State Policy Options To Reduce Prescription Drug Spending

By Thomas Waldrop and Maura Calsyn   February 2020
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Introduction and summary

Prescription drug spending has been rising steadily across the United States since the late 1970s.\textsuperscript{1} Congress is considering multiple approaches at the federal level to reduce drug spending;\textsuperscript{2} but state policymakers can also act independently to address this issue in the interim.

States that wish to lower their prescription drug expenditures face a number of challenges. Federal law preempts the most sweeping, comprehensive state reforms that could lower prescription drug prices.\textsuperscript{3} Moreover, the complexity of the prescription drug supply chain and the myriad interactions that different state agencies have with different parts of the supply chain require a multifaceted approach. However, given the budgetary pressure that drug prices put on states, as well as the harm excessive prices have on residents’ health and finances, many states are considering various policy changes.

This report discusses policy options available to states and Washington, D.C. to lower their drug spending. First, it considers two options targeted at state Medicaid programs: negotiating supplemental rebates and enhancing drug utilization review. The report then discusses reforms that seek to improve a state’s negotiating power, including consolidating purchasing across state programs or with other states; establishing a common formulary across state programs; consolidating procurement of pharmacy benefit manager (PBM) services; negotiating rebates with PBMs; and implementing subscription-based purchasing. Finally, this report discusses reforms to lower the list prices of prescription drugs, including by establishing a prescription drug affordability review board; reference pricing drugs; maximizing participation in the 340B Drug Pricing Program; promoting the use of generics; reducing the cost of physician-administered drugs; and importing drugs from Canada.
Background on U.S. prescription drug spending

Drug spending has risen significantly in recent years. This is due not only to manufacturers setting prices of new drugs at extraordinarily high levels but also to manufacturers increasing the prices of existing drugs, some of which have been on the market for years. This section provides an overview of prescription drug spending trends, as well as background on PBMs—the entities that manage prescription drug insurance benefits for states, employers, and other health care payers.

Spending trends

While estimates vary, the Pew Charitable Trusts estimates that U.S. drug spending exceeds $450 billion annually. This increase in spending represents a significant challenge to state budgets: Data from the Centers for Medicare and Medicaid Services (CMS) show that from 2013 to 2017, average state and federal Medicaid spending on prescription drugs increased by more than 14.8 percent annually. Average Medicaid prescription drug spending as a percentage of state budgets has increased by more than 89 percent over the past 10 years, from 1.3 percent in 2008 to 4.5 percent in 2018.

Medicaid prescription drug spending

The vast majority of state prescription drug spending is done through the Medicaid program. State Medicaid prescription drug spending was nearly $61 billion in 2018, with spending per beneficiary ranging from a low of $185.08 per beneficiary in Wyoming to a high of $1,471.24 per beneficiary in Connecticut. More than 60 percent of this spending is done through managed care organizations (MCOs)—companies that contract with state Medicaid agencies to “[deliver] … Medicaid health benefits and additional services.” State spending on prescription drugs follows national trends; many Medicaid programs are seeing increases in spending due to more expensive specialty drugs, such as those for hepatitis C, diabetes, asthma, and mental health conditions.
While Medicaid coverage of prescription drugs is optional under federal law, every state and Washington, D.C., currently provides this coverage. When states include prescription drug coverage as part of their Medicaid programs, drug manufacturers and states must enter into a rebate agreement under the Medicaid Drug Rebate Program. The program requires states to cover all drugs of a manufacturer that enters into a rebate agreement with the U.S. secretary of health and human services. The goal of the rebate program is to ensure that Medicaid receives significant discounts for prescription drugs. As a result, Medicaid pays some of the lowest prices for drugs in the United States.

What rebates do Medicaid programs receive?
The base rebate amount depends on the type of drug. For most innovator, or brand-name, drugs, the required amount is the greater of the following two options: 23.1 percent of the average manufacturer price (AMP) per unit or the difference between the AMP and the drug’s “best price”—the lowest price per unit the manufacturer provides to most private purchasers—adjusted for inflation by the Consumer Price Index-Urban. For generic drugs, the base rebate is 13 percent of the AMP. In addition to these base rebates, manufacturers must pay an additional rebate if the prices of their drugs rise faster than the rate of general inflation.

Other state program spending
While Medicaid is the largest program for which states purchase prescription drugs, it is not the only program. In addition to Medicaid, states pay for prescription drugs for public employees, retirees, and incarcerated people. As with Medicaid drug spending, state prescription drug spending on other programs has been increasing in recent years. Increases in expenditures are driven by some of the same factors that drive Medicaid drug spending, including more spending on high-priced specialty drugs.

According to the most recent data, states spent $25.1 billion on public employee health coverage in 2013—an average of $805 per month per employee. Overall, prescription drug spending represented approximately 9 percent of total U.S. health spending in 2013. While this proportion has been and is projected to remain stable over the next decade, actual spending has not experienced the same steadiness. Since 2013, overall prescription drug spending has increased by more than 22 percent. State spending on public employee prescription drugs alone is $2.8 billion after inflation.
State spending on drugs for public retirees is similar to the amount spent on public employees. While private retiree health spending has largely shifted from employers to the federal government as a result of the Medicare program, public sector retiree health spending has remained high. Medicare covers much of the cost of retired employees’ health care, but many states provide supplemental coverage for the services that traditional Medicare does not cover, including prescription drugs. In 2013, states spent more than $18.4 billion on retiree health benefits. As with public employees, drug spending represents a considerable proportion of public retiree spending: 89 percent of older adults report taking at least one prescription drug, and more than half report taking four or more prescription drugs. Additionally, the Medicare program is structured in a way that incentivizes states to offer prescription drug benefits for retirees.

Prescription drug purchasing for incarcerated individuals can also be a significant driver of state spending. A 2017 Pew Charitable Trusts analysis of the health spending of 11 state departments of corrections found significant variation in spending. Most states spent between 15 and 23 percent of their corrections health budgets on prescription drugs, but there were two notable outliers: New York, which spent 32 percent of its health budget on drugs, and Texas, which spent only 7 percent on drugs. New York’s high level of spending was driven by hepatitis C drugs, while Texas’ spending was low due to its extensive use of the 340B Drug Pricing Program.

The role of PBMs

PBM contracts typically cover administration of the retail prescription drug benefit, and more than 266 million Americans are covered by health plans that use PBMs. These private entities not only process claims but also help create the plans’ drug benefit. They negotiate with drug companies to obtain discounts, rebates, or other price concessions. For example, the manufacturer may give rebates to encourage the use of certain drugs, such as an additional discount if the manufacturer’s drug is the most commonly prescribed drug from a class of similar medications.

Patients usually do not directly benefit from these discounts when they purchase the drug from the pharmacy; if their out-of-pocket costs are 20 percent of the price of the drug, they will pay 20 percent of the list price, not 20 percent of the price after rebates are counted. However, rebates may reduce health care premiums if they end up back with the insurer or employer and are used to lower health care premiums.
PBMs also set up pharmacy networks that channel patients to preferred pharmacies that have lower cost sharing for patients.32 Most PBMs have their own mail-order and specialty pharmacy businesses that provide lower-priced prescriptions to patients.33 They also review clinical data to evaluate new drugs, allowing them to make contracting and coverage decisions based on information such as formularies and lists of preferred drugs and to create incentives to encourage the use of generic drugs.34

PBMs regularly face a variety of criticisms about their business model, especially their lack of transparency around rebates from drug companies.35 For example, lawsuits have alleged that PBMs pocket rebates from manufacturers that should be passed along to plan sponsors.36 These lawsuits have yet to be resolved, although PBMs have characterized similar lawsuits as being “without merit.”37
Because Medicaid is the largest driver of state drug spending, this report first discusses policy options to lower prescription drug prices through the program. Given the unique federal-state joint financing of Medicaid and the requirements of the Medicaid statute and the Medicaid drug rebate agreement, there are several policy interventions that a state may wish to consider that are specific to the Medicaid program. The following section discusses two of these options: expanding supplemental rebates from pharmaceutical companies and enhancing drug utilization review.

### Negotiate supplemental rebate agreements

Because state Medicaid programs are required to cover most drugs on the market, they are more limited than other payers in how they can lower drug costs. One of the most common approaches is through the use of a preferred drug list (PDL) for Medicaid programs. Private payers often use tiered formularies, or groups of specific drugs, that are typically organized based on cost. While private payers are able to exclude drugs from their formularies outright, states are limited to tiering drugs within their PDL and imposing additional utilization management restrictions on higher-tiered drugs. Prior authorization of nonpreferred drugs—those that require approval from the state before doctors can prescribe and dispense the drug—is a common tool used to ensure that immediate use of the costlier drug is clinically appropriate. In addition, states commonly use step therapy, which requires prescribing a less costly drug or showing that the more expensive drug is medically necessary for the patient before "stepping up."

In addition to federal rebates, nearly every state has negotiated additional rebates for themselves. These supplemental rebate agreements (SRAs) can further inform state decisions about PDL placement and step therapy requirements. However, four states—Hawaii, New Jersey, New Mexico, and South Dakota—do not have any such agreement in place. This has had a serious fiscal effect: In 2018, SRAs and federal rebates combined to reduce prescription drug spending by more than 35 percent.
If these states decide to pursue SRAs, they should first require drug manufacturers to submit additional and more detailed pricing and clinical information. By requiring detailed information about discounts and rebates, states will have a better understanding of the prices charged for specific products. States can leverage favorable PDL placement to ensure that drug manufacturers provide this information and enter into SRAs. One important feature to include in an SRA is an inflation adjustor similar to that included in the federal rebate agreement. This will help to ensure that the rebates borne through an SRA continue to benefit the state as drug companies increase their prices.

Although it is more common for states to enter into SRAs for fee-for-service (FFS) Medicaid drug coverage, 18 states have negotiated supplemental rebates for MCOs, and Minnesota has negotiated additional rebates for hepatitis C drugs. Under an FFS system, services are paid for by the Medicaid program itself rather than through an MCO. As more than 60 percent of Medicaid drug spending is done through Medicaid MCOs, the SRAs represent a large opportunity for saving on prescription drugs.

States that contract out prescription drug benefits to MCOs have two primary methods by which they can reduce retail drug spending: establishing a single PDL for Medicaid MCOs or carving out the pharmacy benefit entirely into FFS. A later section of this report discusses in more detail the benefits of establishing common formularies, but the key concept is that establishing a single PDL across Medicaid creates uniformity throughout the Medicaid system, allowing for a stronger negotiating position for both the remainder of the FFS program and MCOs.

An alternative could be carving out prescription drug coverage from the MCOs entirely and contracting with a single PBM to administer this benefit. Both methods would result in the same outcome of uniformity and increased negotiating power, though carving out could be more efficient, as it would reduce administrative costs associated with splitting the benefit across multiple PBMs.

Supplemental rebates can also include a measure of value as the metric for an SRA. For example, New York requires drug manufacturers to enter into negotiations based on the value, efficacy, or outcome of a drug. This process was used to help achieve prescription drug savings totaling $55 million for fiscal year 2017–2018. Massachusetts imposed a similar requirement as part of its fiscal year 2020 state budget. Washington state has implemented value measures since 2004, focusing solely on a drug’s efficacy as a determinant of PDL placement. Oklahoma has entered into two narrowly tailored contracts promoting value-based purchasing of costly...
drugs—one for anti-psychotic medications and one for bacterial skin infection medications. Each of these examples highlights states’ ability to ensure that they are paying based on a drug’s value.

Enhance drug utilization review

In addition to negotiating supplemental rebates, states can use utilization management tools to help ensure that their Medicaid prescription drug spending is appropriate. Generally speaking, states must have both prospective and retrospective Medicaid drug utilization review (DUR) programs. In prospective review, a state’s Medicaid agency evaluates a proposed prescription prior to dispensing in order to ensure that the drug is not only the most appropriate for a patient but also cost-effective. Often, the responsibility for this review is passed onto the dispensing pharmacist: Arizona, for example, requires the pharmacist to review “patients’ allergies and incompatibilities with a patient’s currently-taken medications.” Retrospective review operates similarly—state Medicaid agencies review drug dispensing after the fact to ensure that prescriptions are medically appropriate and not indicative of fraud or abuse.

While states are required to perform DUR for their FFS drug benefit, this same requirement does not exist for physician-administered drugs or managed care drug benefits. DUR data represent an important opportunity to ensure that Medicaid is operating efficiently in terms of both health and financial outcomes.

By expanding and aligning DUR across the Medicaid program, states can help to ensure that these programs are operating as efficiently as possible. For example, while New Mexico contracts its DUR program to Comagine Health, this program is limited to FFS drug prescribing, which comprises less than 2 percent of the state’s drug spending. Under the Medicaid managed care program, each plan has its own DUR program. Expanding a state’s program to cover managed care and physician-administered drugs would have significant potential for savings.

In 2017, CMS surveyed state Medicaid agencies on their DUR practices and found that 22 states saved less than 10 percent of their overall drug spending through DUR, despite nationwide average savings of 20 percent. According to the same CMS survey, most states do not currently include physician-administered drugs in their DUR programs. Expanding DUR programs to these drugs could result in significant savings by ensuring that medically appropriate, cost-effective drugs are being used in physician-administered care settings as well as outpatient drug settings.
Additionally, many states do not require MCOs to submit detailed information on their DUR processes beyond what federal law requires, resulting in an inability to examine these processes for efficiency and compliance with other state laws. States have approached this requirement in a variety of ways: For example, California requires DUR information to be submitted on a monthly basis from MCOs and include financial information related to pharmacy claims, while Texas explicitly does not require reporting of financial outcomes. This information can also be used to help inform rebate agreements and dispensing patterns through PDL placement.
In addition to programs that solely affect states’ Medicaid programs, there are a variety of policy options that center on consolidating purchasing and negotiating power. Consolidating purchasing across the various agencies and programs that purchase prescription drugs, as well as with other states, would allow states to have a stronger negotiating position in order to extract more favorable prices from manufacturers and other entities in the prescription drug supply chain. Similarly, reforming how drugs are purchased can provide greater access to high-cost drugs than the current approach.

**Consolidate drug purchasing across programs and states**

Consolidating drug purchasing across state programs or multiple states increases states’ ability to negotiate greater discounts with drug manufacturers and potentially reduce administrative costs. Every state and Washington, D.C., currently participates in the Minnesota Multistate Contracting Alliance for Pharmacy, discussed below, so any additional consolidation would be an extension of this existing practice.

California is currently implementing a combined purchasing policy across state agencies. In 2019, in his first official action as governor, Gavin Newsom (D) ordered the consolidation of drug purchasing across all state-run programs—including the California Public Employees’ Retirement System (CalPERS), Medicaid, and the criminal justice system—through the development and use of a single formulary and preferred drug list. California’s Medicaid program, Medi-Cal, currently contracts with more than 20 managed care organizations, which in turn contract with 10 PBMs for pharmacy benefit management. The nonpartisan California Legislative Analyst’s Office has estimated that consolidating drug purchasing would likely save the state “hundreds of millions of dollars annually,” and the Newsom administration estimates that Medi-Cal alone will save the state $150 million per year. Los Angeles County recently announced that it will also join the purchasing program. Because California is in the early stages of evaluation and implementation, it has yet to share any best practices or lessons learned. The state is expected to complete the transition to consolidated purchasing by January 2021.
In addition to programs combining purchasing across agencies, many states also coordinate purchasing for their programs with one another. In 2003, the nation’s first multistate bulk buying pool—the National Medicaid Pooling Initiative—was established to purchase drugs for four states. Since then, the program has expanded to include Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island, and South Carolina, as well as the District of Columbia. In 2005, two other pools—the Top Dollar Program and the Sovereign States Drug Consortium (SSDC)—were established. Among the three pools, more than half of the country participates in drug purchasing pooling for Medicaid.

These programs largely operate through rebates negotiated in addition to SRAs as a result of participation in the programs. For example, Vermont reported an additional 4.7 percent in savings in its first year participating in the SSDC, and New York reported an additional $80.5 million in savings. By building on their collective leverage, states are better able to improve upon individually negotiated supplemental rebates to effect greater savings. States that do not currently participate in a multistate buying pool could also benefit from these savings.

Beyond programs solely focused on bulk purchasing drugs for Medicaid, some states have implemented bulk purchasing programs for other public and private payers. Oregon and Washington state each operate consolidated drug purchasing programs, both of which were initially designed to serve near-elderly, low-income populations. In 2006, the two states combined forces to form the Northwest Prescription Drug Consortium. The program is estimated to have saved more than $130 million in drug costs in 2017. The drug plan, administered by Moda Health in both states, is open to not only state and local government entities but also employer groups, labor organizations, and the uninsured.

Another example of non-Medicaid bulk purchasing is the Minnesota Multistate Contracting Alliance for Pharmacy. The organization was founded in 1985 to purchase prescription drugs for government facilities that provide health care services, such as correctional facilities, departments of health, and public schools and universities. Every state except for Massachusetts participates in the program. The program accrues significant savings for its members, even compared with other group purchasing collectives. An evaluation of the program found that its prices were between 2.8 and 4.4 percent lower than prices for the same drugs purchased by other group purchasing organizations, and its average prices paid were comparable to Medicaid’s best price.
Establish a common formulary using evidence of effectiveness

Establishing a single formulary and PDL is an important step to ensuring that consolidated purchasing is as effective as possible. In doing so, the state bolsters the increased leverage from consolidated purchasing by streamlining its pharmaceutical pipeline. For example, Washington state maintains a combined PDL for its Medicaid, public employee, and worker compensation programs—a useful example of how a state can consolidate across multiple programs to lower drug costs.80

In addition to participating in the Northwest Prescription Drug Consortium, Washington employs an evidence-based drug review process to determine the quality and effectiveness of drugs before their placement on the PDL. Under the program, the Pharmacy and Therapeutics (P&T) Committee reviews evidence of each drug’s clinical effectiveness and safety, including through evidence-based reports compiled by Oregon Health & Science University’s Drug Effectiveness and Review Project.81

Based on the P&T Committee’s recommendations, as well as rebate offers from pharmaceutical manufacturers, Washington conducts an actuarial cost analysis to determine which drugs should be included on the PDL. In addition to ensuring that the drugs on the PDL are therapeutically equivalent or superior to other drugs in the same class, the process ensures that the drugs are purchased at the lowest possible cost to the state. The program has produced savings of approximately $20 million per year for the state.82

Michigan is also among the states that have established a common PDL for their Medicaid program. In 2015, the state implemented a law requiring the development and use of a common PDL for Medicaid beneficiaries, which all MCOs must use as the baseline for their own formulary.83 While MCOs are permitted to offer a more generous PDL, they cannot use a more restrictive one.84 Establishing a single formulary as part of the consolidation of drug purchasing across the state can help ensure that people are choosing the least expensive drug when multiple medically appropriate options are available.85
Considerations for consolidated purchasing and a common formulary design

The following are key issues to consider when designing and implementing consolidated purchasing and a common formulary:

1. Identifying areas for savings
   • Which drugs or conditions are the main drivers for spending?
   • What information is available about negotiated rates with other payers?

2. Defining the scope
   • Will the common purchasing and formulary apply to retail pharmacy drugs, medical spending, or both?
   • Which drugs or classes of drugs should be included?
   • Will the changes affect vulnerable populations’ access to medications?

Consolidate procurement of PBMs and other plan management services

PBMs are a type of third-party administrator (TPA) that payers—both public, such as Medicaid and public employee benefit programs, and commercial—use to manage their pharmacy benefit. PBMs develop formularies, manage drug utilization review, and contract with pharmacies.86

By consolidating the procurement of PBMs and other plan management services such as utilization review across state programs, states can increase their bargaining power and reduce administrative costs. Currently, state PBM services are often split across multiple PBM contracts. For example, New Mexico’s Medicaid PBM services are split across three different PBMs—due to the fact that each MCO administering part of the program uses a different PBM—and California’s Medicaid PBM services are split across 10 MCOs.87 These splits reduce states’ ability to negotiate effectively with PBMs and can result in inconsistent care. Requiring all MCOs to use the same PBM would allow for greater negotiating power and reduce inconsistencies in prescription drug coverage throughout the state.

A notable example of states pursuing the consolidation of PBM services is New Jersey’s use of “reverse auctioning” for its state employee and retiree plans. In 2017, state legislators passed a bill to reform drug purchasing for the state’s public employee programs aimed at addressing rising drug spending and “rooting out PBM
profiteering” in public programs. Beginning in 2018, New Jersey used a reverse auctioning system to select a PBM, under which PBMs bid against each other to charge less than their competitors for the same level of services. The new bidding method is expected to save at least $1.6 billion over the course of the three-year contract period. The reverse auction process includes price comparisons and real-time auditing, establishing apples-to-apples comparisons of what each PBM should be spending on drugs. A New Jersey task force on improving the quality and value of state health care benefits also recommended including value measures in TPA contracts, a reform that would be most feasible from a consolidated perspective.

After consolidating PBM purchasing, states could implement a similar system for choosing the PBM with which to contract. This increased bargaining power would enable greater negotiations for PBM service pricing and make auditing the selected PBM for compliance with state laws easier.

Considerations for modifying procurement processes for PBMs and other plan management services

The following are key issues to consider when designing and implementing a new procurement policy for PBMs and other plan management services:

1. Determining contracting issues
   • When do the current contracts expire?
   • How do union agreements treat changes to employee benefits?

2. Identifying services to consolidate
   • Which plan management services are the primary drivers of spending?
   • To what extent are plan management services operated by overlapping entities?

3. Determining legal issues
   • How does the state’s existing procurement law interact with a potential reform?
   • What provisions need to be included in the request for proposals to avoid issues of potential invalidation?

Regulate rebates with PBMs

Beyond rebates negotiated with pharmaceutical manufacturers, states can also effect savings by regulating how rebates with PBMs are treated. While regulation of PBMs is not uncommon, only three states—Arkansas, Louisiana, and New York—have imposed regulations on PBMs that go beyond sharing information regard-
As enacted, each of these state’s bills prohibits spread pricing, which occurs when a PBM reimburses a pharmacy for less than the amount charged to the health plan and retains the difference. In other words, these states prohibit PBMs from marking up the price of prescription drugs charged to all plans.

Montana passed a similar bill in its Legislature, but Gov. Steve Bullock (D) vetoed the bill in May 2019, citing concerns that it would burden regional and nonprofit health insurers. The Legislature failed to override this veto in June.

Spread pricing can have significant fiscal effects on state Medicaid budgets. An analysis by the Massachusetts Health Policy Commission on the state’s Medicaid program found that nearly 25 percent of prescriptions had spread pricing of more than $10, and nearly 10 percent of prescriptions had spread pricing of $50 or more.

Prohibiting or limiting spread pricing can be combined with other PBM regulations, such as New Jersey’s reverse auctioning method. Consolidating a state’s PBM contracts could increase its negotiating power, allowing it to leverage greater rebates and discounts. By negotiating with PBMs to ensure that spread pricing is minimized or by including limitations in contract renewals, states can lead in the adoption of this policy.

**Pursue a subscription-based purchasing model**

In addition to the aforementioned reforms, states can reduce their prescription drug spending—particularly on high-cost drugs—through subscription-based purchasing. This purchasing model is especially useful for high-cost drugs, such as those used to cure hepatitis C. Subscription-based purchasing operates similarly to other subscription services: The state pays a negotiated fee to the drug manufacturer, which then provides the state with an unlimited supply of a particular drug.

Louisiana is the first state to use such a model. In 2019, the state negotiated a five-year contract—under which it pays around $60 million per year—for unlimited access to hepatitis C drugs from Asegua Therapeutics, the subsidiary of Gilead Sciences that produces the cure. The program is expected to treat around 10,000 patients between July 2019 and December 2020—more than twice as many as the 3,846 treated during the five years prior to the program.

Washington state has also entered into a subscription-based purchasing model for hepatitis C drugs. The state entered into a four-year contract with AbbVie and is expected to spend around the same amount of money per year—$80.4 million—
as it had before while treating nearly twice as many patients.\textsuperscript{100} The program is expected to reduce the cost of treatment by more than 70 percent per patient.\textsuperscript{101}

States should explore entering into similar arrangements for hepatitis C treatments as well as other high-cost prescription drugs. For example, drugs for preexposure prophylaxis (PrEP), the preventive treatment for HIV, can have a list price of around $1,800 for a 30-day supply.\textsuperscript{102} In 2017, Massachusetts’ Medicaid program spent around $22 million on PrEP drugs, and California spent around $50 million.\textsuperscript{103} If these levels of spending were maintained under a subscription program similar to that of Louisiana or Washington for hepatitis C drugs, the states would be able to provide access to PrEP drugs for potentially thousands more people at risk for HIV infection. Implementing such a policy would prevent many new infections and save states significant amounts of money that would otherwise be spent treating new HIV cases. Similarly, curing, rather than treating, hepatitis C patients is a much more cost-effective approach to addressing the disease.
Policy options to lower the unit prices of prescription drugs

In addition to the reforms discussed above that focus on increasing states’ negotiating power, there are a number of reforms designed to directly lower the unit price of prescription drugs: establishing a prescription drug affordability board, reference pricing drugs, and maximizing state facilities’ 340B participation. These policies are discussed below, as well as options to promote the use of generic drugs, lower the cost of physician-administered drugs, and import lower-priced drugs from Canada. All of these reforms function outside of the Medicaid program and seek to reduce prescription drug costs more directly.

Establish a prescription drug affordability board

The National Academy for State Health Policy (NASHP) has written model legislation establishing a prescription drug affordability board, calling it similar to “states’ regulation of consumer payment rates for essential services, such as clean drinking water, safe and consistent electricity, and public transportation.”¹⁰⁴ It describes the board’s duties as “[looking] at valuable drugs and [determining] at what cost they are affordable – at what cost will everyone who needs the drug be able to afford the drug.”¹⁰⁵

Maryland will be the first state to put this type of board into place. In April 2019, the Maryland General Assembly passed a bill based on NASHP’s model legislation, and it became law on May 25, 2019, without the signature of Gov. Larry Hogan (R).¹⁰⁶ The bill will be implemented over the next several years, starting with the establishment of the board and the publication of its first report. In its study of the state’s pharmaceutical distribution and payment system, the board is required to examine several approaches to reducing drug prices, including the possibility of setting upper limits.¹⁰⁷

The board is limited to regulating only drugs that the public sector pays for—whether through Medicaid FFS, Medicaid MCOs, or other state and local government programs. For this reason, it is unable to truly establish payment rates for these drugs as the NASHP legislation proposes. Because of this limitation, Maryland’s
board is more comparable to the “maximum allowable cost” approach that several payers and PBMs use, rather than actual rate setting. Under this approach, payers or their PBMs determine the upper limit of what a health plan will pay for a given drug. Maryland’s approach essentially delegates the determination of such a list to this board and, notably, does not impose these limits on all payers in the state, such as commercial health plans. Additionally, the board is required to submit a plan to make these prescription drugs more affordable—potentially by imposing an upper limit—to the state’s Legislative Policy Committee for approval before such a plan can be implemented. The board is also required to study the effect that an upper limit would have on prescription drug availability.

The effect of a prescription drug affordability board will not be as large if it is restricted to regulating only state-purchased drugs. Maryland’s approach has acknowledged this, with the legislative text requiring the board to submit a plan to make prescription drugs more affordable for nonstate payers by January 1, 2024. Including similar language in their legislation and including a tight timeline will allow other states taking this approach to ensure the efficacy of these boards.

Considerations for establishing a prescription drug affordability board

The following are key issues to consider when designing and implementing a prescription drug affordability board:

1. Designing the scope
   • Which drugs will be subject to review by the board?
   • Which payers will have access to the prices?
   • What information and data will the board consider when setting limits?

2. Determining the timeline
   • Will there be a review process for board recommendations?
   • Over what time period would any recommendations be implemented?

Use reference pricing

Reference pricing can be a viable approach for lowering spending for certain prescription drugs. Reference pricing for prescription drugs establishes a single price across a class of drugs—groups of drugs with similar characteristics. Therapeutic classes, for example, sort drugs based on the condition or disease they are meant to
Drugs can also be assigned to classes based on their mechanism of action, the biochemical reaction that happens after a person takes a drug; their mode of action, which is the body’s reaction to a drug; or the drug’s chemical structure. Drug reference pricing sets the price at some point within a class of drugs—potentially the minimum, median, or another percentile—and requires enrollees to pay the difference between the reference price and the charged price for a drug within that class. It is usually applied to drug classes that have price variation within the same formulary tier and have low generic utilization.

Reference pricing for prescription drugs is meant to encourage patients to choose lower-cost drugs and encourage drug manufacturers to charge less. Prescription drugs that are best suited for reference pricing are those that are interchangeable within a class that has no therapeutically superior drug. It is also critical that reference pricing approaches consider patient safety in order to ensure that switching drugs will not cause adverse effects.

Due to these challenges, drug reference pricing has been relatively limited in the United States. In California, CalPERS plans to implement a reference pricing pilot program starting in 2020 that will apply to limited classes of prescription drugs: inhaled corticosteroids, thyroid agents, and oral estrogen. When determining which drugs would be good candidates, CalPERS and its pharmacy vendor, the University of Massachusetts Medical School of Clinical Pharmacy Services, focused considerable attention on patient safety and the needs of the population taking the drug. These factors led to CalPERS choosing a small number of drug classes due to concerns about interchangeability and patient outcomes, forgoing higher savings potential. While precise estimates of future savings are not yet available, CalPERS expects the program to help lower or stabilize drug spending in the selected classes.

More expansive examples of reference pricing illustrate the importance of careful design and the need to ensure that reference pricing does not simply shift costs to patients. Arkansas’ state employee plan has had reference-priced prescription drugs since 2005. The plan currently reference prices 12 classes of drugs. Evaluations of the Arkansas program as a whole have not yet been conducted, but an evaluation published in the Journal of Managed Care & Specialty Pharmacy found that after about four years of reference pricing for proton pump inhibitors, state spending on these drugs decreased by nearly half despite “essentially unchanged” utilization.
The most dramatic example of prescription drug reference pricing is the Reta Trust, which purchases health insurance for the employees of 55 Catholic organizations and has used reference pricing for outpatient drugs since 2013. Prior to implementing the program, a Reta analysis found dramatic price variation within therapeutic classes, with a monthly price variation of “$222 between the least and most costly drug within the 30 therapeutic classes that had the highest prescription rates.”

Reta currently has reference prices for 1,302 outpatient drugs from 78 therapeutic classes. Under the program, an employer’s contribution for a drug is limited to the least expensive drug in the class. In cases where a patient has a medical need for a more expensive drug, physicians can request a clinical exemption. This sweeping program saved employers $1.3 million over 18 months of implementation, and the use of low-priced drugs increased. However, much of these savings appear to be a result of shifting costs to employees; there was also a 5.2 percent increase in cost sharing.

### Considerations for pharmaceutical reference pricing

The following are key issues to consider when designing and implementing a reference pricing policy:

1. **Identifying areas for savings**
   - What are the main drivers of cost among retail drug spending?
   - What information is available about utilization and prices for drugs included in medical benefit spending?

2. **Defining the scope**
   - Will the policy apply to retail pharmacy drugs, medical spending, or both?
   - Which drugs or classes of drugs should be included?
   - Will the changes affect vulnerable populations’ access to medications?

3. **Educating enrollees and providers**
   - How will enrollees learn information about the program, including participating providers, pricing structure, included services, and the exemption process?
   - How will providers be informed of the reference-priced drugs?

### Maximize participation in the 340B program

The 340B Drug Pricing Program is a federal program meant to allow covered entities—organizations providing care to low-income and otherwise vulnerable populations such as children, HIV/AIDS patients, cancer patients, and Native Americans—to "stretch scarce federal resources as far as possible, reaching more
eligible patients and providing more comprehensive services.” The program, named after section 340B of the Public Health Service Act, requires pharmaceutical companies to provide these organizations with discounts similar to those provided under the Medicaid Drug Rebate Program.

The program requires covered entities to register with the Office of Pharmacy Affairs (OPA) within the U.S. Health Resources and Services Administration in order to receive the statutory discounts, but it does not require that drugs purchased under this discount agreement be limited to the patients through which the entity is eligible to participate in the program; for example, a hospital can purchase drugs for all of its patients, regardless of their payer status or administration method, at the same reduced rate. The 340B program can result in savings for states both through maximizing participation and ensuring that participating providers are maximizing those savings.

Six distinct hospital types and 10 distinct clinic types are eligible for participation in the 340B program as a covered entity. Of the 6,146 hospitals in the United States, 1,507 participate in the 340B program through one of the six eligibility categories. Additionally, there are 5,432 clinics participating through one of the 10 nonhospital eligibility categories. States could offer assistance to the remaining hospitals throughout the state to ensure that all eligible hospitals are aware of their eligibility under federal law as well as the state regulations on how such hospitals may operate. Due to the resource-stretched nature of eligible entities, there is a possibility that hospitals do not currently have the staff resources needed to confirm eligibility and apply with OPA. Similarly, nonhospital entities would likely find it more difficult to work through this process due to their smaller staff numbers.

Beyond ensuring that all eligible entities participate in the program, states can also ensure that their policies promote the highest savings within those covered entities. The 340B program prohibits “duplicate discounts,” or receiving both Medicaid rebates and the 340B discount. As a result, all 340B drugs dispensed to Medicaid patients must be identified to ensure that drug manufacturers are not paying discounts on these drugs twice.

While states have regulations in place to help avoid duplicate discounts, these regulations allow for two possible approaches to the issue: excluding all Medicaid prescriptions from the 340B program or identifying all 340B prescriptions when they are billed to Medicaid. This has the potential to create confusion among providers and reduce the efficacy of the regulations. The regulations may also result in the loss
of potential rebates, as states neither purchase a drug under the 340B program nor claim the Medicaid rebate to which they are entitled. By changing these regulations to allow just one of the two approaches, states can reduce provider confusion and ensure that the highest savings are achieved, particularly if supplemental rebates are pursued.

California is pursuing such a change as part of its consolidated purchasing strategy, and although detailed estimates are not yet available, Gov. Newsom’s administration anticipates savings. Minimizing regulatory confusion is an important step toward maximizing participation in and savings under the 340B program.

Promote the use of generic drugs

Another option that states can use to reduce prescription drug expenditures without sacrificing quality is increasing the use of generic drugs. Generic drugs, also called multisource drugs, operate identically to the brand-name drug on which they are based in terms of dosage form, safety, strength, route of administration, quality, and performance. These drugs are often cheaper than their brand-name alternatives because the companies producing generic drugs are not required to conduct studies to show safety and efficacy, as such studies were already done for the brand-name drug.

Nearly 85 percent of Medicaid prescriptions in 2018 were for generic drugs, but generic drugs represented less than 20 percent of Medicaid spending in 2018. A 2019 study of drug prices by brand status found that generic drugs were, on average, 18 times less expensive than brand-name drugs. Generic drugs also introduce competition into prescription drug markets, counteracting the market power of brand-name manufacturers. While generic prescription rates are already high, there are a variety of tools available to promote the further use of generic drugs, including generic substitution and incentive programs.

Generic substitution is the practice of substituting a brand-name drug with its generic equivalent at the point of dispensing—often a pharmacy. While every state except Oklahoma has laws permitting generic substitution, only 12 states require pharmacists to dispense a generic drug. By amending these laws to require, rather than permit, generic substitution, states could accrue additional savings. Although not all prescriptions can be shifted to a generic counterpart, small shifts would represent significant savings, given the high price of brand-name drugs relative to generics.
In addition to legislative mandates, incentive programs can be used to promote the prescription and dispensation of generic drugs. Through these programs, which operate similarly to shared savings programs, providers receive increased payments for switching patients from brand-name to generic prescriptions. One example of this is BlueCross BlueShield of Michigan’s Blue Reward$ program. The program, which operated for three months in 2007, paid an additional $100 for each patient who switched from brand-name statins to a then-newly available generic statin. The program was effective in influencing prescriber behavior: Physicians received $2 million in incentive payments over the course of the program, while annual drug spending by BlueCross BlueShield of Michigan decreased by $5 million and its enrollees paid around $1 million less in copayments.

However, it is important to ensure that the promotion of generic drugs does not come at the expense of patient quality outcomes. There are instances when a brand-name drug is medically appropriate: For example, a patient may be allergic to an inactive ingredient used in a generic version, or some aspect of the patient’s drug regimen may mean that the generic drug is medically contraindicated. Additionally, many generic drugs are produced in factories in India and China that the U.S. Food and Drug Administration routinely cites for data falsification or manipulation violations.

For generic substitution approaches, one important safeguard for patients is ensuring that providers retain the ability to require the dispensing of a brand-name drug when medically appropriate. Every state that allows for generic substitution currently permits prescribers to require the brand-name drug be dispensed, though the methods for doing so vary significantly. Additionally, establishing a robust appeals process and ensuring that patients are educated about it can help allay the risks of medically inappropriate generic prescriptions. This process can be based on a step therapy appeals process, which more than 25 states have established in some form.

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Reduce the cost of physician-administered drugs

Health plans also pay for drugs that are primarily administered by doctors in hospitals or other health care facilities. Many of these are expensive specialty drugs, such as oncology drugs and treatments for autoimmune diseases. Nonretail drugs comprise about 28 percent of total prescription drug spending nationally, according to a report by the Altarum Institute.
PBM contracts typically cover administration of the retail prescription drug benefit. In contrast, drugs that are administered in medical settings by injection or infusion are separately purchased by the provider. The health plan then reimburses the provider for the drug as well as the provider’s services.\textsuperscript{148}

Nevada’s state employee health plan analyzed the costs of specialty drugs administered in medical facilities and found that there were large differences in the costs charged for these drugs depending on the site of care.\textsuperscript{149} To address this variation, the state required specialty drugs administered in medical settings to be purchased through the plan’s specialty pharmacy under its PBM contract. Providers could only purchase a drug through other channels if they found it available at a lower price. This switch lowered costs for the plan by $800,000 in 2017.\textsuperscript{150}

The Minnesota Health Action Group—a coalition of more than 50 in-state employers, including state departments and county and local governments—has undertaken a large-scale project to better understand specialty drug spending and improve data collection on the costs and utilization of physician-administered drugs.\textsuperscript{151} The action group’s key recommendations include requiring the submission of national drug codes (NDCs) in addition to J-codes on medical claims, as well as additional information on the quantity of medication prescribed, such as a unit definition and days of supply. While J-codes only indicate the chemical name of the drug, NDCs indicate the chemical name, dosage, and number of units in a package.\textsuperscript{152}

In conversations with the Center for American Progress, the Minnesota Health Action Group explained that its member employers will use this information to inform future decisions about prior authorization, utilization management, and provider contracts.\textsuperscript{153} It hopes this additional information will improve employers’ ability to manage health outcomes, especially by tracking complications and ensuring that drugs are appropriate for patients, consistent with patients’ diagnoses, and administered in the appropriate settings and amounts. Employers also plan to use these data to provide feedback to providers on how their practices compare with other providers’ costs and use of specialty drugs.

Import prescription drugs

While many of the reforms discussed in this report pertain to purchasing drugs within the United States, the ability to import prescription drugs from Canada is also an option for states looking to reduce prescription drug costs. The practice is permitted
under limited circumstances under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: In order to establish an importation program, states must apply to the U.S. secretary of health and human services for a waiver from the general prohibition of importation of drugs. While no secretary has yet approved a waiver, Colorado, Florida, Vermont, and Maine are in the process of pursuing one.

Vermont enacted a law in 2018 that allowed the importation of drugs from Canada and required the Vermont Agency of Human Services (VAHS) to study and report on the drugs that would create the most savings for the state, establish a state mechanism to regulate the importation, and apply for a federal waiver. In its initial report, the VAHS found that for 17 prescription drugs—including insulin, contraceptives, and treatments for HIV and multiple sclerosis—importation could result in annual savings between $1 and $5 million for commercial payers. The report concluded that importation would not generate significant savings for the Medicaid program, largely due to the state’s rebate agreements. In addition to this evaluation, the state established two new state-level licenses—prescription drug importer-wholesaler and Canadian prescription drug supplier—that would report to the Vermont Office of Professional Regulation. The state has yet to apply for a federal waiver to implement this program.

The approaches of Colorado, Florida, and Maine are much more recent. Colorado Gov. Jared Polis (D) signed an importation bill in May 2019, and Govs. Ron DeSantis (R-FL) and Janet Mills (D-ME) signed importation bills in June 2019. All three states’ bills require the state to apply for an importation waiver with the federal government. Similar to that of Vermont, Colorado’s and Florida’s laws require the state to import drugs that are likely to have the “highest potential for cost savings,” and Maine’s law requires the state to comply with federal law, including “requirements regarding … cost savings.” Due to the recency of these state laws, projections on cost savings as a result of the potential for importation are not yet available. During the bill signing ceremony, Gov. DeSantis announced that he is currently working with the U.S. Department of Health and Human Services regarding the program but noted that he does not anticipate the program being operational until later in 2020. Similarly, Colorado’s program is not expected to go into effect until 2021.

While drug importation has the potential for savings, it is also important to guard against negative outcomes, such as failing to ensure drug safety, as well as to overcome barriers to implementation, such as contracting and drug supply chain issues. One of the largest concerns held by both opponents and proponents of importation programs is the feasibility of ensuring that the imported drugs are the proper drugs and were not intentionally or inadvertently contaminated during the importation
process. However, many drugs in Canada are approved under similar safety and quality standards and are made in the same facilities as U.S. drugs. All four states have taken steps to address this concern, including requiring the entities involved in the importation process to submit to regular audits and reporting requirements.

In addition to ensuring drug safety, policymakers must work to address any implementation issues. For example, there are concerns that Canadian companies would decline to contract with Vermont due to the fact that the country is currently facing shortages for thousands of drugs. While importation advocates such as the NASHP disagree with these concerns, multiple medical groups asserted in a letter to the Canadian health minister last year that the Canadian medicine supply is not sufficient to support importation. Similarly, Canadian Prime Minister Justin Trudeau has emphasized that the Canadian health ministry would continue to focus on ensuring that Canadians have access to medicines at affordable prices.
Conclusion

Prescription drug spending is increasing rapidly across the United States. There are a variety of tools that states can use to reduce spending on prescription drugs. While some reforms can be accomplished through executive action, others will require legislative participation and therefore may not be available to implement until the 2020 legislative session. Some methods, such as reference pricing and negotiating supplemental rebate agreements, have the potential to generate significant savings for the state, while others, such as promoting generic drug use and drug importation, are likely to provide more modest savings. Patient outcomes must be a central component of any reforms to reduce prescription drug spending. If not implemented carefully, some reforms have the potential to reduce patient access to necessary drugs or promote the prescription of medically inappropriate drugs in the name of reducing costs. Policymakers should carefully examine their states’ current legislative framework surrounding prescription drugs and ensure that policies are maximizing state savings.

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