State drug pricing laws

Ten actions states are taking to address rising Rx spending

Building a better working world

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Introduction

Few policy topics feel as personal — and are as bipartisan — as the cost of prescription drugs. In a poll gauging Americans' top health care priorities for the new Congress, 90% of Democrats and 82% of Republicans said that taking action to lower prescription drug prices was "extremely important" to them. Legislators eager to deliver on campaign promises following the 2018 midterm elections kicked off 2019 by launching investigations and holding hearings into rising drug prices. The Trump administration continues to roll out proposals following the release of their Drug Pricing Blueprint in May 2018. However, federal legislators and regulators struggle to find the right balance between creating affordability without limiting access or stifling innovation. The complexity and range of challenges — from high-cost generic and specialty drugs to aggressive use of patent protections, the role of insurers and pharmacy benefit managers (PBMs) and the complex supply chain — mean that there is no single policy solution that can address all consumer pricing concerns.

Amid federal uncertainty, states are pushing the envelope on prescription drug pricing policy, fulfilling their role — once again — as the "laboratories of democracy." In 2018, 28 states passed nearly 45 bills to curb rising prescription drug prices, with more than 170 pieces of legislation being introduced nationally. The 2018 midterms also provided an opportunity for state officials to showcase their prescription drug policy chops. Several newly anointed governors proposed lofty drug pricing proposals right out of the gate, from statewide group purchasing programs to stronger negotiation tactics with purchasers. State legislatures also wasted no time introducing bills to address the rising cost of prescription drugs as they kicked off the 2019 legislative session — with nearly 30 bills in 11 states being introduced in just the first week. State attorneys general also continue to engage in protracted legal battles as they defend their state laws in court and some take aggressive action by proactively suing drug makers for what they deem as anti-competitive or price gouging practices. Meanwhile, pharmaceutical companies are on the defensive as they raise concerns about the fairness, efficacy and challenges of complying with a new patchwork of state laws, making for challenging waters for stakeholders to navigate.

10 themes

Ten themes emerge in reviewing state action on drug pricing. These themes are outlined along with sample enacted and proposed state legislation within each of these areas.

1. Transparency:

The pharmaceutical industry has long faced criticism about its lack of transparency. For many policymakers, increasing transparency into the system is the logical first step in driving down prices, lifting the veil and providing insight into rising costs across the supply chain. Price transparency bills often require manufacturers, PBMs and others in the drug supply chain to report pricing and other information aimed at explaining price increases or launch price decisions. This might include detailed information about outlays that impact pricing — such as marketing and R&D costs, profits and rebates — along with other disclosures. Vermont passed the first drug price transparency law in 2016, and since then several other states have followed suit. In 2018, 26 bills were introduced to make prescription drug pricing more transparent, with five signed into law.

In 2017, California passed a robust transparency law requiring prescription drug manufacturers and PBMs to provide advance notice of certain price increases along with a justification for the increase. It also requires insurers to report which drugs make up the highest share of spending and how premiums are impacted by prescription drug costs. The law would eventually make all of this information available online for the public to review, a provision that is currently being challenged by drug makers in court.

While transparency legislation in and of itself does not drive prices down, the hope is that making such information public will lead manufacturers to lower drug costs by shedding light on questionable practices and their impact on consumers. The information gleaned from such transparency efforts is often analyzed by task forces or submitted to state agencies to determine next steps in their drug pricing efforts.

State	Bill number	Status (year)	Detail
CA	SB 17	Enacted (2017)	Requires manufacturers to notify purchasers at least 90 days prior to the planned effective date of a price increase for a prescription drug and provide information justifying these increases. It also requires manufacturers to notify purchasers when launch prices of new drugs exceed a set threshold for specialty drugs under the Medicare Part D program. All insurers must also include, in their yearly report, drugs that make up the highest share of spending. All PBMs who receive a notice of an increase in wholesale acquisition cost (WAC) must notify their public and private purchasers of the increase.
CT	HB 5384	Enacted (2018)	Amends PBM disclosures to include health plan clients' formularies, including changes and exclusions, and requires the insurance commissioner to post this information publicly. Allows health carriers to submit written complaints if a drug that increased in price more than 25% results in premium increases more than a dollar a month. Requires manufacturers to report on net drug cost after rebates and utilization in response to health plan complaints. Requires drug manufacturers to inform the state when it has submitted a drug approval application to the Food and Drug Administration (FDA). Requires the state to annually list 10 drugs whose WAC has increased by 25% or more and requires manufacturers to provide price increase justifications.
OR	HB 4005	Enacted (2018)	Requires drug manufacturers to annually report prescription drug prices and costs associated with developing and marketing prescription drugs, and imposes penalties for failure to comply. Requires health insurers that offer prescription drug benefits to report information about prescription drug prices and the impact of prescription drug prices on premium rates. Requires annual public hearings on prescription drug prices.

2. Price gouging and rate setting:

While transparency laws may highlight rising pharmaceutical pricing, many bills lack a deterrent or penalty and thus do little to address costs. Some price transparency bills, however, also have a component that imposes penalties on manufacturers for price increases the state determines to be unjustified. While many states do not have the power to cap or reduce drug prices, they do have the power to impose various fines and civil penalties, or mandate other rebates or refunds from manufacturers.

In 2017, Maryland passed the first "price gouging" law, enabling the state attorney general to sue generic drug makers for "unconscionable" price increases. However, in a win for generic drug makers, a U.S. Fourth Circuit panel blocked the law due to its violation of the commerce clause, which was upheld in early 2019 by the Supreme Court. No other state has passed an anti-price-gouging bill to date, although over a dozen have been introduced.

Maryland also passed a bill in mid-April of this year to establish a payment-setting board for drugs, which would determine whether drug costs or price hikes pose affordability challenges and set payment ceilings for drug purchases and payer reimbursements. Six other states (FL, MN, NJ, NM, OH, RI) considered some kind of rate-setting legislation in 2018, none of which passed and which are likely vulnerable to legal challenges despite the momentum. Another proposal from Massachusetts Governor Charlie Baker (R) would enable the state's Medicaid program to negotiate supplemental rebate agreements with drug manufacturers if it is determined that the manufacturer has priced the drug excessively.

State	Bill number	Status (year)	Detail
IN	SB 415	Introduced (2019)	Prohibits a manufacturer or a wholesale distributor from engaging in price gouging in the sale of an essential off-patent or generic drug. The Office of the Secretary of Family and Social Services may provide a written notice of a price increase to the attorney general if such an increase is at least 50% of the WAC during a 12-month period, and a 30-day supply of the drug costs $80 or more. Manufacturers must submit to the attorney general a statement that explains the price increase. The attorney general may bring action against a manufacturer under this bill.
MA	HB 1	Introduced (2019)	Under the governor's budget proposal, the state's Medicaid program (MassHealth) would be allowed to negotiate supplemental rebate agreements directly with drug manufacturers, including value-based agreements. It also provides MassHealth with additional tools to encourage manufacturers to engage in good-faith negotiations for supplemental rebate agreements, including a public process to determine the value of a drug and referral to the Health Policy Commission (HPC) to assess if the manufacturer has priced the drug excessively. If the HPC concludes that the manufacturer's pricing of the drug is unreasonable, HPC may refer the drug to the Office of the Attorney General for appropriate action.
MD	SB 759/HB 768	Passed (2019)	Establishes a Prescription Drug Affordability Board, which will be responsible for identifying brand-name drugs or biologics that have a launch WAC of $30,000 or more or a WAC increase of $3,000 or more in the last 12 months. The board will also identify biosimilar drugs that have a launch WAC that is not at least 15% lower than the reference brand biologic, as well as generic drugs that have a WAC of $100 or more for a 30-day supply and that increased by 200% or more in the past year. The state can also identify other drugs that may create an affordability challenge for the state health care system and patients. On or before Dec. 31, 2023, if the board finds the drug is unaffordable, it can establish an upper payment limit that applies to all payers.

3. PBM regulation and rebate practices:

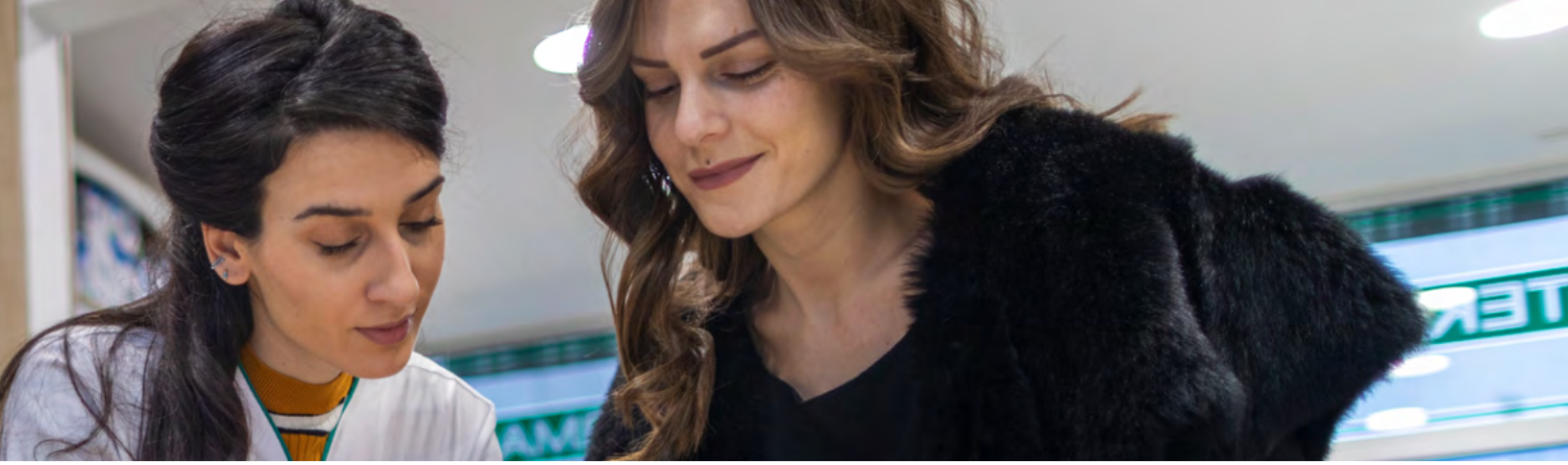
One of the most popular and bipartisan themes in state drug pricing legislation in 2018 was the regulation of pharmacy benefit managers (PBMs). More than 90 PBM bills were introduced last year with 20 states enacting 31 of them. States led the charge in banning gag clauses in PBM contracts last year — followed by legislation at the national level — and are looking into further action to gain insight into the "black box" of PBM contracts, increasing regulation and licensure requirements and cracking down on practices that harm patients.

Several states have passed bills prohibiting PBMs from engaging in "claw back" practices that require a pharmacy to charge a patient more in cost-sharing than what the PBM pays the pharmacy for the drug or more than the cash price of the drug (if the patient filled the prescription without insurance). When this is done, plans or PBMs are said to "claw back" the additional amounts throughout the year to the detriment of both patients and pharmacists.

In Montana, a new proposal goes a step further in entrusting its insurance department with the authority to oversee PBMs and ensure rebates shared within the prescription drug supply chain result in consumer savings. The bill would require that all rebates PBMs receive from drug manufacturers are passed on to insurers that in turn are used to lower out-of-pocket costs for enrollees.

States are also engaging in legal action against PBMs and scrutinizing the numerous state PBM contracts. In Ohio, for example, Attorney General Dave Yost filed a lawsuit against OptumRX for allegedly overcharging the state $16 million for generic drugs, claiming that they failed to pass along discounts for medicines purchased by the Ohio Bureau of Workers' Compensation.

State	Bill number	Status (year)	Detail
TX	HB 2360/ SB 1076	Enacted (2017)	Prevents a health benefit plan issuer that covers prescription drugs from requiring an enrollee to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of: (1) the applicable copayment, (2) the allowable claim amount for the prescription drug, or (3) the amount an individual would pay for the drug if purchasing the drug without using a health benefit plan or any other source of drug benefits or discounts.
AK	HB 240	Enacted (2018)	Requires PBMs to register biennially as third-party administrators with the state's Division of Insurance. Establishes rules for pharmacy audits and for calculating pharmacy overpayments. Requires pharmacy benefit managers to disclose their methodology and sources for drug reimbursement amounts and to establish an appeals process for reimbursement of multi-source drugs.
MT	SB 71	Introduced (2019)	Regulates health insurers' administration of pharmacy benefits for consumers. Prohibits the practice of spread pricing and requires all compensation remitted by the manufacturer or distributor to be retained by the health plan for the purpose of lowering premiums.



4. Out-of-pocket costs:

About one in four consumers say that they have a difficult time affording their prescription medication, a number that could increase with the proliferation of high-price specialty drugs. Fittingly, states are focused on passing bills that help their residents afford access to drugs by imposing limits on the amounts they must pay out of pocket or providing support for out-of-pocket costs.

In 2016, for example, the District of Columbia passed legislation that imposes a limit on copayment or coinsurance amounts through a health benefit plan for specialty drug prescriptions. Other proposals include one from New Jersey, which requires insurers to limit enrollee out-of-pocket costs to $100 for up to a 30-day supply of any single drug (or $200 for bronze level plans on the state exchange) and would not subject prescription drug benefits to deductibles in high-deductible health plans. Some legislation would create prescription drug assistance programs, such as a one-year pilot program in New Hampshire that would pay out-of-pocket drug costs for seniors who have reached the coverage gap in Medicare Part D.

States are taking different views on how to address manufacturer "coupons" in regard to out-of-pocket costs. California, for example, passed a bill prohibiting manufacturers from offering coupons or other reductions in an insured patient's out-of-pocket costs if a therapeutically equivalent, lower-cost generic drug is available, aiming to tamp down on practices that reduce patient incentives to choose lower-cost products. States like Virginia and West Virginia, however, passed bills requiring insurance plans count copay coupons toward enrollees' out-of-pocket maximums. And an Arizona law, which mirrors a Trump administration proposal, takes a middle road – requiring insurance plans to count copay coupons toward enrollee out-of-pocket maximums unless a lower-cost generic equivalent is available.

State	Bill number	Status (year)	Detail
DC	21-32	Enacted (2016)	Prohibits public and private insurers, with few exceptions, from setting patient out-of-pocket costs (copayments and coinsurance) for specialty drugs at more than $150 for a 30-day supply or $300 for a 90-day supply.
NH	SB 260	Introduced (2019)	Directs the Department of Health and Human Services to develop a one-year, prescription drug assistance pilot program to pay out-of-pocket prescription drug costs for seniors who have reached the coverage gap in standard Medicare Part D.
NJ	A 2431/ S 1865	Introduced (2019)	Requires insurers to limit enrollee out-of-pocket costs to up to $100 for up to a 30-day supply of any single drug, and limit enrollee out-of-pocket costs to up to $200 for bronze-level plans sold through the state ACA exchange. Says that high-deductible health plans cannot subject prescription drug benefits to the plan's deductible. Requires that health plans have an enrollee appeals process to gain coverage of drugs not on their formulary.

5. Utilization management:

In addition to affordability, states want to ensure appropriate access to drugs. As part of New Jersey's out-of-pocket spending bill, health plans are required to have an enrollee appeals process to gain coverage of drugs not on their formulary. Similarly, several states have moved to regulate how health plans implement utilization management tools to control costs and ensure appropriate prescription drug use, passing laws that ban or restrict insurers' use of step therapy (which requires patients to try a less expensive drug before insurance will cover a more expensive therapy) and prior authorization (which requires a physician obtain approval from a health insurance plan before prescribing a specific medication) for certain populations. While these measures also limit their ability to control costs, it addresses access and patient advocacy concerns raised by opponents to such methods.

State	Bill number	Status (year)	Detail
CO	S 203	Enacted (2017)	Prohibits carriers from requiring a covered person to undergo step therapy and requires them to provide coverage for the drug prescribed as long as the drug is on the carrier's prescription drug formulary, when the patient has tried the required drug while under his or her current or previous health insurance plan and it was discontinued due to lack of efficacy.
WV	H 2300	Enacted (2017)	Provides access to a clear and convenient process to request a step therapy exception determination that should be granted if the drug is contraindicated or could cause adverse reaction or harm, the patient has tried the drug previously and was discontinued due to lack of efficacy, the patient is stable on a prescription drug selected by their provider, or it is otherwise not in the best interest of the patient.
NJ	S 727/A 2033	Proposed (2019)	This measure regulates PBMs as organized delivery systems and limits use of prior authorization.

6. Medicaid spending controls:

Rising Medicaid expenditures are a big concern for states, with an expected increase of 5.7% annually that threatens to strain both federal and state budgets. While Medicaid has some built-in cost controls, high-cost specialty drugs continue to be a driver of increased spending. Directly limiting state spending on prescription drugs in Medicaid is one approach that states are targeting to drive down these costs.

In April 2017, New York passed a Medicaid drug expenditure provision that allows the state Department of Health to set an annual projected spending cap for prescription drugs. Under the cap, if total Medicaid drug spending in a year is projected to exceed the growth target, the state may identify specific drugs for referral to a Drug Utilization Review Board and reach out to the manufacturer to see if they can agree on a satisfactory rebate for the specified drugs and/or limit access to the drug through existing utilizations controls. Ohio failed to advance a similar ballot measure in November 2017, the Ohio Drug Price Relief Act, which was aimed at capping the amount state agencies pay for prescription drugs at the rate paid by the Department of Veteran Affairs.

States are also exploring ways to rein in drug costs through the Medicaid waiver process. Massachusetts, for example, requested a waiver from the Centers for Medicare and Medicaid Services (CMS) to use a "closed" Medicaid drug formulary – but it was denied by CMS in mid-2018. Since then, the Trump administration has proposed a demonstration project that would allow five states to negotiate prices directly with drug makers using a closed formulary. The states, however, would have to give up the automatic rebates they receive through the Medicaid Drug Rebate Program, which amount to at least 23% of list prices in exchange for guaranteed drug coverage. Drug makers and patient advocates have pushed back against the legality of such proposals, expressing concerns about access to specific drugs. Proponents note the need to control runaway Medicaid costs and the beneficial use of formularies in the private market.

State	Bill number	Status (year)	Detail
NY	AB 3007/ SB 2007	Passed (2017)	Imposes a Medicaid drug spending cap as a separate component within the Medicaid global cap. The Department of Health and the Division of the Budget shall assess on a quarterly basis the projected total amount to be expended in the year on a cash basis by the Medicaid program for each drug, and the project annual amount of drug expenditures for all drugs. The Drug Utilization Review Board will determine whether to recommend a supplemental rebate for a drug considering the actual cost of the drug to the Medicaid program including (1) the drug's impact on spending, (2) any significant and unjustified price increases of the drug, and (3) whether the drug may be priced disproportionately to its therapeutic benefits.

7. Biosimilar substitution:

According to the Congressional Budget Office (CBO), branded specialty drugs accounted for just 1% of prescriptions but account for about 30% of net drug spending in both Medicare Part D and Medicaid in 2015. Many of these high-cost specialty drugs are classified as biological products, leading states to propose legislation aimed at increasing the use of cheaper, biosimilar versions. Unlike generic versions of other branded drugs, the FDA has yet to deem biosimilars as "interchangeable" with biologic products, and cannot currently be substituted without prior approval from the prescriber. Some of these laws allow pharmacists to substitute an interchangeable biosimilar product if certain conditions are met, while others allow prescribers the ability to note if substitutions are not allowed. A recently proposed law in Arkansas would also allow pharmacists to make biological product substitutions when there are cost savings for the patient.

State	Bill number	Status (year)	Detail
SD	SB 75	Enacted (2018)	Permits pharmacists dispensing a prescription drug order for a biological product to select an interchangeable biological product of the prescribed product. Prohibits pharmacist from dispensing an equivalent or interchangeable biological drug product if a brand name has been prescribed unless patient is informed of selection and given right of refusal. Permits prescriber to prohibit a pharmacist from selecting an equivalent drug product or interchangeable biological product by hand-writing "brand necessary" on the prescription drug order.
WV	HB 4524	Enacted (2018)	Unless instructed otherwise by the purchaser, permits a pharmacist to select a less expensive, interchangeable biological product provided that the pharmacist provide notice to the patient about the selection. Would permit prescriber to prohibit interchange by stating that the brand pharmaceutical or the specific biological product is medically necessary.
AR	HB 1269	Introduced (2019)	Allows pharmacists to make biological product substitutions when there will be cost savings for the patient. The pharmacist must disclose the amount of the savings at the request of the patient.

8. Importation:

In 2018, Vermont became the first state to enact a law authorizing drug purchasing from Canada, with eight other states introducing similar importation legislation and newly elected Democratic governors in Wisconsin, Colorado, Michigan and Maine also expressing interest. Vermont's law orders the state to develop a proposal to allow for drug importation from Canada, which must be carefully crafted to meet federal requirements including establishing checks and balances to ensure it meets federally mandated cost savings and drug safety and efficacy requirements. Before the state can implement its program, the Vermont Agency for Human Services must obtain approval from HHS.

Most state importation legislation focuses on high-cost and/or highly utilized drugs to be identified for inclusion in importation programs. An analysis in Utah suggested the state would save $70 million in the private sector and another $20 million to $30 million in state-funded insurance programs through an importation program that features 15%–20% discounts on imports for drugs like insulin, along with other expensive drugs such as those for hepatitis C or HIV. While opponents of the legislation are concerned about drug safety, proponents argue that Canadian drugs are made by reputable companies and often in the same facilities as US drugs. Canadian health experts also caution that cross-border sales could result in drug shortages and exacerbate affordability issues for Canada's government-run health system.

State	Bill number	Status (year)	Detail
VT	S 175	Enacted (2018)	Establishes a wholesale importation program to import predetermined, high-cost drugs from Canada.
FL	HB 19/SB 1528	Passed (2019)	Establishes a wholesale Canadian drug importation program. The state would contract with a vendor to provide services under the program, and the vendor would develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for savings to the state.
OK	HB 940	Introduced (2019)	Requires the state Department of Health to work with the Health Care Authority to create a wholesale Canadian drug importation pilot program. The Health Care Authority will be responsible for identifying the 5 to 10 highly prescribed drugs through the state Medicaid program. The drugs identified will be imported from Canada.

9. Group purchasing:

As one of his very first actions as governor, California Governor Gavin Newsom (D) ordered the state health department to consolidate Medicaid drug purchasing power and develop a state bulk purchasing program for small businesses, private health plans and the self-insured. At least four other newly elected Democratic governors also have voiced interest in pooling state purchasing power, such as Wisconsin's Tony Evers, who is exploring how to partner with other states to further increase negotiating leverage.

Group purchasing bills instruct state agencies to explore different approaches to drug purchasing and drug price negotiations, often through multiagency collaboration and/or through the work of task forces. In Oregon, for example, a bill under consideration directs the administrator of the Oregon Prescription Drug Program to cooperate with California for the bulk purchase of drugs. Other bills — such as that of Massachusetts — establish special commissions to examine the prospect of bulk purchasing and the potential cost savings and public health benefits.

State	Bill number	Status (year)	Detail
MA	S 695	Introduced (2019)	Establishes a special commission to examine the prospect of establishing a system for bulk purchasing and distribution of pharmaceutical products with a significant public health benefit and the potential for significant health care cost savings through overall increased purchase capacity.
NV	SB 226	Introduced (2019)	Requires the Department of Health and Human Services to enter into agreements to purchase prescription drugs on behalf of certain health benefit plans. Under this bill, the department must develop a formulary of prescription drugs to be used for all health benefit plans funded by a state agency. The department will negotiate and enter into agreements to purchase drugs included in that formulary on behalf of those plans.
OR	HB 2679	Referred to committee (2019)	Directs the administrator of the Oregon Prescription Drug Program to cooperate with California for the bulk purchase of prescription drugs. The administration must solicit cooperation from California by Dec. 31, 2019.

10. Outcomes-based and subscription-based models:

In June of 2018, Oklahoma became the first state to launch an outcomes-based pricing program under its Medicaid program, following approval of its plan by CMS. Since then, the state has entered into several contracts that stipulate if patients using the medications do not meet specified performance benchmarks, manufacturers could be on the hook for paying additional rebates. Later in 2018, CMS also approved Michigan's plan to enter into outcomes-based contracts in its state Medicaid program, followed by Colorado's approval by CMS in early 2019.

Also in 2018, Louisiana became the first state to approve a subscription-based model for Medicaid drugs — which some are calling a "Netflix model" — in order to expand access to critical therapies such as hepatitis C drugs. Under the model, the state pays a drugmaker a fixed annual cost over a number of years to provide unlimited access to the drug. In March of 2019, Louisiana accepted a bid by Gilead subsidiary Asegua Therapeutics to fulfill its first-in-the nation subscription model to provide an unlimited five-year supply of Gilead's authorized generic for hepatitis C to state Medicaid beneficiaries and prisoners. In their call for proposals, Louisiana said manufacturer bids — of which there were three — should not exceed the $35 million the state spent on those drugs the prior year. In April, Washington state announced it awarded AbbVie a contract for Mavyret, under which the state will buy hepatitis C medicines through a similar, subscription fee model and hopes to expand the arrangement to the commercial market and neighboring states. Indications are that New York may also be interested in the model and there are talks of expanding to other drug therapeutics such as Naloxone/Narcan, an opioid antagonist used to treat opioid overdoses, and pre-exposure prophylaxis for HIV.

Conclusion

State experimentation with drug pricing is expected to continue throughout 2019 and beyond. As early lessons emerge and states push the boundaries on efforts to rein in costs, more legal battles will likely ensue as drugmakers and other stakeholders push back on laws that threaten to expose "trade secrets," break down systems that reward pharmaceutical innovation and benefit other players in the supply chain. While the Trump administration continues to roll out its drug pricing plan at the federal level, most observers expect the divided Congress will only address the issue on the margins. This leaves companies, stakeholders and consumers watching to see which state and federal proposals move forward, how compliance and enforcement will be managed, what lessons have been learned, and what effect (if any) these state initiatives will have on pharmaceutical pricing trends and patient access.

Sources:

1. POLITICO/Harvard T.H. Chan School of Public Health, "Americans' Health and Education Priorities for the New Congress in 2019," December 11–16, 2018.
2. National Academy for State Health Policy, "Center for State Rx Drug Pricing," March 2019.
3. InsideHealthPolicy, "Inside Drug Pricing," March 2019.

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