During the past few years, states have addressed the high cost of prescription drugs with innovative or unconventional policies. This report provides a snapshot of several state actions taken during the 2019 legislative session. You can find extensive reports and information on these topics and others at NCSL’s Prescription Drug Policy Resource Center. Through the center, you can also access NCSL’s Prescription Drug Law Database, where you can find direct links to the text of more than 5,475 pieces of proposed and enacted legislation.

Importation

Although not a new idea, the importation of prescription drugs from sources outside the U.S. has been rapidly gaining the attention of state lawmakers. The Food and Drug Administration (FDA) has always held that importing drugs into the United States for personal or commercial use is against federal law. This is because pharmaceutical products from foreign pharmacies are not subject to the FDA’s rigorous inspection, efficacy and safety standards. However, the ban has not been enforced in many cases. According to a Kaiser Family Foundation poll conducted in 2016, 8% of respondents, or about 19 million adults, said they or someone in their household had, at some point, used the Internet or crossed a border to buy prescription drugs at prices that are sometimes 40% to 60% less than U.S. retail.

Although the FDA considers the importation of pharmaceuticals illegal, some state legislators have chosen to test the waters and see if there is room for compromise. In 2018, Vermont became the first state to pass legislation to develop an importation program. An initial report to the legislature suggested that the program would mean approximately $1 million to $5 million annual savings for the state’s private health plan enrollees.

Vermont’s measure specifies that the program must ensure cost savings and comply with federal safety and efficacy standards. President Trump recently announced that he backs state importation programs. However, Health and Human Services Secretary Alex Azar, who must approve these proposals, has openly criticized them.

Plans in two other states—Colorado (SB 05) and Florida (HB 19)—have also been endorsed by Trump. For 2019, at the time of this report, at least 28 bills have been introduced in 16 states.
As states scrutinize the prescription drug supply chain, they are analyzing the role of pharmacy benefit managers (PBMs). PBMs are third-party administrators of prescription drug coverage for insurers and employers, who pay a fee to PBMs for their services. These services include developing and maintaining formularies (lists of drugs), performing utilization management, processing claims, and negotiating discounts and rebates with manufacturers.

Until recently, PBMs have been largely unregulated, leaving many state lawmakers to wonder if this adds to the increase in drug prices. As a result, PBMs have found themselves thrust into the spotlight and measures related to PBMs have topped the list of state actions. With 175 bills proposed in the 2019 sessions alone, and 15 bills enacted in 10 states, legislative approaches vary widely.

**Spread pricing**

One PBM business model that has generated enormous curiosity is spread pricing. In spread pricing, PBMs are compensated by retaining the difference, or spread, between the amount they charge an insurer, and the amount they reimburse a pharmacy on behalf of the insurer.

Spread pricing can be described best by an example. For instance, a pharmacy purchases a bottle of medicine for $5. A patient uses their insurance benefit to fill a prescription and their PBM pays the pharmacy $10 to cover the cost, allowing the pharmacy to pocket $5. The PBM also bills the insurer $20 for the medication. The $10 difference between what the PBM paid the pharmacy and what it billed the insurer is the spread, which the PBM keeps. PBMs purport that this pricing structure helps to fund patient services, administer claims and provide utilization management.

In summer 2018, Ohio’s attorney general, Dave Yost, made headlines when he announced the results of an audit performed on PBMs who worked with Ohio Medicaid’s managed care organizations (MCOs). Auditors discovered that PBMs charged a 9.8% spread across all drugs. Moreover, PBMs charged an approximate 31% spread on generic drugs. In response, statehouses across the nation have pursued measures that prohibit spread pricing.
**Gag Clauses**

One theme recurring from 2018 is the elimination of contractual gag clauses between PBMs and pharmacists. Gag clauses prohibit a pharmacist from disclosing a cheaper alternative to patients, sometimes enforced by a fee. To date, 33 states have enacted legislation related to gag clauses. Similarly, copay clawbacks—when a patient’s copay is more than the total cost of the drug to the PBM or insurer and those entities essentially “claw back” the overpayment from the pharmacy—are also often prohibited in these measures.

**Fiduciary Duty**

Some states are considering requiring PBMs to act as a fiduciary. A fiduciary is a person or entity who holds a legal or ethical responsibility to act in the best interest of their clients. At the time of this report, one state—Nevada—had implemented a law requiring that a PBM has a fiduciary duty and at least four states have considered such laws. Nevada’s law specifies that a PBM has a fiduciary duty to a third party with which it has entered into a contract to manage that party’s pharmacy benefits plan. This means the PBM must act in the best interest of the pharmacies or consumers it serves, rather than the best interests of a health plan.

**Registration and Licensing**

Other state actions would require PBMs to either be licensed or registered with a state administrative agency before conducting business in the state. Often, the agency that oversees PBMs is the office of the insurance commissioner, which can investigate claims of wrongdoing. Typically, these laws require a PBM to apply for and annually renew their registration, pay fees, and maintain a board—as well as identify their members. At least 20 states have enacted this type of legislation in recent years.

**Manufacturer Price Transparency**
A recurring theme is transparency in how prescription drugs are priced. Fifty bills in 21 states were introduced on this topic in 2019 and, as in the case of PBMs, the actions states took were diverse.

Several states pursued legislation to commission a workgroup or a study to investigate increasing drug prices but so far only one bill has passed. Indiana (HB 1029) enacted legislation to form a prescription drug pricing study committee tasked with investigating issues consumers face related to prescription drug pricing, access and costs.

Another common approach is to require disclosure of certain information to the state. Shedding light on the entire supply chain, sweeping legislation was enacted in Washington (HB 1224) requiring insurance carriers, PBMs and manufacturers to report various data to the health care authority.

The bill is comprehensive, but highlights include:

- Insurers must report the 25 prescription drugs most frequently prescribed by health care providers participating in the plan’s network, as well as the 25 costliest prescription drugs.
- PBMs must report the total dollar amount of all discounts and rebates received from the manufacturer, as well as how much of those rebates are retained by the PBM for each drug on the PBM’s formularies. PBMs must also disclose how much they pay retail pharmacies and the negotiated price that health plans pay the PBM for each drug on the PBM’s formularies.
- A manufacturer must submit to the state a description of all factors used to make the decision to either set or increase the list price of the drug. In the event of a price increase—defined as a list price increase of 20% or more annually, or a 50% increase over three years—a covered manufacturer must submit the amount of the increase and provide a reason why. This includes any drug a manufacturer intends to introduce at a list price of $10,000 or more for a course of treatment lasting less than one month or a 30-day supply. It would also include drugs already on the market costing more than $100 for a course of treatment lasting less than one month or a 30-day supply.

**Step-Therapy and Prior Authorization**

Policies affecting step-therapy, also known as “fail first,” and prior authorization protocols were also on the minds of state lawmakers in 2019. These utilization management tools are often used by insurers and PBMs to encourage providers and patients to choose less costly treatments while still maintaining an optimal quality of life. PBMs and carriers sometimes make patients start on a cheaper alternative drug and “step” through to the next, more expensive, tier if necessary. A health care provider must obtain prior authorization from the plan or PBM to start a patient on a higher tier.

As of May 2019, at least 16 bills in 11 states were enacted related to these mechanisms. Several measures would require insurance carriers to develop a clear request process when step-therapy is used. In their 2019 sessions, Oklahoma (SB 509) and Washington (HB 1879) enacted this type of legislation. An example of language is excerpted below from the Washington law:

“*When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception through which the prescription drug utilization management can be overridden in favor of coverage of a prescription drug prescribed by a treating health care provider.*”
At least two states—Arkansas (SB 446) and North Dakota (HB 1469)—adopted laws prohibiting step-therapy protocols specifically for cancer patients.

Several measures also modified the prior authorization and appeals process. In Kentucky (SB 54), health insurance carriers will be required to develop and adopt a process for electronically requesting and transmitting prior authorization for a prescription drug by health care providers. Under the new law, insurers will be required to render a decision for urgent health care services, and to notify the covered person or provider of that decision, no later than 24 hours after the completed request is received. If the member is requesting nonurgent health care services, the carrier must render a decision and notify the covered person or provider within five days of receipt.

**Conclusion**

Though some states have concluded their legislative sessions, the conversation on how to make prescription drugs more affordable continues. While there is bipartisan agreement in Congress that action must be taken, progress is slow. In response, state lawmakers have taken up the mantle to try to alleviate the high cost of drugs for both their constituents and their state budgets. Even though policymakers may disagree in many other topic areas, state legislators have come together to develop real world solutions to the drug cost conundrum. As the clock winds down in statehouses across America, time will tell as to what new laws will prevail and how effective they will be.