.

From the University of Arizona James E. Rogers College of Law.

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Colleagues Unknown — How Peer Evaluation Could Enhance the Referral Process

Gregory E. Brisson, M.D.

My email was written in good faith, but still the subject was delicate. I was looking for a specialist who would be a good fit for my patient, an anxious gentleman who required extra time at office visits to get answers to his many questions. He had seen my go-to consultant in this specialty, a seasoned physician with a gentle bedside manner. That visit had not gone well. Whatever the reasons, he wanted a new doctor. Rather than blindly referring him to any available physician in the division, I emailed a cadre of colleagues to get their recommendations.

They didn't have any. Their experience with the division in question was as limited as mine. I considered resending the email to the entire general-medicine mailing list, but I had concerns about maintaining confidentiality, and physicians' mailboxes are already inundated. Instead, I contacted a specialist who was new to the system. She could see the patient the next day, though he would have to drive an hour to the city where her clinic was located. He agreed. With the expectations of both parties managed, the visit went smoothly.

Finding patient-centered solutions has always been one of the challenges and rewards of clinical medicine, but stories like this one are becoming routine. I regularly receive emails from peers who need help navigating the system. Colleagues at other institutions describe similar experiences. These observations raise questions about how doctors refer and shed light on the reality that generalists and specialists increasingly don't know each other. It's now the norm for U.S. physicians to work in large groups — networks that can span counties or cross state lines.[1] In such systems, there's little opportunity for interaction among colleagues.

It wasn't always this way. Earlier in my career, I knew most of the doctors at my hospital. I was generally aware of who was kind, curious, and a good collaborator — qualities I value in consultants. When I made a referral, it was usually to someone I knew firsthand whom I could trust. That started to change in the past decade.

The group I work for merged with several hospitals and grew from hundreds of physicians to thousands — I can't possibly know them all, no matter how many meet-and-greet socials I attend. Hospitalist programs inflamed the problem by disconnecting generalists from hospitals,