

Spotlight on 2018 State Drug Legislation Summary: The Year in Review

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In 2018, states showed an increasing eagerness to further regulate the pharmaceutical market with the goal of decreasing prices and increasing access to prescription drugs for their residents. This year, forty-four states considered 227 bills to address rising drug costs, of which 55 became laws in thirty-two states. Only two states with active legislative sessions, North Carolina and Alabama, did *not* consider legislation with the aim of reducing prescription drug costs or ensuring access to prescription.[\[1\]](#) In the first six parts of the “Spotlight on State Drug Legislation” series, The Source detailed the most popular state legislative efforts to control drug costs. In this last installment, we review these efforts, examine two novel laws passed that did not fit into the categories discussed previously, and discuss whether these efforts will meaningfully address drug costs.

Commonly Considered Legislation in 2018

The Source compiled a comprehensive [2018 Pharmaceutical Legislation](#) spreadsheet detailing all state drug legislation considered and passed in 2018 ([click](#) to download). Below we recap some of the most noteworthy laws. Click on the title (where applicable) to read previous posts in the “Spotlight on State Drug Legislation” series.

[Gag-clause and/or Clawback Prohibition](#): The most commonly considered and passed legislation of 2018 ensured that pharmacists could help patients choose the most cost-effective way to purchase prescriptions. Twenty-one states passed legislation prohibiting gag-clauses in contracts with pharmacists, bringing the total number of states with this protection to twenty-seven. Following the wave of support for these laws, in September 2018, President Trump signed two [federal laws](#) passed by Congress to expand these protections nationwide: the Patient Right to Know Drug Prices Act ([S.2554](#)), which bans gag-clauses in employer-sponsored and individual drug plans, and the Know the Lowest Price Act ([S.2553](#)), which bans such clauses in Medicare Part D and Medicare Advantage plans.

[Pharmacy Benefit Manager Regulation](#): The second most popular legislation to control drug prices in 2018 required licenses or other disclosures from PBMs. Thirty-two states considered 55 bills to regulate PBMs, of which 19 became law in 15 states, but the provisions of these laws varied substantially. Many of the bills required PBMs to be licensed by the state or prohibited them from giving patients financial incentives to use mail-order pharmacies.

[Price Transparency](#): Following the momentum generated last year when California and Nevada passed drug transparency laws, in 2018, twenty-three states considered and six states passed laws demanding more transparency into how drugs are priced and how rising drug prices affect insurance costs. The provisions of the new laws ranged from establishing commissions to study drug costs to requiring disclosures from insurers and manufacturers about drugs prices and rebates.

[Drug Importation](#): In May 2018, Vermont Governor Phil Scott signed [S 175](#) into law, making Vermont the first state to begin development of a wholesale importation program for prescription

drugs. Eight other states considered, but did not pass, similar legislation to create a state agency that will act as a licensed drug wholesaler to import drugs from Canada. Vermont's law requires the U.S. Secretary of Health and Human Services to determine which drugs can be safely imported.[\[2\]](#) As a result, while Vermont's law may survive legal challenges that overturned a similar law in Maine,[\[3\]](#) its effects on drug prices may be modest.

[Price Gouging Prohibitions](#): Following Maryland's passage of HB 631 in 2017, fifteen states introduced legislation in 2018 prohibiting "unconscionable" or "unjustified" price increases for pharmaceuticals. In April 2018, however, the 4th Circuit Court of Appeals held that Maryland's law is unconstitutional because it violates the dormant commerce clause. While the legal battle over Maryland's law continues (see The Source's ongoing [coverage](#) for details), the lawsuit had a chilling effect on pharmaceutical price gouging laws and none of them passed through the state legislature.

[Rate Setting Legislation](#): Seven states considered legislation to directly set the prices paid for pharmaceuticals. While Florida considered a single-payer system that includes setting prices for drugs, the other six states considered bills that would set rates only for drugs.

Regulation of Formularies: In 2018, thirteen states considered and three states passed legislation to limit how PBMs and insurers create or change formularies. The Source did not previously detail these laws as they aim at consumer protection rather than cost containment. Most of the laws only prevent insurers from changing the drug formulary for the term of the insurance policy. Some states went further and restricted some practices PBMs use to reduce drug expenditures. For example, Minnesota (HF 3196 / SF 2897) and New Mexico (SB 11) limited the

use of step-therapy requirements, while California (SB 1021) prohibited formularies with more than four tiers and limited cost sharing for covered outpatient prescription drugs. While these laws may be important consumer protections, they are unlikely to address rising costs as they may increase patient access to expensive drugs at the risk of increasing drug expenditures by insurers.

Biologic Substitution Laws: Nine states – Alaska, Connecticut, Michigan, New Hampshire, South Dakota, Vermont, West Virginia, Wisconsin, and Wyoming – strengthened their generic substitution laws by including interchangeable biosimilar drugs in laws requiring pharmacists to dispense a lower priced generic drug when available, unless otherwise specified on the prescription. The provisions of these laws are straightforward and mirror other generic substitution laws, but they require the federal Food and Drug Administration (FDA) to certify that a biosimilar product is “interchangeable”, something it has not yet done for any biosimilar. With the passage of new laws in these nine states, only four states – Oklahoma, Arkansas, Mississippi, and Alabama – remain without biologic substitution laws.

Innovative Bills Passed in 2018

Two states, Maine and Vermont, enacted laws with pioneering provisions. Maine enacted LD 1280/SP 432, making it the first state in the country to require drugs distributed in the state to be made available at a fair market price and without restrictions to generic manufacturers for use as samples to accelerate the development of lower-cost generics.^[4] Congress has considered similar legislation, the [Creating and Restoring Equal Access to Equivalent Samples Act](#) (CREATES Act), but that legislation has been stalled for years (See The Source’s

[coverage](#) of the most recent consideration). Maryland also considered, but did not pass, similar legislation. Such laws, when enacted, should prevent brand-name drug manufacturers from using closed distribution systems and Risk Evaluation and Mitigation Strategy (REMS) restrictions to prevent generic competition beyond the expiration of the patent for the drug (see [the Source issue brief](#) for more details).

Using a slightly different approach, Vermont enacted a law to explore purchasing pharmaceuticals directly from a wholesaler for the state's Medicaid program. [\[5\]](#) In May 2018, Vermont's governor signed a law to create a working group to "investigate and analyze prescription drug pricing throughout the prescription drug supply chain in order to identify opportunities for savings for Vermont consumers and other payers and for increasing prescription drug price transparency at all levels of the supply chain." In November 2018, the group recommended that the Department of Vermont Health Access, the state's Medicaid program, explore a contract with a single drug wholesaler to supply drugs to Medicaid-enrolled pharmacies for the Vermont Medicaid program because the working group "believes that both savings and transparency can be achieved through channel simplification." [\[6\]](#) The group, however, did not receive any responses to a request for information from wholesalers. As a result, it is unclear whether Vermont can implement a direct purchasing arrangement or whether the pharmaceutical industry will participate in state cost-containment programs.

Will Any of These New Laws Have a Meaningful Impact on Drug Prices?

Many of the new laws target specific problems in the market for pharmaceuticals, but will have minimal effects on drug prices as

a whole. For example, prohibiting gag-clauses will save patients money in co-payments, but will have almost no effect on drug prices as a whole. In addition, preventing price gouging or allowing drugs to be imported from Canada when the manufacturer raises the price of a generic may deter behavior like that of the Pharma Bro Martin Shkreli, who raised the price of Daraprim 4000% overnight.[\[7\]](#) These laws, however, are unlikely to meaningfully affect drug prices, because manufacturers can simply sell new drugs at a higher initial price or raise prices slowly over time.

The laws with the greatest potential to decrease drug costs are those that either set rates directly or meaningfully increase competition among drug manufacturers. If any state can muster the political will to pass rate setting legislation, it will directly control the price of drugs in that state. Any state that implements rate-setting for drugs, however, will likely face substantial legal challenges and threats to end drug distribution to the state from the pharmaceutical industry. In order to minimize intimidation from the industry, states interested in establishing prices for drugs should band together and force the industry to negotiate with them collectively to maximize their purchasing power. In addition, a multi-state alliance would decrease the administrative complexity of a rate setting program since one committee could set prices for multiple states. No state, however, appears poised to pass rate-setting legislation, so whether rate-setting can control drug prices without stifling research to develop innovative new drugs remains unknown.

The Source's Pick for Top Legislation Passed in 2018

At the top of our list for laws passed in 2018 to address rising

drug costs are the innovative laws passed in Vermont and Maine. Vermont's efforts to enter into a direct drug purchasing arrangement for distribution to the state's Medicaid recipients should allow the state to eliminate the middlemen in the drug distribution chain and offer prescriptions at low cost to the state. If the program were expanded, and all residents could purchase drugs from the state's drug program, it could substantially reduce drug prices in the state. Not surprisingly, however, the industry seems to be blocking these efforts. As Vermont is unable to move forward with the direct purchasing plan, their efforts are the runner up for The Source's pick for legislative effort of the year.

The Source's #1 pick for top legislation of 2018 goes to Maine's law that requires manufacturers of brand-name medications to sell samples to developers of generic medications. [\[8\]](#) Generic manufacturers need samples of the brand-name medications to complete required bioequivalence testing for FDA approval, [\[9\]](#) but brand-name manufacturers have successfully prevented developers of generic medications from accessing samples in order to extend the drug's exclusivity in the market beyond the length of the patent. By ensuring generic manufactures' access to necessary samples, Maine's new law has the potential to meaningfully increase competition in the pharmaceutical market. As Maine should expect substantial legal challenges to the law, the state should be commended for its willingness to stand up to the powerful brand-name pharmaceutical industry. This law represents a substantial step on the journey to ensure that pharmaceutical companies are rewarded for innovative new treatments and not creative legal tactics.

In summary, 2018 was a banner year for pharmaceutical legislation and state lawmakers made substantial efforts and

progress toward addressing rising drug prices. In prohibiting gag-clauses, states spurred the federal government into action to protect patients from paying unreasonable out of pocket costs. In other areas, like rate-setting and drug-importation programs, states appear to be at the forefront of these efforts and may serve as models for federal action in the coming years. Stay tuned to The Source as we continue to follow these and other state efforts to contain rising drug costs.

[1] In 2017, in the current legislative session, North Carolina passed [H 466](#) to regulate pharmacy benefit managers, but it did not consider any bills in 2018.

[2] 18 V.S.A. §4651. Wholesale Prescription Drug Importation Program.

[3] *Ouellette v. Mills*, 91 F. Supp. 3d 1 (D. Me. 2015).

[4] 32 MRSA §§13800

[5] Vermont Act 193 (2018).

[6] Vermont Agency of Human Services. **Vermont Medicaid Drug Wholesaler Savings Initiative, Report to the House Committee on Health Care and the Senate Committee on Health and Welfare**, November 15, 2018. Available from: <https://legislature.vermont.gov/assets/Legislative-Reports/Sec.11a-Act-193-Prescription-Drug-Cost-Savings-and-Price-Transparency.pdf>

[7] Michael E. Miller. **‘Pharma bro’ Martin Shkreli and the Very American Debate Over Maximizing Profit**. *The Washington Post*. September 23, 2015.

https://www.washingtonpost.com/news/morning-mix/wp/2015/09/23/pharma-bro-martin-shkreli-and-the-very-american-debate-over-maximizing-profit/?utm_term=.89ce1e11ba79

[8] 32 Maine Revised Statutes §13800 and 13800-A

[9]

<https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm075207.htm>