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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. 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.

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. In early 2019, the U.S. Su-
triggered when a drug costs
increased in price by 25% or
$3,000 or more per year or has
$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
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 Mary-
town law and most state bills in-
clude, which functions as a catch-
all. Beyond the specified price
triggers, a board can review any
prescription drug when it deter-
moves that the drug creates af-
dorability challenges for the state
health care system and patients.

The pending state bills gener-
ally 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 pro-
vided by the manufacturer, in-
cluding information on research
and development costs and prices
elsewhere. Maryland's law, how-
ever, takes a more conservative
approach. Maryland's board re-
ports its determinations to the
state's legislative policy commit-
tee, 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 gen-
eral. Maryland's board cannot set
a payment limit without approval
of the legislative policy commit-
tee or the governor and state at-
orney general.4 Drug manufac-
tures 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 recommenda-
tions on spending targets for
drugs to the joint standing com-
mittee 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 legis-
lators — which the drug industry
has reinforced — that such boards
may ultimately reduce access to
certain cutting-edge drugs. Mary-
land also limits its board's author-
ity to regulate the prices of drugs
that are in short supply, which
therefore preserves access to es-
cential 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 prece-
dent for other payers by selling
certain drugs at prices below cur-
rent levels. States may need to
act collectively to simultaneously
drive down prices and ensure ac-
to drugs. The current con-
solidated state of the pharma-
cutical industry, in which many
drug makers face little or no di-
rect competition, exploits the frag-
mentation of the states.

Still, we believe that such ef-
forts by state legislators repre-
sent laudable experiments to ad-
dress a recognized problem. State
drug-pricing reform efforts are
building on each other; many of
the bills proposing drug-cost re-
view boards also incorporate ele-
ments from price-transparency
laws. For example, under Mary-
land's law and the bills intro-
duced in other states, drug manu-
facturers 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
An audio interview with Prof. Sklar is available at NEJM.org

PERSPECTIVE

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, that they interfere with interstate commerce and violate the First and Fourteenth Amendments. 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 exercise a stronger influence over price spikes and still survive legal challenges.

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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