

Spotlight on 2018 State Drug Legislation: Part 2 – Rate-Setting

**Update: This post was written before the end of the 2018 legislative session. For the most recent count of states that passed these legislation, see the [Spotlight on 2018 State Drug Legislation Summary: The Year in Review](#) or download our [Summary Chart](#).*

Prescription drug spending remains an important issue to many Americans. According to a poll by the Kaiser Family Foundation, the affordability of prescription drugs is the top health care priority for voters.[\[1\]](#) In response to public outcry, many states have taken up the mantle of improving affordability and access to prescription medications. In 2018, only two states with legislative sessions, South Carolina and Alabama, did *not* consider legislation with the aim of reducing prescription drug costs or access. Forty-four states[\[2\]](#) introduced bills and twenty-nine states passed legislation to increase oversight of the pharmaceutical industry.

The Source is publishing a multi-part analysis of these legislative attempts. In our previous post in this series, Drug Importation: The Next Frontier for State-action to Control Prescription Drug Costs, we reviewed state efforts to implement their own drug importation programs. In this post, the second in our review of state efforts to address rising drug prices, we detail state efforts to implement pharmaceutical rate-setting programs.

Rate-setting to Control Drug Prices

Rate-setting is a price setting mechanism in which a government agency sets a “ceiling price” for goods or services. Many other countries, including Great Britain, France, Japan, and the Netherlands use rate-setting to establish prices and control overall expenditures for health services. For details on how some of these countries establish rates for pharmaceuticals, see The Source’s issue brief comparing International Drug-Pricing Policies. At the state level, Maryland has an all-payer model that sets rates for all hospital services, but not pharmaceuticals. The Source analyzed Maryland’s experience and what other states, including California, can learn from Maryland’s experience.

In March 2018, U.S. Senator Claire McCaskill and the U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Office released a report showing that “the prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017.” [\[3\]](#) As a result of escalating drug costs for existing drugs, many states have considered legislation to prevent excessively rising prices.

States Considering Rate-setting for Drugs

In 2018, seven states –Florida, Maryland, Minnesota, New Jersey, New Mexico, Ohio, and Rhode Island– considered some form of rate-setting for pharmaceuticals (see map below), but none of the bills passed. [\[4\]](#) Florida’s bills ([SB 1872](#) and [HB 1385](#)) [\[5\]](#) would create a comprehensive single-payer health care system that includes pharmaceuticals. At the other extreme, Rhode Island’s effort ([S 2550/H 7042](#)) sets maximum prices only for drugs for which the State Board of Pharmacy determines are “so high that it jeopardizes the state’s ability to meet the needs

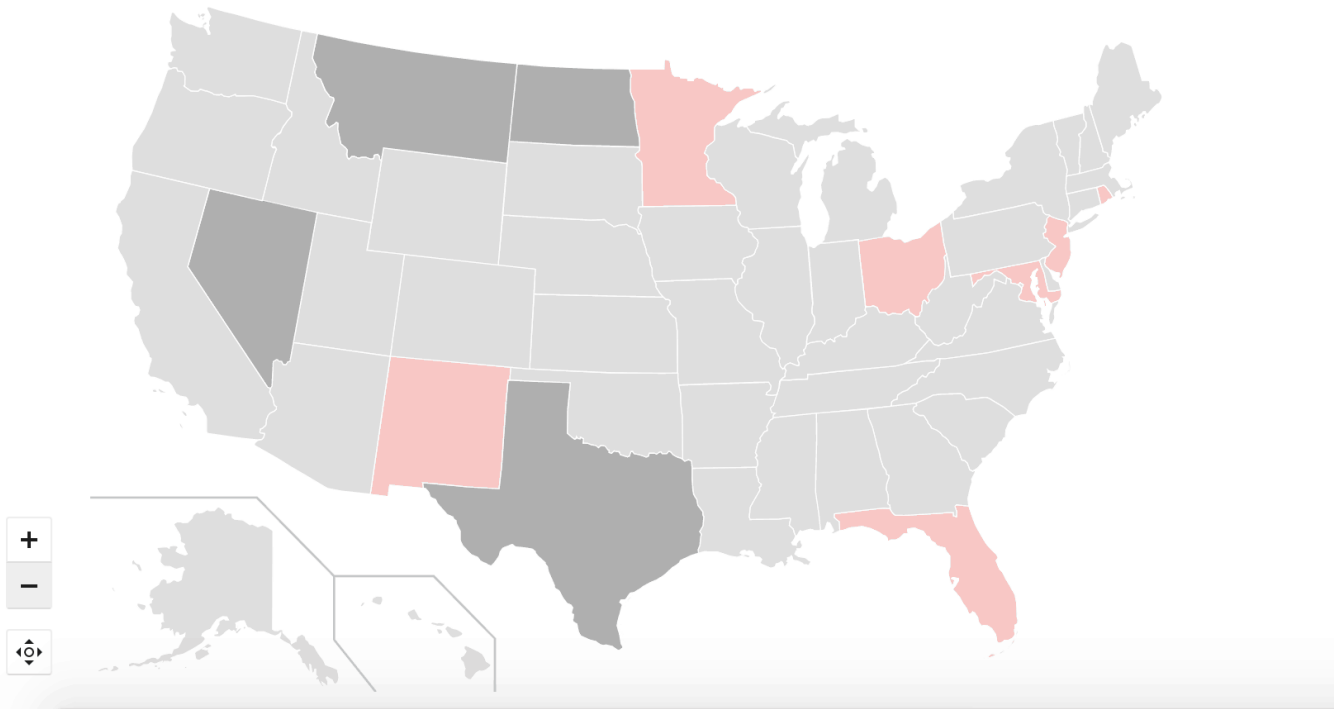
of the state's population for that drug." Once the board makes that determination, the "board may set the maximum allowable price that the manufacturer can charge for that prescription drug that is sold for use in the state." [\[6\]](#) Other states chose to tie their rates to standard benchmarks. For example, Ohio's bill, [SB 253](#), would limit the amount insurers, both public and private including Ohio's Medicaid program, would pay to no more than the amount the United States Department of Veterans Affairs (VA) reimburses for the same drug. Due to issues with preemption by federal laws, self-insured employers and the Federal Employees Health Benefits Program would be [exempt from this law](#). Similarly, New Mexico's bill, [SB 8](#), requires its proposed interagency, the pharmaceuticals purchasing council, to consider benchmarking pharmaceutical prices to those paid by the state's medical assistance plans. New Mexico's bill, however, only applies to state purchasers and is not a rate-setting bill that applies to all state residents.

The remaining three states –Maryland ([HB 1194](#) / [SB 1023](#)), Minnesota ([SF 2801](#)), and New Jersey ([S 983](#) / [A 583](#))– introduced bills based on the National Academy for State Health Policy (NASHP)'s [Rate-Setting Model Legislation](#). This model legislation establishes a Drug Cost Review Commission, similar to a public utility commission, that establishes a payment rate for certain drugs and requires all payers to pay no more than that ceiling. This commission would operate similarly to Maryland's Health Services Cost Review Commission (HSCRC), which sets rates for services at hospitals in Maryland.

Pharmaceutical Rate-Setting Legislation

Rate setting legislation either establishes the price of a prescription drug or sets the maximum amount a payer can pay for a drug. Click on highlighted states to see rate-setting legislation considered or enacted in the 2018 session. See [The Source Blog](#) for more information.

Key: ■ Enacted ■ Considered ■ No Legislative Session



Mechanics of the Rate-setting process

Under NASHP's model legislation, all drug manufacturers must notify the Drug Cost Review Commission prior to increasing the cost of an existing drug above a threshold (10% or \$10,000 in a year for patented drugs or 30% or \$300 in a year for generic drugs) and prior to introducing a new drug with a cost of more than \$30,000 annually or per course of treatment. Along with the notice of the price hike, manufacturers must explain the reason for the price increase. The Commission will review these disclosures to determine if the cost of these medications has led or will lead to excess costs for health care systems in the state. Finally, the model legislation provides that "[i]n the

event the Commission finds that the spending on the prescription drug product under review creates excess costs for payors and consumers, the Commission shall establish the level of reimbursement that shall be billed and paid among payors and pharmacies/administering providers, wholesalers/distributors and pharmacies/administering providers, and pharmacies/administering providers and uninsured consumers or consumers in a deductible period.”[\[7\]](#)

The bills introduced in Maryland and Minnesota very closely follow NASHP’s model legislation. New Jersey’s bill uses more general language and allows the Commission to set a maximum allowable cost for any drug that the Commission establishes to have an “excessively high price”.[\[8\]](#) In Minnesota and New Jersey, lawmakers introduced the bills and then referred them to the state committee health services, where the bills have remained inactive. Maryland’s legislature held a hearing on its bill and the Health and Government Operations Committee significantly amended the bill. The amended bill establishes the Drug Cost Review Commission to collect and analyze data about drug pricing in Maryland, to compare those prices to other states and countries, and to make recommendations about “how to make the prices of drugs in the United States comparable to the price of drugs in other countries.”[\[9\]](#) The amended bill, however, removes all rate-setting provisions. The Maryland House passed this amended bill in a 135-2 vote, while the Maryland Senate Finance committee gave the bill a favorable report before the bill died without a vote in the Senate. Although the removal of the rate-setting provisions diminishes the bill’s impact, Maryland’s efforts to pass this legislation should be viewed as promising movement towards a consensus on ways to address rising drug prices in the state.

Legal challenges to Rate-setting for Pharmaceuticals

A primary barrier to state efforts to address rising drug costs is preemption by federal laws. In 2005, the District of Columbia passed a law preventing pharmacies from selling patented drugs at “excessive prices”, which the law defined as a price 30% or more above the cost of the drug in other high-income countries, including the United Kingdom, Germany, Australia, or Canada.[\[10\]](#) In a civil suit filed by the Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO), the trade organizations that represent the interests of pharmaceutical and biotechnology companies, the court found that federal patent law preempted the D.C. law.[\[11\]](#) In that ruling, however, the court indicated “there is no express provision in the patent statute that prohibits states from regulating the price of patented goods.”

While the ruling in *BIO v. DC* may serve as a hindrance to state efforts to set rates for patented drugs, legal scholars from U.C. Hastings, in a white paper with contribution from The Source, argue that NASHP’s model legislation should not face similar preemption by federal patent law because it applies to both patented and generic drugs. In addition, Feldman et al. say “[i]t is not possible to predict how the courts will rule on an issue, and the constitutionality of state regulation of pricing rates for drugs (patented or unpatented) is largely uncharted territory.”[\[12\]](#) Nonetheless, efforts by states that are willing and able to pass rate-setting laws that target both patented and generic drugs will help shape the contours of what actions are permissible within the bounds of federal preemption.

Conclusion

In the past legislative session, seven states attempted to pass

laws that set rates for drugs. While none of the measures passed, the attempts should be seen as a step beyond price transparency to protect patients and insurers from high drug costs by limiting how much they can pay for a drug. These seven states are spearheading the effort to move beyond “naming and shaming” laws to effectuate legislation with meaningful limits on drug costs. As such, they may significantly shape the boundaries of state actions to control drug costs.

[1]

<https://khn.org/news/drug-prices-not-the-health-law-top-voters-health-priorities-for-2017/>

[2] Alabama, Montana, North Dakota, and Texas did not have a 2018 regular legislative session and therefore did not consider bills to address rising drug costs.

[3] Senate Committee on Homeland Security and Governmental Affairs. **Brand name Drugs Increasing at 10x Cost of Inflation, McCaskill Report Finds**. March 26, 2018. Available from: <https://www.hsgac.senate.gov/media/minority-media/breaking-brand-name-drugs-increasing-at-10x-cost-of-inflation-mccaskill-report-finds>

[4] The New Jersey and Ohio legislatures are still in session, but there has been little official action on the pharmaceutical rate setting bills.

[5] The text of SB 1872 and HB 1385 are not identical, but the portions of the bills that pertain to prescription coverage is the same.

[6] An Act Relating to Businesses and Professions—Pharmacies. SB

2550 and HB 7042- Rhode Island 2018 Leg. Session.

[7]

https://nashp.org/wp-content/uploads/2017/07/Prescription-Drugs-Rate-Setting_Model-Legislation.pdf

[8] NJ [S 983](#) / [A 583](#) Reg. Session 2018.

[9] MD [HB 1194](#) / [SB 1023](#) Reg. Session 2018.

[10] D.C. Code § 28-4554 (2005). Invalidated by *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (holding the Act to be preempted by federal law).

[11] *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) at 14.

[12] Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu, and Katherine Gudiksen. **States' Rights: A Patent Law Analysis of NASHP Rate-Setting Model Act**. March 2018. Available from: <https://nashp.org/wp-content/uploads/2018/03/White-Paper-2018.pdf>