

HEALTH

Prescription Drug Policy

A Bipartisan Remedy



Prescription Drug Policy: A Bipartisan Remedy

The National Conference of State Legislatures is the bipartisan organization dedicated to serving the lawmakers and staffs of the nation's 50 states, its commonwealths and territories.

NCSL provides research, technical assistance and opportunities for policymakers to exchange ideas on the most pressing state issues, and is an effective and respected advocate for the interests of the states in the American federal system. Its objectives are:

- Improve the quality and effectiveness of state legislatures.
- Promote policy innovation and communication among state legislatures.
- Ensure state legislatures a strong, cohesive voice in the federal system.

The conference operates from offices in Denver, Colorado and Washington, D.C.

Executive Summary

Almost everyone in his or her life takes a prescribed medication, and 1 in 3 Americans [reported](#) taking at least one medicine per year. [The U.S. Government Accountability Office \(GAO\) reports](#) that retail prescription drug spending accounts for almost 11% of all personal health care spending. This share was 9.8% in 2010 and has remained relatively stable for the past decade. Other [research](#) shows that as the amount a person spends on medicines increases, the likelihood they will adhere to their regimen goes down. In addition, [research shows](#) that as a patient's medication access and adherence decreases, the prevalence of poor health outcomes rises—a significant [driver](#) of overall health care costs.

The cost of prescription drugs not only affects consumers but also fiscally impacts states. States pay for medicines used in state Medicaid programs, health plans for state employees and for state prison populations. According to the Medicaid and CHIP Payment and Access Commission, gross spending in the U.S. for [prescription drugs in Medicaid](#) totaled \$66.7 billion in 2019 and, on average, states spend [between 4-5%](#) of their Medicaid budget on prescription drugs.

A [Kaiser Family Foundation](#) analysis of drug pricing data from 2014-2018 showed the price of some medicines, particularly brand name and specialty drugs, rose on average, while prices of generic products generally declined. Further, [research conducted by GoodRx](#) reports since 2014, the price of brand name medicines increased by 33%, more than a majority of other health care goods and services, including both hospital and physician services.

NCSL convened a bipartisan Prescription Drug Policy Recommendations Work Group of legislators from across the country to discuss issues and state policy options related to prescription drug access and affordability. From those discussions, three broad recommendations emerged. Within these domains, group members chose to highlight eight state policy options:

Recommendation One: Determine the true cost of prescription drugs.

- Require price and cost transparency throughout the supply chain.
- Establish a prescription drug affordability board.
- Prohibit excessive price increases.

Recommendation Two: Streamline procurement processes and create new purchasing models.

- Procure pharmaceuticals through purchasing pools and alternative payment models.
- Leverage savings and prevent duplicate discounts under the federal 340B program.
- Pursue importation agreements with other countries.

Recommendation Three: Encourage or introduce competition into the supply chain.

- Increase state oversight of market competition.
- Reform pharmacy benefit management (PBM) practices.

This report explores these recommendations and policy options based on the discussions and feedback from the legislators in the work group. As state legislators consider these options, they may ask questions to learn more about benefits, opportunities and challenges related to these strategies, and many others, in their states. Legislators can guide policy discussions and may want to convene a variety of stakeholders from all sectors and perspectives. Policymakers modifying or creating policies may consider how effective they are in terms of costs and outcomes and balance those factors with potential unintended consequences or future hurdles as prescription drug policies continue to develop. Prescription drug access and affordability—along with new challenges and opportunities—will continue to be issues for state leaders to consider.

NCSL Prescription Drug Policy Recommendations Work Group

In 2019 and 2020, the National Conference of State Legislatures (NCSL) brought together a bipartisan group of state legislators to examine prescription drug policies and develop a set of recommendations for fellow state leaders. Together, they discussed strategies that not only have potential to make prescription drugs more accessible and affordable, but might lower costs across the health care system. This report is a culmination of those efforts.

Over the course of six meetings, three broad recommendations emerged. Within these domains, legislators focused on eight state policy options:

Recommendation One: Determine the true cost of prescription drugs.

- Require price and cost transparency throughout the supply chain.
- Establish a prescription drug affordability board.
- Prohibit excessive price increases.

Recommendation Two: Streamline procurement processes and create new purchasing models.

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Prescription Drug Policy Recommendations Work Group Members

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| • <i>Arthur Orr, State Senator, Alabama</i> | • <i>Bonnie Cullison, State Delegate, Maryland</i> |
| • <i>Cathy Giessel, State Senator, Alaska</i> | • <i>Joseline Peña-Melnyk, State Delegate, Maryland</i> |
| • <i>David Wilson, State Senator, Alaska</i> | • <i>David Carlucci, State Senator, New York</i> |
| • <i>Jack Ladyman, State Representative, Arkansas</i> | • <i>Gustavo Rivera, State Senator, New York</i> |
| • <i>Susan Lontine, State Representative, Colorado</i> | • <i>Howard Anderson, State Senator, North Dakota</i> |
| • <i>Andria Bennett, State Representative, Delaware</i> | • <i>Judy Lee, State Senator, North Dakota</i> |
| • <i>Dean Burke, State Senator, Georgia</i> | • <i>Greg McCortney, State Senator, Oklahoma</i> |
| • <i>John Mizuno, State Representative, Hawaii</i> | • <i>Louis DiPalma, State Senator, Rhode Island</i> |
| • <i>Ed Charbonneau, State Senator, Indiana</i> | • <i>Shane Reeves, State Senator, Tennessee</i> |
| • <i>Cindy Kirchhofer, State Representative, Indiana</i> | • <i>Jim Dunnigan, State Representative, Utah</i> |
| • <i>Steven Sheldon, State Representative, Kentucky</i> | • <i>Evan Vickers, State Senator, Utah</i> |
| • <i>Fred Mills, State Senator, Louisiana</i> | • <i>Eileen Cody, State Representative, Washington</i> |
| • <i>Heather Sanborn, State Senator, Maine</i> | • <i>Matthew Rohrbach, State Delegate, West Virginia</i> |

Acknowledgments

The National Conference of State Legislatures (NCSL) gratefully acknowledges Arnold Ventures for their support of this project. NCSL would also like to thank the Association for Accessible Medicines (AAM), Pharmaceutical and Research Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO), America's Health Insurance Plans (AHIP), Pharmaceutical Care Management Association (PCMA), National Association of Medicaid Directors (NAMC), McKesson Corporation, Sentry Data Systems, and Patients for Affordable Drugs for their participation in work group meetings.



Introduction

“The finger-pointing and blame game that always happens is frustrating. Manufacturers blame insurers and PBMs, the PBMs blame manufacturers and insurers, and the insurers blame manufacturers and PBMs – patients shouldn’t be caught in the middle of this circle.”

– Delegate Bonnie Cullison (D-Md.)

When a person is diagnosed with an illness, prescription drugs can be a vital part of treating and managing his or her condition. A prescription drug not only can improve a person’s quality of life, but sometimes might be what saves a person’s life. From antibiotics to cancer therapies, almost everyone at some point in their life takes a prescribed medication. In fact, a [survey](#) by the Centers for Disease Control and Prevention showed 1 in 3 Americans report taking at least one medicine annually with an estimated 19.1% of adults between the ages 45 to 64 taking five or more. Furthermore, the [U.S. Government Accountability Office \(GAO\) reports](#) retail prescription drug spending accounts for almost 11% of all personal health care spending, a figure that was relatively stable over [the past decade](#).

But medicines cannot work if patients do not take them as prescribed. In one [study](#), 36% of patients surveyed said they did not take their medicines as prescribed in order to save money, instead paying for other living essentials such as food and rent. Researchers also determined that as the cost of a prescription goes up for patients, the likelihood that they will adhere to their regimen goes down. Other [research shows](#) that as a patient’s medication adherence decreases, the prevalence of poor health outcomes rises—a significant [driver](#) of overall health care costs.

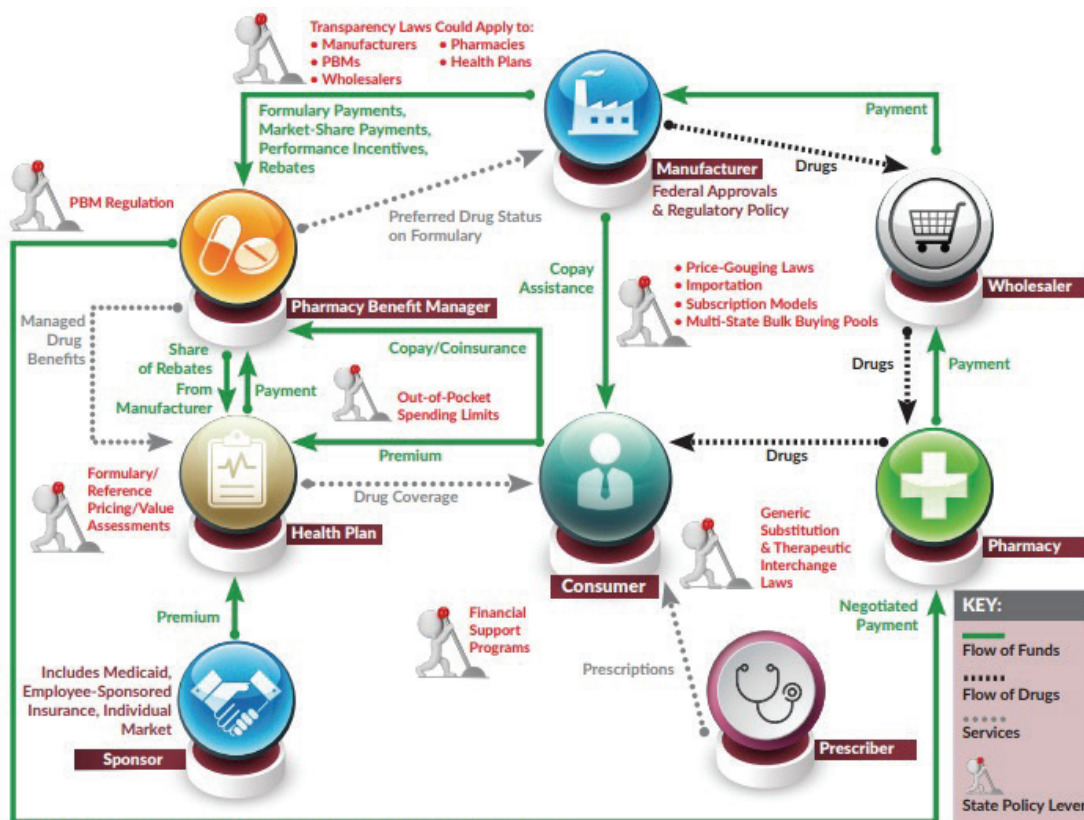
High prices not only affect consumers, but also state budgets through Medicaid programs, health plans for state employees and state prison costs. According to the Medicaid and CHIP Payment and Access Commission, gross spending in the U.S. for [prescription drugs in Medicaid](#) totaled \$66.7 billion in 2019. Furthermore, the [Centers for Medicare & Medicaid Services \(CMS\)](#) projects prescription drug spending to increase approximately 5.4% annually over the next five or more years.

On average, states spend [between 4-5%](#) of their Medicaid budget on prescription drugs but that strongly depends on the state. As states strive to be fiscally balanced and control Medicaid spending, even a predicted rise in expenditures may be difficult to absorb.

The Prescription Drug Supply Chain

The prescription drug supply chain is harder to understand than many other consumer goods due to the numerous actors and interconnected relationships. Federal regulations and laws further complicate the system. Figure one demonstrates the directional flow of money, services and products, as well as the variety of policy levers available to policymakers at different points in the chain.

Figure 1. State Policy Levers in the Retail Prescription Drug Supply Chain

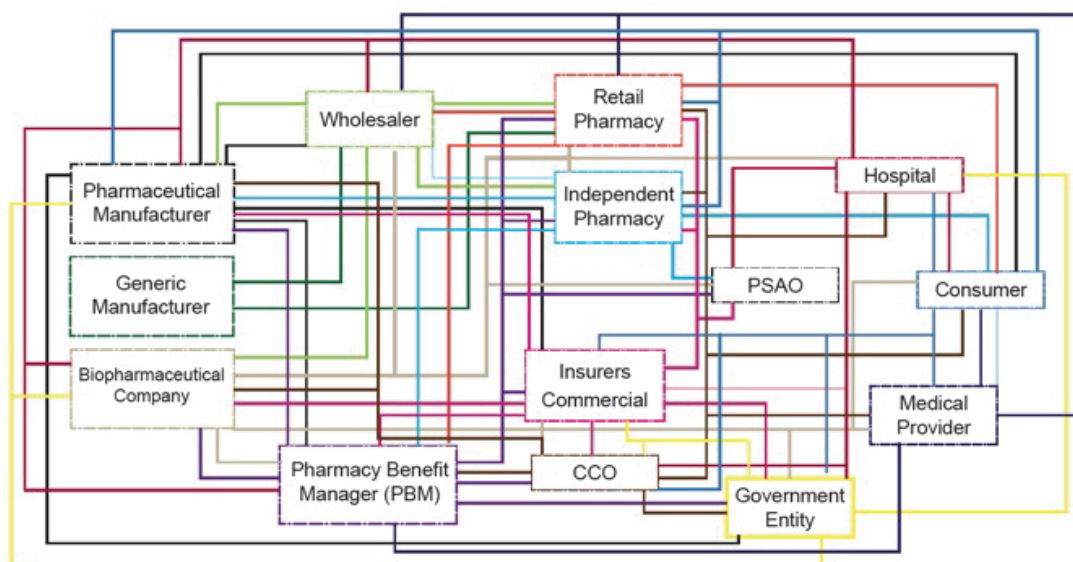


Note: Model represents non-specialty prescription drugs covered by health insurance.

Source: Adapted by the Kansas Health Institute from "Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System," Health Affairs Blog, June 13, 2017.

Figure two demonstrates a greater level of detail into the direct and indirect relationships each entity has in the chain.

Figure 2. Pharmaceutical Supply Chain Direct Transactional Relationships



Source: Oregon state schematic from Joint Task Force on Fair Pricing of Prescription Drugs report 2018, p.56

Please note:

CCO = coordinated care organizations (Medicaid)

PSAO = Pharmacy services administrative organizations

One way to think about the prescription drug supply chain is to organize the system into three parts: upstream—where drugs are created and priced; midstream—where drugs are purchased and distributed; and downstream—when the consumer receives the medication.

Legislators expressed being overwhelmed by the intricacies of the drug supply chain, making obvious and effective solutions difficult to identify. A policy’s unintended consequences on other areas of the supply chain are almost impossible to predict. Group members consistently communicated that trying to solve these issues is like playing the game “whack-a-mole,” where policy alternatives aimed at one area of the supply chain cause issues to spring up elsewhere in the system.

Group members used several criteria to aid in making recommendations, including:

- Personal familiarity with certain policy angles through professional or legislative experience.
- Political feasibility, as well as support from party and leadership.
- Strategies with an established workplan, guidance or metrics to gauge program or policy performance outcomes or goals.
- Popularity among constituents and willingness of stakeholders to engage in the legislative process.
- Impact on the health care quadruple aim: reducing overall health care costs, improving patient health, improving patient experience and improving provider experience.

Group members emphasize that while only eight policy options are highlighted in this report, lawmakers should review the breadth and depth of possible legislative alternatives that might be appropriate for their states and constituents.

Supply Chain Organization:

Upstream

Manufacturers (brand name and generic producers)

Midstream

Pharmacy benefit managers (PBMs), health plans and plan sponsors, pharmacy services administrative organizations (PSAOs), wholesalers

Downstream

Providers (pharmacists or prescribers), hospitals, patients, consumers

Recommendation One: Determine the true cost of prescription drugs

“Whether you are making motors, chicken dinners or generating electricity, it doesn’t matter what business you’re in, there’s a process that you follow. Your product needs to be priced so that people can afford to buy it.” Senator Arthur Orr (R-Ala.)

A [Kaiser Family Foundation](#) analysis of drug pricing data from 2014-2018 showed the price of some medicines, particularly brand name and specialty drugs, rose on average, while prices of generic products generally declined. Supporting this further, [research conducted by GoodRx](#) reports since 2014, the price of brand name medicines increased by 33%, more than most other health care goods and services, including both hospital and physician services.

Drug manufacturers set a product’s initial list price that reflects the significant amount of human and financial capital needed to bring a viable drug to market. The cost of bringing a new therapy to market varies. Some [studies](#) have estimated costs around \$985 million and the Pharmaceutical Research and Manufacturers of America (PhRMA) puts the [average cost](#) at \$2.6 billion. While new medicine creation is heavily [funded by the National Institutes of Health](#), this is primarily for early research and proof of concept. It is often private-sector companies that take on the larger risk of bringing these innovations over the finish line.

Though manufacturers set the initial list price, a number of factors influence the amount actually paid by states or consumers. Rebates for formulary placement negotiated between drug manufacturers and pharmacy benefit managers (PBMs)—companies that manage prescription drug benefits on behalf of payers—also play a key role.

PBMs use [formularies](#)—lists of covered drugs—as a mechanism to control spending. Medicines included on formularies are categorized into consumer cost-sharing tiers, with the lowest amount a patient pays at the bottom tier, and the highest amount at the top tier. Manufacturers give rebates to PBMs for more favorable placement on the PBMs formulary. PBMs typically then share rebates with insurers who pass some of the savings on to consumers in the form of lower premiums. This arrangement can also mean drugs with the highest prices, like brand name, specialty or biologics, can be placed on the lowest patient cost-sharing tier.

During the discussion, group members conveyed since the supply chain for prescription drugs is complicated and unlike the distribution of other consumer goods, it makes the economic comparison of pharmaceuticals to other markets impractical. Lawmakers identified three potential factors related to supply chain transparency influencing policy decisions:

1. Create uniformity in data across purchasing and reporting agencies to ensure usefulness and comparability. Reliable and accurate data is needed to understand costs and pricing at various points in the system.
2. Standardize terminology across industries, organizations and government institutions.
3. Implement processes to simplify the supply chain and revise it to function in a more straightforward way.

Group member tip: As the profit structure stands, there are few incentives for any entity in the supply chain to lower prices. To lower prices, consider addressing the lack of incentives that exist throughout the system.

OPTIONS AND STRATEGIES

Requiring price and cost transparency throughout the supply chain.

“How do you figure out return on investment when the information you need is protected by anti-trust laws?” *Senator David Wilson (R-Alaska)*

Apart from patients, almost every entity that participates in the supply chain keeps certain cost and pricing information secret. Not only are the methods manufacturers use to establish drug prices protected by federal anti-trust laws, but the contractual terms between PBMs, health plans, pharmacies and manufacturers are also considered proprietary. According to industry experts, these safeguards are critical to maintaining a competitive and robust market.

Looking to shine a light on factors contributing to drug prices, transparency initiatives have piqued legislator interest. Current state prescription drug [transparency laws](#) generally require manufacturers, PBMs, health insurers and others to report various data to a state agency, such as a department of insurance or board of pharmacy. Industry organizations challenged statutes in California, Nevada and Oregon alleging federal trade secret regulations preempt state law. Some states have created a workaround to report data that has been stripped of identifying information and aggregated. This allows state agencies to access confidential data and analyze the prescription drug market without violating federal law.

Questions remain whether transparency efforts are effective policy levers. [Analyzing 35 prescription drug pricing laws](#) with a transparency component enacted between 2015-2018, researchers from the USC Schaeffer Center found most are uninformative and do little to affect prices. Industry experts echo these concerns, adding that these measures stifle innovation and harm manufacturers’ ability to create new medicines. Furthermore, if pricing contracts and negotiations between supply chain actors are disclosed, patients may be affected in the form of higher prices and less choice across the health care system. In contrast, [experts at the University of California, Hastings College](#) agree transparency laws may not directly affect price, but the information gained through these laws may help guide future legislative or regulatory action.

STATE EXAMPLES

As of summer 2021, 12 states have transparency laws requiring manufacturers to report certain information about price increases: **California, Connecticut, Maine, Minnesota, Nevada, North Dakota, Oregon, Texas, Utah, Vermont, Virginia** and **Washington**. Of these 12 states, seven have laws requiring manufacturers to report launch price information, eight outline reporting requirements for PBMs and nine require health plans to report certain cost and pricing data. Some state laws pertain to other supply chain actors such as wholesalers and distributors. Unique to [Nevada](#), legislation enacted in 2018 requires manufacturers, health plans and PBMs to report various information on essential diabetes medicines. In 2020, those provisions were expanded to essential asthma drugs.

Applies to:	Manufacturer Price Increases	Manufacturer Launch Prices	Pharmacy benefit managers (PBMs)	Health Plans
California (2018)	●	●		●
Connecticut (2018)	●	●	●	●
Maine (2019)	●	●	●	●
Minnesota (2020)	●	●	●	
Nevada (2018 and 2019)	●		●	
North Dakota (2021)	●		●	●
Oregon (2018 and 2019)	●	●		●
Texas (2019)	●		●	●
Utah (2020)	●		●	●
Vermont (2018)	●	●		●
Virginia (2021)	●		●	●
Washington (2019)	●	●	●	●

Establish a prescription drug affordability board.

Prescription drug affordability boards (PDABs) are increasingly being looked at as a tool to lower drug costs. While some differences exist, the overarching goal of a PDAB is to identify prescription drugs that pose affordability challenges and make recommendations to the legislature. These recommendations might include setting spending targets or upper payment limits. Another function of a PDAB is to collect information and analyze data to aid in legislative decision-making.

Affordability boards face some potential challenges. [Research from Manatt](#) points out that not only are the recommendations a board proposes limited to state regulated plans, but the board may lack legal authority to promulgate enforceable rules. Critics [argue](#) PDABs encourage governmental price controls rather than promote free market solutions. Drugmakers also [oppose](#) PDABs, reasoning that advancements in technology would stall.

Group member tip: Create a 50-state PDAB with legislative representation from all 50 states, the District of Columbia, and the territories. This could streamline information across states, avoid duplication of efforts and encourage the federal government to act on controlling prescription drug costs.

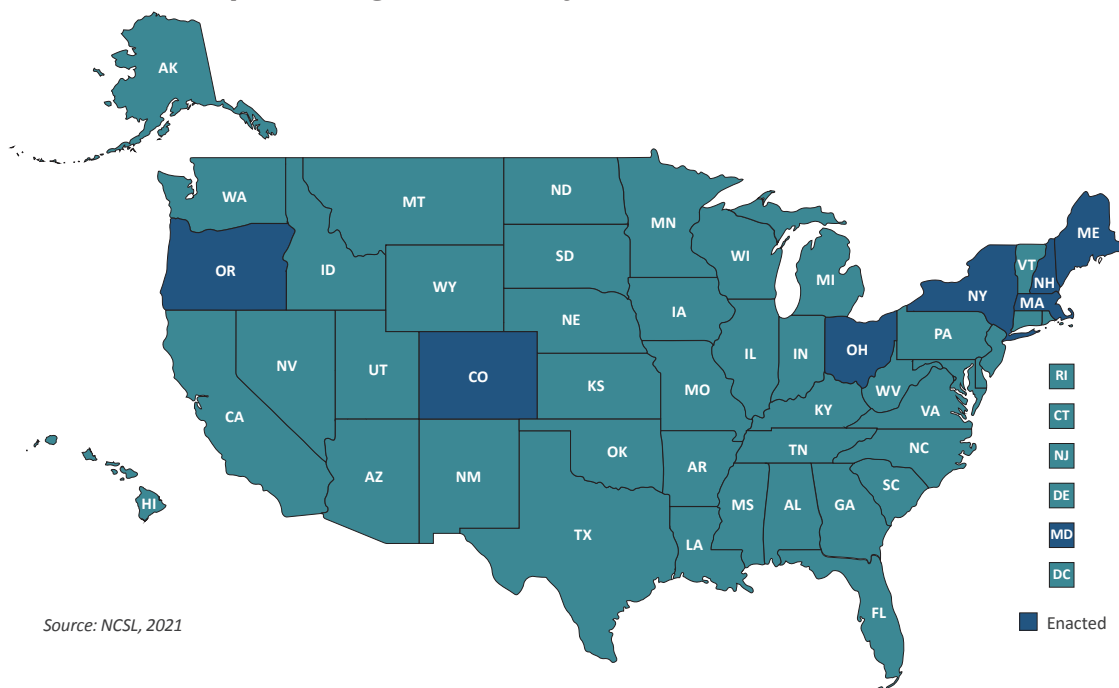
STATE EXAMPLES

Eight states—[Colorado](#), [Maine](#), [Maryland](#), [Massachusetts](#), [New Hampshire](#), [New York](#), [Ohio](#) and [Oregon](#)—have established some version of a PDAB. [New York's 2017 law](#) establishes an annual prescription drug spending cap for the state Medicaid program. For certain covered drugs, should the amount the state spends exceed the cap, the state can negotiate additional rebates with manufacturers. New York [reports](#) the amount triggering the cap has decreased since the program began, and overall spending on prescription drugs has been lower than projected. [Massachusetts also uses a spending cap](#). In both states, if the cap is surpassed and a rebate agreement is not reached then certain drugs will be subject to a value assessment.

In a differing approach, the primary charge of the [Maryland Prescription Drug Affordability Board](#) is to study the prescription drug supply chain, collect data and conduct cost reviews on prescription drug products possibly posing affordability challenges. Maryland's PDAB is expected to report its findings to the legislature by December 2023.

In 2020, [Ohio's Prescription Drug Transparency and Affordability Council](#) released a report of six policy recommendations regarding the transparency, pricing, and accessibility of prescription drugs in the state, some of which mirror options in this report.

State Prescription Drug Affordability Boards (PDAB)



Prohibit excessive price increases.

As previously mentioned, [studies](#) show that prices of medicines have increased 33% since 2014, more than many other health care goods and services, including hospital and physician services. Some states have looked closely at similar data and defined certain drugs that exceed a certain threshold as “price gouging”—when a seller excessively raises the price of their product, often without a practical explanation.

As entities along the supply chain compete for revenue, manufacturers set the initial list price. Drugmakers suggest list prices are the result of significant investments of time and capital needed to develop ground-breaking medicines. Others argue drug companies take advantage of consumers’ willingness to pay by charging ever higher prices.

The Institute for Clinical and Economic Review (ICER), an independent non-profit organization, compares a prescription drug’s price to its potential effectiveness, and the effect it has on national spending. In a January 2021 [report](#), ICER identified seven drugs that substantially impact national spending and also experienced large price increases that were not supported by new clinical evidence. These drugs had an annual list price increase over 5.66%, which was more than double the medical consumer price index. ICER attributes an additional \$1.2 billion in annual drug spending to these seven drugs alone. While ICER is widely recognized for analyzing the cost effectiveness of drugs, some argue its methods of evaluation are subjective and open to interpretation.

A coalition of 51 states and territories, joined by a large health insurer, have three separate lawsuits pending in federal court accusing more than 25 generic pharmaceutical manufacturers and 15 individuals of anti-trust violations. The [suit](#) alleges drugmakers conspired to fix or increase prices on over 200 generic medicines for almost a decade, and made plans to divide the market to avoid competition. The accused drug companies strongly deny any wrongdoing, and the case is still pending as of publication.

Did you know?

A widely publicized price gouging example, in 2015 the U.S. [Senate Special Committee on Aging](#) found the price on an anti-parasitic medicine climbed from \$13.50 a pill to over \$750, an increase of more than 5,000%. A year later, a 50-year-old treatment used for emergent, life-threatening allergic reactions became the second national controversy. An [investigation by the House Oversight and Government Reform Committee](#) found that after the drug was purchased in 2007, the purchasing manufacturer raised the price of the medicine approximately 500%.

Insulin—commonly used to treat [diabetes](#)—is currently [under scrutiny](#) for potential price gouging. Unlike people diagnosed with type 2 diabetes who can possibly control their condition without insulin, people living with type 1 diabetes require insulin to survive. [Research](#) shows that the cost of insulin tripled between 2002 and 2013, and recent [surveys](#) point to a growing number of people identifying affordability as the reason they ration their insulin, sometimes with grave outcomes.

STATE EXAMPLES

The most prominent example of state price gouging legislation passed in **Maryland** with a 2017 law, [The Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs Act](#). The law prohibited a manufacturer or wholesale distributor from engaging in price gouging for the sale of an essential off-patent or generic drug. Almost immediately after its passage, the Association for Accessible Medicines (AAM), the generic drug industry trade group, filed suit in federal court on the grounds the law ran afoul of the Commerce Clause. AAM charged the state was attempting to regulate interstate commerce, and when [the court agreed](#), the law was subsequently struck down. [Experts suggest](#) to avoid this pitfall and increase

Given the attention surrounding insulin, legislation to address its affordability continues to gain bipartisan attention. To protect consumers from rising prices, some states have implemented laws capping the copayment for insulin. As of summer 2021, [17 states](#) have some variation of a monthly copayment cap law. Though capping the copayment of medicines alleviates the cost a person pays at the pharmacy counter, copayment caps have little impact on initial list prices. Furthermore, consumers' costs are likely to increase further upstream in higher health plan premiums.

Minnesota's Alec Smith Insulin Affordability Act has a copayment cap and an additional requirement for manufacturers to pay into a patient assistance fund. The law was named for **Alec Smith** who died at age 26 after aging off his parents' health insurance plan and could no longer afford the cost of his insulin. As of publication, this law is being challenged in federal court.

Did you know?

Filed in July 2020, *Pharmaceutical Research and Manufacturers of America (PhRMA) v. Williams, et al.*, the trade group PhRMA asked the court to declare the Minnesota law unconstitutional, arguing it violates the Takings Clause by requiring drugmakers to provide insulin at a reduced price. The case, which Minnesota Attorney General Keith Ellison is **defending**, was heard December 2020 in federal court and, at the time of publication, a decision has not yet been handed down.

[illegible]



Recommendation Two: Streamline procurement processes and create new purchasing models.

A diverse range of mechanisms to control spending have emerged, which include streamlining current procurement efforts and creating novel ways to pay for drugs. However, any cost savings measure a state adopts applies only to state regulated plans such as Medicaid, state employee health plans and fully insured health plans.

States already receive federal statutorily required rebates under the Medicaid Drug Rebate Program (MDRP) but states can achieve additional savings by negotiating optional [supplemental rebate agreements \(SRA\)](#) with manufacturers. States can enter into these agreements with approval from CMS under a [state plan amendment \(SPA\)](#). A state plan is the agreement each state has with the federal government outlining program specifics such as services and populations covered, reimbursement methodologies for providers and other administrative actions.

Leveraging the federal [340B Drug Pricing Program \(340B\)](#) is another way states might find additional savings. Created in 1992, 340B stretches limited federal resources by providing reduced price outpatient prescription drugs to over [42,000 eligible health care facilities](#), called “covered entities,” certified by the Health Resources and Services Administration (HRSA). The U.S. Government Accountability Office (GAO) [estimates](#) covered entities can achieve 20-50% savings off list prices. Covered entities—including disease-specific advocacy organizations, certain categories of hospitals and federally qualified health centers (FQHCs)—may use the savings generated by 340B discounts to increase prescription drug access to rural communities and underserved populations. These entities serve more than 10 million people in all 50 states, the commonwealths and territories.

Did you know?

States do not regulate self-insured health plans as those are guided by the federal [Employee Retirement Income and Security Act \(ERISA\)](#). Plans of this type typically cover large employers of 500 or more who choose to take on the financial health risk of their employees. Even though states lack statutory authority over these plans, alternative payment models could be applied to self-insured contracts should those companies choose to adopt them.

Instead of patients receiving their prescriptions through Medicaid or a state employee health plan, patients treated by a 340B covered entity could utilize participating pharmacies, which may lower the reimbursement cost for that particular payer. States could also reduce their spending by leveraging 340B pricing in their state correctional health programs. According to a 2019 [National Governors Association \(NGA\) report](#), at least 16 states have contracts with covered entities to care for and administer certain specialty medicines to people who are incarcerated.

An important note is that when the MDRP and 340B were created, critics voiced concerns that because certain Medicaid patients could also be eligible for 340B drugs, discounts for those drugs could be unintentionally duplicated. Thus, a key federal regulation stipulates that duplicate discounts are prohibited under 340B.

Adding another layer of complexity, covered entities may contract with non-affiliated pharmacies, known as contract pharmacies, to dispense drugs to patients on their behalf. Contract pharmacies increased 4000% between 2010-2020, which [340B providers](#) say are vital to providing prescription drug access to their patients. [Opponents](#) contend contract pharmacies lie outside the original scope of 340B, and are being misused by large hospital and pharmacy systems to generate revenue.

As states consider how to optimize savings in their Medicaid and 340B programs, they might also think about how some of the same policy options might be applied to other state regulated plans. As with other areas of the supply chain, the prescription drug procurement process offers a wide range of policy options for legislators and only three—purchasing pools, prescription drug importation and alternative payment models—are highlighted in this report.

Medicaid Drug Rebate Program

Created by the Omnibus Budget Reconciliation Act of 1990, the [Medicaid Drug Rebate Program \(MDRP\)](#) established mandated rebates. Rebates vary by drug and are based on several factors, including [average manufacturer price \(AMP\)](#), or [list price](#), how fast AMPs rise relative to inflation and Medicaid Best Price.

[Medicaid Best Price](#) is an agreement that directs Medicaid programs to receive the lowest, or “best” price that a manufacturer offers most other purchasers, except certain other government programs—the Veterans Health Administration, for example.

For brand name drugs, the rebate amount is a percentage of the AMP (typically 23.1%) or the difference between AMP and the “best price,” whichever is greater. This is in addition to a rebate paid if AMPs rise faster than inflation over time.

Generic drugs have a statutory rebate amount of 13% of AMP with no “best price” requirement and an additional rebate if prices grow faster than inflation.

CMS [estimates](#) that 600 manufacturers currently have national rebate agreements with the federal government and, although voluntary, all 50 states and the District of Columbia participate in the MDRP.



OPTIONS AND STRATEGIES

Procure pharmaceuticals through purchasing pools.

“There is nothing that precludes states from purchasing in a different way than they do right now – from creating a multi-state compact or coalition that states could leverage, including utilization of a reference rate approach.” Senator Louis DiPalma (D-R.I.)

Forming a bulk purchasing pool might capture additional state savings. By leveraging the purchasing power across states or agencies, the goal is for all parties in the pool to receive lower prices. Currently, five operational multi-state bulk purchasing pools negotiate supplemental rebate agreements on behalf of the states with whom they contract.

Three purchasing pools are Medicaid-focused: the National Medicaid Pooling Initiative (NMPI), the Top Dollar Program (TOP\$) and the Sovereign States Drug Consortium (SSDC). These pools generate savings through a [preferred drug list or PDL](#). A PDL is a pre-approved list of outpatient medicines a payer authorizes based on its cost effectiveness and, generally, how medically appropriate it is compared to other drugs. Drugs not included on the PDL may require prior authorization or a higher copayment.

According to program administrators, states using these strategies typically save between 3-5%, but amounts vary based on several factors including whether the state negotiates as a single purchaser, with a partner state or by entering into a multi-state agreement.

STATE EXAMPLES

The three purchasing pools focused on state Medicaid programs are:

[The National Medicaid Pooling Initiative \(NMPI\)](#)

- Operational since 2003. At present, 10 states—Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island and South Carolina—plus the District of Columbia participate. NMPI covers 3.8 million people and has supplemental rebate agreements with more than 90 pharmaceutical manufacturers.

[The Top Dollar Program \(TOP\\$\)](#)

- Starting with two member states in 2005, there are now six participating states: Connecticut, Idaho, Louisiana, Maryland, Nebraska and Wisconsin.

[The Sovereign States Drug Consortium \(SSDC\)](#)

- Founded as a non-profit structure in 2005, 13 states take part in the SSDC: Delaware, Iowa, Maine, Mississippi, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Utah, Vermont, West Virginia and Wyoming. Collectively, the consortium covers 5 million people.

In addition, two more pooling initiatives either apply to other non-Medicaid state and local government agencies or are open to citizens who live in certain states: the Northwest Prescription Drug Consortium (NPDC) and the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP).

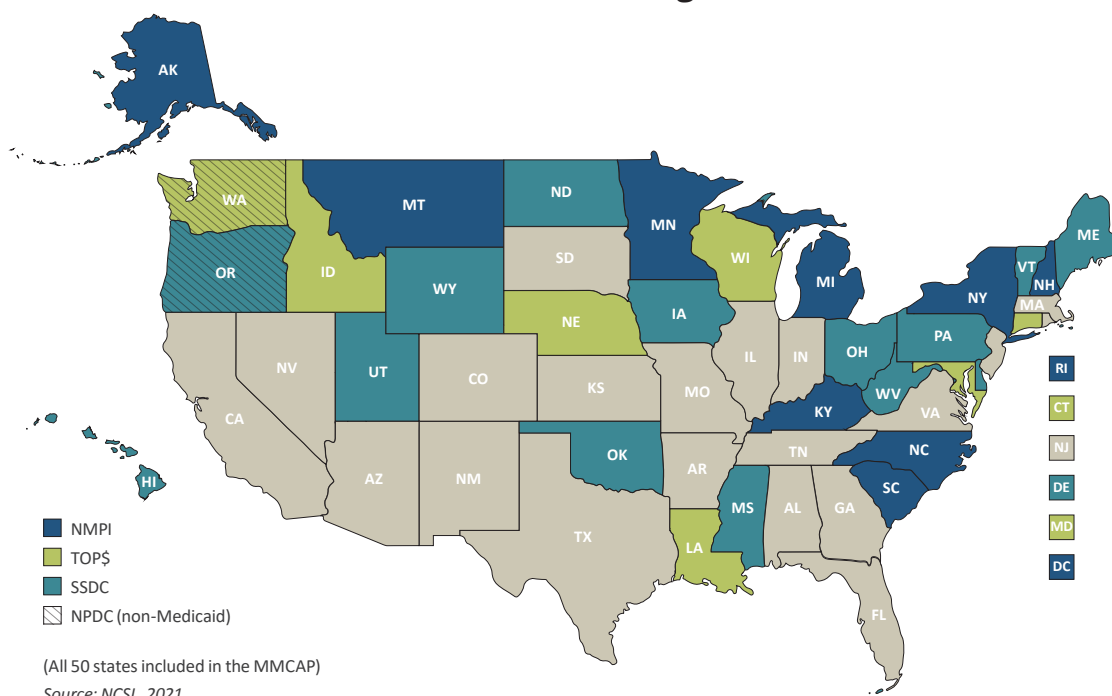
The Northwest Prescription Drug Consortium (NPDC)

- The NPDC is an interstate agreement between **Oregon** and **Washington** which provides a discount card program to residents in those states. Discounts are applied point-of-sale at participating locations. According to the consortium's website, the NPDC facilitates more than \$800 million in annual drug purchases for over 1 million people in participating groups and facilities.

The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)

- Founded in the mid-1990s, MMCAP combines the buying power of state agencies (such as public health departments), counties, cities and school districts in all 50 states.

Pharmaceutical Multi-State Bulk Purchasing 2021 Pools



Instead of pooling resources with other states, some lawmakers are consolidating the purchasing clout within their own borders. Created in 2019, [New Mexico's Interagency Pharmaceutical Purchasing Council](#) is tasked with finding ways to leverage the collective purchasing power of the state's agencies and report their findings annually to the legislature. Legislators use the information to inform fiscal policy in the state.

California embarked on a similar path in 2019 and state agencies—including Medi-Cal, the state Medicaid agency covering [12 million people](#)—were directed, [by executive order](#), to implement a combined drug procurement strategy. Implementation is in initial stages and, [according to the California Legislative Analyst office](#), the potential savings generated could be hundreds of millions of dollars.

Purchasing through alternative payment models (APMs).

Alternative payment models—which often tie payment to the quality of care—are another potential cost-savings measure of mounting lawmaker interest. Federal rules in the MDRP require state Medicaid programs to cover all federal Food and Drug Administration (FDA) approved drugs produced by participating manufacturers, which means states may face even greater affordability challenges.

States might pursue a variety of APMs including:

- **Subscription-based:** A contracted, fixed amount paid to a manufacturer in exchange for unlimited access to a treatment.
- **Outcomes-based:** Payment is tied to key metrics or performance outcomes.
- **Evidence-based:** Existing evidence of effectiveness for a particular treatment is assessed to estimate potential value.

While APM strategies are growing in state Medicaid plans, they may run contrary to the federal [Anti-Kickback Statute](#), which prohibits anyone from receiving compensation in exchange for inducing business from a federal health program. Moreover, Medicaid Best Price could mean that any price concession offered by a manufacturer under an APM might set the benchmark for all Medicaid programs. Providing some clarity, a recent final rule from [CMS](#) allows manufacturers who enter into APMs with state Medicaid programs to report multiple best prices for a particular drug, as long as they offer the same APM to all states.

STATE EXAMPLES

In an effort to eliminate hepatitis C in the state Medicaid and incarcerated populations, [Louisiana](#) was the first state to adopt a subscription-based model to manage the state spend on hepatitis C drugs. Hepatitis C virus (HCV) is a liver disease that can have serious health complications such as liver cancer and cirrhosis, or scarring, of the liver. If left untreated, HCV can lead to liver failure and death. HCV is curable, but available anti-viral products can cost tens of thousands of dollars for a full course of treatment. In addition, researchers who [followed](#) inmates infected with HCV determined that the disease, if unchecked, can result in costly hospitalizations – approximately \$155,000 per person, per year in additional costs to the state.

In the contract, one manufacturer will provide Louisiana unlimited access to its HCV treatment for no more than \$35 million a year (Louisiana’s previous average annual cost for HCV anti-viral) until 2024. As of summer 2021, the [Louisiana Department of Health](#) reports more than 7,500 of the 31,000 people identified with HCV have been treated since the program began in July 2019. Plans to eliminate HCV in [Washington](#) by 2030 using a similar model are also underway. According to Hep C Free Washington, preventing new infections and providing treatment to people living with HCV will [reduce state expenditures in the long term because of the decrease in overall health care costs](#).

Using outcomes-based agreements, [Oklahoma](#) pegged payment to metrics such as hospitalizations and patient adherence. For example, in one contract the state receives a higher rebate if patients adhering to their regimen are hospitalized. In return, the state will not require prior authorization for patients to receive that specific treatment. [Colorado](#), [Massachusetts](#) and [Michigan](#) have also gained approval from CMS to enter into outcomes-based APMs with manufacturers, but as of publication no other state contracts have been announced.

Did You Know?

Scientific advances in gene or cell therapies are bringing new hope to patients who previously had limited treatment options.

For instance, researchers who evaluated children diagnosed with spinal muscular atrophy (SMA) found those who received a type of gene therapy showed remarkable results after two years. None of the children required mechanical ventilation to assist with breathing when, in comparison, only 8% of patients left untreated survived to the same age without permanent ventilation.

With costs of these treatments reaching into the millions, purchasers are considering different ways to pay for these treatments. Reinsurance, high-risk pools and mortgage-based payments—similar to an amortized loan—are just a few of the models being explored.

Leverage savings and prevent duplicate discounts under the federal 340B program.

Under 340B, manufacturers sell products to covered entities at steeper discounts (20-50% according to the GAO) than what is offered through Medicaid Best Price. As noted, federal law prohibits state Medicaid programs from receiving manufacturer rebates for drugs already discounted under the 340B Program. A [50-state Kaiser Family Foundation survey of Medicaid pharmacy directors](#) revealed that avoiding duplicate discounts has been costly as well as administratively burdensome for some states, leading certain lawmakers to pursue a variety of ways to ease this obligation.

Both manufacturers and covered entities are subject to audits from HRSA to ensure program compliance, but states are ultimately responsible for making sure 340B drugs are excluded from Medicaid rebates billed to manufacturers. States using a fee-for-service payment model in their Medicaid program must choose and identify which drugs will be carved-in to the program or carved-out and covered under 340B. To help states accomplish this, HRSA established the [Medicaid Exclusion File](#) that requires covered entities to report which products will be included under 340B. Managed care plans who administer a state Medicaid program must also have an exclusion process for 340B drugs in place before a contract is finalized.

[Best practices released in 2019 from CMS](#) outline seven strategies states might use to avoid duplicating discounts, including limiting the ability of contract pharmacies to dispense 340B drugs. [340B Health, an organization representing 1,400 covered entities, raised concerns](#) that restricting the use of contract pharmacies may decrease access to medication and care for the most vulnerable patients. As mentioned previously, opponents point to the significant increase in contract pharmacies as expanding the intended scope (or use) of 340B.

STATE EXAMPLES

States have pursued a variety of activities to manage duplicative discounts. In addition to the strategies listed in the table, several states—including **Massachusetts, Minnesota, Montana, Oregon, Rhode Island, South Dakota, Utah** and **West Virginia**—prohibit covered entities, or a contract pharmacy acting on their behalf, from receiving a lower reimbursement than Medicaid for drugs provided under 340B. [Montana's](#) law goes a step further by setting a reimbursement floor based on a calculation using [national average drug acquisition costs or NADAC](#)—the national average at which retail pharmacies purchase prescription drugs from manufacturers or wholesalers.

Legislators may want to convene key stakeholders, including state Medicaid pharmacy directors, to determine which 340B strategies are already in place, and ascertain where modifications can be made that are appropriate for their state.

340B Management Strategies	Number of States
Use of the Medicaid Exclusion File (MEF)	38
Prohibition on contract pharmacies in FFS	36
Use of NCPDP fields* to identify 340B claims	31
Prohibition on contract pharmacies in managed care	18
340B entities not allowed to carve into managed care	5
Use of medical claims modifiers to identify 340B claims	7
340B entities not allowed to carve into FFS	2

Notes: *NCPDP fields allow pharmacies to indicate on a claim that a drug was purchased through the 340B program.

Source: 2019 KFF and Health Management Associates (HMA) survey of Medicaid officials in 50 states and DC, April 2020, and NCPDP Reference Guide

Pursue importation agreements with other countries.

[Analysis](#) from researchers at the RAND Corporation report that medicines in many other economically developed countries are less costly than in the U.S. This is due, in large part, to price controls used by other nation's governments. As such, many state lawmakers are interested in the safe [importation](#) of medicines from other countries, particularly Canada.

Before a pharmaceutical can be sold in the U.S., it must go through a rigorous approval process by the FDA prior to its distribution. Current federal law bars states from pursuing importation arrangements unless a drug's safety and efficacy can be certified by the FDA.

A landmark FDA final [rule](#) issued in September 2020 permits states, wholesalers and pharmacists seeking to import pharmaceuticals from Canadian sources to submit proposals to the federal government outlining how their plan would generate savings while not posing any additional threat to patient safety. Litigation filed in federal court after the rule's release argues the rule not only runs contrary to federal law, but evidence to support that imported products can be safely guaranteed or effective at reducing costs is lacking.

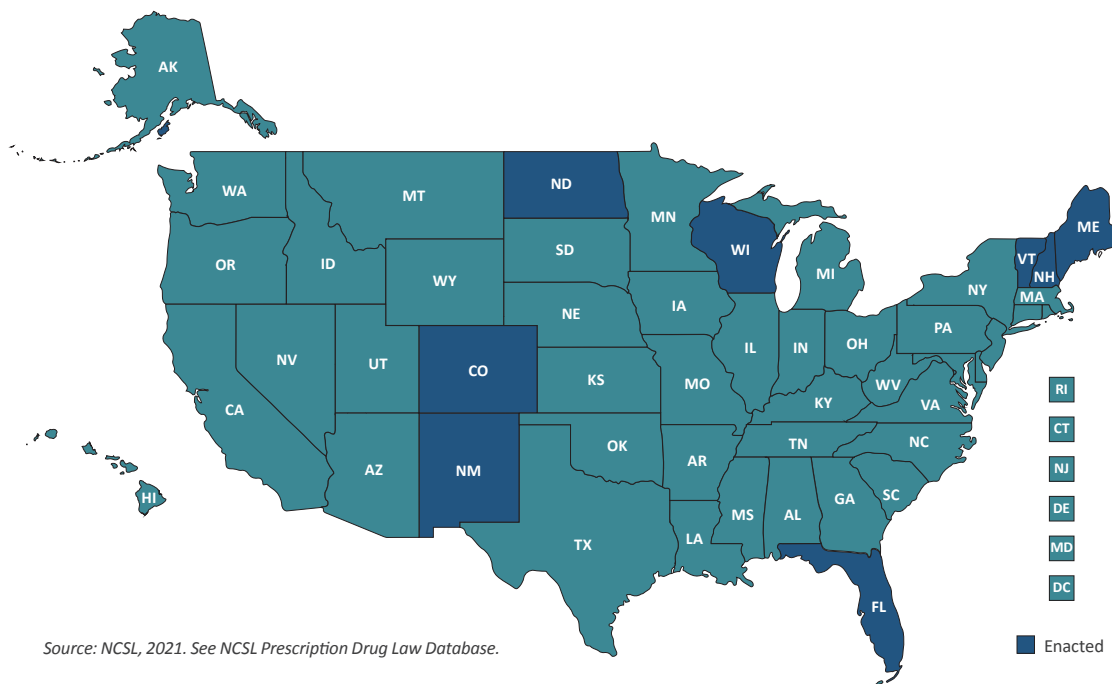
One primary concern to importation strategies is that the drug supply chain could be compromised with counterfeit or substandard products. Even with support from the U.S. government, the prescription drug market in Canada is considerably smaller than in the U.S., so finding a Canadian partner could prove challenging. Critics also suggest that because some high-cost drugs such as biologics and specialty drugs do not qualify for importation, the impact of these policies may be limited.

STATE EXAMPLES

As of summer 2021, eight states—**Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Vermont** and **Wisconsin**—have laws to allow a process for prescription drug importation. Some state policies limit the importation of drugs to those purchased from Canada, but laws in [Florida](#) and [Colorado](#) provide a second pathway to purchase drugs from countries other than Canada.

Agencies in Florida and Colorado have pursued requests for proposals from wholesalers and suppliers, but as of summer 2021 no contractual agreements have been announced from either state.

Recent State Drug Importation Laws



Did You Know?

Interest in pharmacy tourism, a somewhat related policy, is now an alternative for one state's employee health plan. **Utah's** "[Health Insurance Right to Shop](#)" law enacted in 2018 allows state employees who use certain high-cost, specialty medications to participate in a pharmacy tourism program. The [Public Employee Health Plan](#) has contracted locations in Mexico and Canada where members receive roundtrip airfare, transportation to and from the clinic or pharmacy in the desired country, and \$500 cash back for taking part. Program administrators [report](#) saving \$225,000 in the first year alone.

Recommendation Three: Encourage or introduce competition into the supply chain.

In an economic sense, more competition in a product’s supply chain puts pressure on suppliers to lower prices. The same principle is often considered by legislators regarding prescription drug policy. Many policy solutions influencing competition require action at the federal level; however, state-level actions still exist.

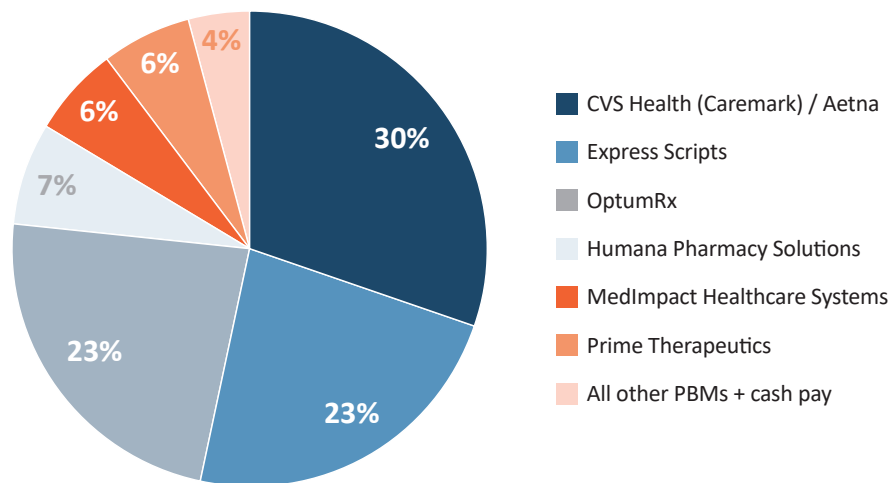
Generic medicines account for approximately 90% of all prescriptions and comprise 22% of total drug spending, [according](#) to the trade group Association for Accessible Medicines (AAM). In 2018, annual savings generated by generic drugs totaled \$293 billion. Fostering generic drug creation and increasing the number of generic drugs available in the market might increase competition and aid in lowering prices—but patent laws and processes complicate these efforts.

New, innovative drugs are protected by an exclusivity period, [usually a decade or more](#), which prohibits other companies from selling generic versions of the same drug during that time. Manufacturers can [extend their patents](#) by changing aspects of the drug such as the drug’s formulation or method of delivery. The [1984 Hatch-Waxman Act](#), meant to encourage generic drug development, established a framework to make it easier for generic manufacturers to challenge these patents in court—but some [experts say that process can also take years](#) to resolve.

Similarly, recent vertical “megamergers” between PBMs, health plans and distributors, as well as both retail and specialty pharmacies, are also raising questions about whether these deals bolster or undermine competition. Those in favor of these unions argue that by vertically integrating and controlling all or some aspects of the supply chain, a firm can ramp up production while simultaneously reducing costs. Opponents contend vertical acquisitions and mergers have the [opposite effect](#).

Another part of the supply chain where competition can be encouraged is among administrators of pharmacy benefits. Pharmacy benefit managers (PBMs) play a significant role in the supply chain with only a handful of companies largely influencing the PBM market, as shown in the pie chart.

PBMs have played a role in the supply chain since the 1970s. According to the industry’s trade group [Pharmaceutical Care Management Association](#), PBMs administer the prescription drug benefit for the health plans of 266 million people covered under commercial health plans, self-insured employer plans, state employee health plans, Medicaid managed care plans and many others. PBMs fulfill a wide variety of administrative functions such as formulary management, claims processing and drug utilization review processes.



*Note: Values do not total to 100% due to rounding
Source: Drug Channels Institute, 2018*

OPTIONS AND STRATEGIES

Increase state oversight of market competition

Brand name drugs are protected by patents with substantial time periods and manufacturers can use a [variety of methods](#) to extend them. Even though the Hatch-Waxman Act outlines an easier pathway to challenge drug patents in court, brand and generic pharmaceutical companies might settle litigation out of court with financial agreements. These payments, sometimes called “pay-for-delay” deals, compensate generic manufacturers to postpone product entry into the market. In 2013, [the Supreme Court found](#) these deals, in many circumstances, to be illegal—but some arrangements still occur. The [Federal Trade Commission \(FTC\)](#) [has called these deals anticompetitive](#) and estimates these contracts cost consumers and taxpayers \$3.5 billion in higher drug costs every year.

Another growing concern to state lawmakers is the consolidation of markets within other health care sectors. After a preliminary incorporation deal is struck between two organizations, the Department of Justice (DOJ), the FTC or both will investigate the transaction. State attorneys general are also important players and may pursue action as well. [Guidelines](#) issued by DOJ and FTC in 2020 explain how evaluations of mergers and acquisitions are conducted and rationalizes that vertical mergers weaken competition. Despite the agencies highlighting numerous examples of how vertical mergers may prove anticompetitive, they stop short of prohibiting them.

STATE EXAMPLES

A first in the nation law, [California bans “pay-for-delay deals”](#) on the principle that they are anticompetitive and shifts the onus to manufacturers to prove they are not. AAM challenged the law in federal court arguing it was in violation of the Commerce Clause. [In July 2020, the ninth Circuit](#) disagreed and dismissed the case.

Relatedly, another [California law](#) enacted in 2020 allows the state to enter into partnerships with drugmakers to produce generic drugs and at least one form of insulin. A report assessing the feasibility of this action is due to the legislature in 2023. In 2021, [Washington state](#) became the second state to enact similar legislation.

Historically, states have approached antitrust issues with litigation rather than legislation. However, [research](#) suggests states may pass broader reforms to strengthen state oversight on these types of transactions such as imposing a waiting period and requiring notification to the state attorney general. Moreover, a state may consider charging filing fees to boost the state’s financial resources to conduct audits of mergers.

State laws have generally focused on mergers and acquisitions in other areas of the health care system, such as hospital and provider group consolidation, as well as [certificates of need](#). Although states are limited in their ability to review and regulate “megamergers,” lawmakers may adopt [policies](#) affecting smaller mergers exempt from federal review, such as requiring oversight of these deals by the state attorney general.

Did You Know?

In the case, [Pharmaceutical Care Management Association \(PCMA\) v. Rutledge](#), PCMA claimed since their members offer a type of employee benefit, their business practices are guided by the federal [Employee Retirement Income Security Act of 1974](#), or ERISA. As such, PCMA argued, [Arkansas Act. 900](#)—which requires PBMs to pay pharmacies for generic drugs at or above the pharmacy’s acquisition cost—is preempted by federal law and should be reversed. In December 2020, the Supreme Court disagreed with this interpretation and [clarified](#) that cost-control measures are a state matter and states may regulate health insurers’ third-party contractors. Since then some states, including North Dakota, have successfully petitioned the federal court to reconsider previous rulings striking down state law.

Reform pharmacy benefit management (PBM) practices.

All 50 states have at least one law that relates to PBMs, but a wide variety of policies have been implemented including:

- **Providing for state licensure or registration.** A starting point may be to know which companies are doing business in the state. This might be done by requiring PBMs or third-party pharmacy benefit administrators to obtain a license or register before they may conduct business. This function is often managed by the state department of insurance or board of pharmacy.
- **Requiring certain pricing and cost information be reported to the state.** As mentioned earlier, many states have transparency laws requiring information be reported from certain supply chain entities—including data from PBMs on rebates, payments and fees collected from drug manufacturers, insurers and pharmacies.
- **Using a PBM that offers a traditional, or pass-through, pricing model versus a spread pricing model.** In a spread pricing model, the PBM keeps a portion of the amount, or spread, between what the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary's prescription. With a pass-through contract, the PBM passes through the amount charged by the pharmacy to the health insurer. Since no spread is collected, PBMs typically charge an administrative fee.
- **Creating a process for a reverse auction to allow PBMs to compete for state prescription drug purchasing contracts.** Used with regularity in other public procurement contracts, a reverse auction is an online bidding process in which PBMs anonymously compete for the state's business through a portal managed by a third party. PBMs can view proposals from other firms and adjust their offers during several rounds of bidding.

Group member tip: Some states have audited contracts between state Medicaid managed care organizations and the PBMs that administer the prescription drug benefit and have found these audits to be an informative decision-making tool. If an audit has not been conducted in your state, request one be performed if and when feasible.



STATE EXAMPLES

Louisiana's 2019 law encompasses all the provisions outlined above, and also establishes a Pharmacy Benefit Manager Monitoring Advisory Council to make recommendations and assist with PBM regulation oversight. **Maine** authorizes insurers to oversee the business practices of any third-party administrators with whom they contract, which includes PBMs. Like Louisiana, more than a dozen states prohibit the use of spread pricing models in PBM and health plan contracts, including those in Medicaid managed care.

In 2018, an initial reform pursued by **West Virginia** removed—or carved-out—the pharmacy benefit from their managed care contracts and reported a **savings of \$54.4 million in the first year**. **In 2021 the state enacted several other provisions related to PBMs** including conditions for licensing and registration, prohibitions against patient steering and data reporting requirements.

The first to operationalize a reverse auction process, **New Jersey** awarded the combined contracts for the state and school employee health benefits programs to a single PBM in 2019. Over the three-year term of the contract the state projects a savings of more than \$1 billion, reporting a **cost decrease of 25%** in the first nine months alone.

Legislation enacted in 2020 allows agencies in **Maryland** to procure a PBM contract through a reverse auction process. The Maryland Prescription Drug Affordability Board will set the terms that all bidders must agree to before participating. The contract will cover the prescription drug benefits for **116,306 state employee and retirees**.

Group member tip: Even when legislation passes, keep in mind it can take a long time to write the regulations and fully implement the policy.

Conclusion

“Good legislation doesn’t seem to get anywhere unless the people are ringing the phones or lighting up the e-mailboxes. Just understand that no matter what you try to do in this area, there will be resistance from somebody.” *Senator Evan Vickers (R-Utah)*

The topic of health care often ignites people’s opinions and perspectives, but prescription drug policy is an issue where legislators have found some common ground. Beyond the handful highlighted in this report, lawmakers may consider a range of policy options that might be best suited to meet their state’s unique population.

Throughout this project, legislators shared their successes and challenges and exchanged myriad ideas. Group members expressed that for any policy lever to be successful, it needs support from chamber and committee leadership, as well as from key stakeholders such as industry, providers and executive-level state agencies. Most importantly, the group stressed, is the value of patient voices and grassroots efforts.

Legislators in this work group emphasized their constituents cannot afford to wait for federal action to address prescription drug access and affordability, and the wide array of strategies available to fellow policymakers should not be overstated. States have enormous power—as long as they are willing to reach across the aisle and learn from one another.

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