



Center for State **Rx** Drug Pricing

Prescription Drug Affordability Review Board Q&A

Why would a state set up a prescription drug affordability review board?

A prescription drug affordability review board gives states the ability to limit how much its residents pay for certain high-cost drugs. Because drug costs involve many complicated issues and affect numerous stakeholders, a drug affordability review board would bring the parties together, increase transparency, and set an upper payment limit for drugs.

How would the drug affordability review board operate?

A drug affordability review board would be impartial and would examine the cost a drug would impose on the health care system and set an upper payment limit that applies throughout the state health care system – from distributors to doctors, pharmacies, hospitals, insurers, and consumers. A state could have its affordability review board consider a combination of factors to determine if a drug price leads to “excess cost,” presents an affordability challenge to the state health care system, or leads to high out-of-pocket costs for patients. Drug companies will have the opportunity to report to the board and explain their prices. Other entities, such as insurers and pharmacies, will have the same opportunity. All the information necessary to make an informed decision will be presented to the affordability review board. Additionally, states can establish an advisory or stakeholder council to advise the affordability review board. Advisory or stakeholder councils may include manufacturers, employers, insurers, providers, researchers, consumer advocates, etc.

Would the drug affordability review board have oversight over all drugs?

No, states will be able to set review “triggers” to determine which high-cost drugs create affordability challenges. States can determine separate triggers for brand-name, generic, and single-source generic drugs.

The National Academy of State Health Policy’s (NASHP) model [bill](#) contains the following triggers:

- Brand-name drugs with a \$3,000 wholesale acquisition cost (WAC) price increase in a 12-month period;
- New brand-name products with a WAC of \$30,000 per year or for a course of treatment;
- Generics costing at least \$100 per year or for a course of treatment with a 200 percent WAC increase in a 12-month period; and
- Biosimilars with WAC prices that are discounted less than 15 percent of their reference products. The NASHP [model](#) also gives the review board the authority to review other drugs that may pose an affordability challenge and to respond to public comment/request for review.

Is there a legal precedent for drug affordability review boards?

Determining maximum payment levels for health care and other public goods is a state practice that has existed for decades. States regulate insurers and other public goods and services in markets with little or no market competition. A drug affordability review board would build on the various regulatory precedents for drugs that have only a few suppliers.

Can a single state regulate its drug costs?

Yes, individual states can regulate how much their health plans and other private insurers pay or reimburse for drugs and what their consumers pay. States have a huge stake in the cost of prescription drugs as payers of medical services for state and local government employees and retirees, Medicaid beneficiaries, incarcerated people, and university system employees. States determine how much they will reimburse providers for every health care service and product covered by their Medicaid and state employee health insurance programs. For drugs, this includes setting maximum allowable costs for generics and off-patent brand drugs and establishing payment limits for patent-protected, brand-name drugs. States set consumer rates for public utilities such as electricity and water because they are important to public well-being and controlled by just a few companies.

Wasn't Maryland's anti-price-gouging bill struck down? How are these boards different?

Some opponents of affordability review board legislation have compared this to the anti-price-gouging bill that was struck down in Maryland last year. An affordability review board would not encounter the same legal challenges if it clearly defines its jurisdiction over only drugs sold in the state.

What happens if a manufacturer refuses to sell a drug in a state because of this rate regulation?

The pharmaceutical industry may argue that it will no longer make drugs available in a state with an affordability review board. There are several reasons why that is unlikely to occur:

- First, it would require major shifts in the supply chain to prevent drugs from reaching one state, and the generic industry has already argued in court that it is not possible to manage the distribution of drugs to limit their geographic distribution.
- Second, the pharmaceutical industry already sells the same drug at many price points to different payers and in different distribution channels in order to make sales.
- Third, there are drugs on the market that are therapeutically similar to each other in terms of treatment effect. When one drug manufacturer leaves a market, it means that sales of a competing alternate treatment increase. To the extent that all manufacturers of drugs in a specific class won't exit the market at once, it is unlikely that one manufacturer would choose to disadvantage itself by doing so.
- Fourth, setting an upper payment limit for a drug should benefit manufacturers. If payer and consumer costs decline, more patients will be able to afford the drugs and sales will increase.

Would an affordability review board affect the rebate system?

Affordability review board legislation does not limit rebates or other price concessions negotiated between payers and manufacturers. Rebates and other price concessions would certainly continue for drugs that do not come under the board's jurisdiction. For high-priced drugs affected by the affordability review, the rebate mechanism should no longer be necessary because the deep discounts of the rebates would become transparent discounts at the pharmacy counter. The drug industry complains that rebates cause high drug prices. A statewide upper payment limit for a drug would eliminate the need for rebates. However, the model does not ban rebates.

Will a statewide drug affordability review board create a single formulary that leaves consumers with few or no drug choices?

No, a state drug affordability review board would not limit or otherwise dictate what drugs are available to patients and prescribers. What drugs are covered and how they are covered would remain the decision of each health insurer and state health program. A board would not make value and coverage decisions about individual drugs. The board would only look at drugs that create affordability challenges to consumers and the state, then it would consider how to address those affordability challenges so more people would have access to important medicines.

How would affordability review affect pharmacies and wholesalers?

There should be little or no effect on standard operating procedures in the regular drug distribution systems. Pharmacies would not segregate drugs that are regulated by the board from drugs that are not regulated by the state. There would be only one payment rate for a drug that the board has acted on.

How does the board make sure consumers capture savings at the point of sale?

It would be optimal if pharmacies and distributors made their revenue from new or increased professional fees rather than marking up the cost of the drugs at each point in the supply chain — from wholesalers to distributors and pharmacies. To alleviate any potential concern of pharmacies and distributors about their ability to increase professional fees, the board would take into consideration how players in the supply chain will be remunerated.

Will creation of a drug affordability review commission result in legal challenges under the US Commerce Clause?

The Commerce Clause prohibits state laws and policies that place a *significant burden* on the interstate commerce of a company. This act would not fall under the purview of the clause. Experts do not expect that an affordability review process for a small number of drugs would create a significant burden that would violate the Commerce Clause.

How does imposing an upper payment limit differ from price fixing?

Setting a limit on what payers pay for certain drugs is not “setting” a price. Manufacturers remain free to set whatever price they wish for drugs, but a state will only pay up to a price ceiling for those drugs.

Is there any benefit to the pharmaceutical industry from an affordability review board?

Yes, there are clear benefits to the industry:

- More transparency about costs and prices will improve the industry’s public image. Pharmaceutical manufacturers are increasingly supportive of efforts to increase transparency and upper payment limits would be determined in a transparent, public process.
- More utilization or sales of expensive drugs as a result of affordability review, coupled with lower costs for consumers, will generate revenue for the industry. Manufacturers stand to make as much money from a lower-cost/higher-utilization approach as netted by a higher-price/lower-utilization strategy.
- Rebates should become unnecessary for drugs with statewide upper payment limits, and the industry claims that rebates are the reason for their very high prices.

NASHP helps state leaders advance legislation to contain prescription drug prices and tracks states’ efforts at its [Rx State Legislative Tracker](#). State officials who are interested in the drug affordability review board model legislation can access a legislator’s guide and additional background materials. Contact [Jennifer Reck](#) to receive this material for state officials only.