



Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges

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KEY THEMES

- States are actively seeking to implement innovative payment models for prescription drugs to address cost concerns while achieving public health goals.
- The primary challenges for states in launching new payment models are operational factors, including limited data capacity for tracking people's health outcomes and the lack of well-established contracting models.
- Drug payment reforms could spread if there was more clarity around what is allowed by current law and regulations, and further regulatory flexibility or CMS guidance could allow for states to implement advanced reforms that fully shift payment from utilization to broader individual or population health improvement.

Introduction

While more stable in recent years, health care expenditures continue to be one of the fastest growing areas of state budgets. Total state Medicaid expenditures increased by 7.3% between fiscal years 2017 and 2018,¹ which is in addition to rising health care costs for state employee health plans, health care delivery for inmates in correctional settings, and other state health programs. Given most states have balanced budget requirements, greater spending on health care has put pressure on other spending priorities, including education, transportation infrastructure, and other social services.

Although states are implementing multiple initiatives to address overall health care spending,² the introduction of multiple new, costly therapies has caused many states to focus on prescription drug spending. Heightened interest followed an increase in Medicaid prescription drug spending by 24% in 2014 due both to coverage expansions and the release of high-cost, but transformative, specialty drugs for Hepatitis C.³ These spending shocks were unanticipated, and, because state budgets are often prospectively set on an annual or bi-annual basis, states were limited in their ability to absorb these unexpected, short-term health expenditure increases. While Medicaid drug spending growth slowed in 2017 and 2018, it remains a significant state budgetary concern, given the growing pipeline of high-cost, but transformative, pharmaceutical treatments and gene and cell therapies that address conditions disproportionately affecting Medicaid beneficiaries.^{4,5}

As a result, some states are exploring the use of alternative payment arrangements for prescription drugs that would move away from traditional volume-based payments. However, several challenges inhibit the successful implementation and spread of such new payment arrangements by states. This brief examines a range of new payment models for prescription drugs being implemented or considered by states, including value-based payment models that tie drug payments to observed outcomes (i.e., outcomes-based contracts) and those that are population-based payment models (such as “subscription” models). We specifically focus on cross-cutting operational, regulatory, and legal challenges that limit the effectiveness and spread of these models and also identify potential policy options for moving ahead. The brief was developed from discussions with state leaders and national experts, along with a review of published articles and reports about state prescription drug payment reforms.

Increasing State Activity Addressing Prescription Drug Spending

State governments are increasingly interested in prescription drug spending, with over 2,000 relevant bills introduced in state legislatures between 2015-2019 and 300 new laws enacted by 49 states during that time period.⁶ State strategies span many areas, such as price transparency across the pharmaceutical purchasing and distribution chain, state-wide pooled purchasing, and enhanced negotiation with manufacturers. For example, some states participate in multi-state bulk purchasing programs using common formularies, such as the National Medicaid Pooling Initiative and Sovereign States Drug

Consortium.^{7,8} Moreover, some states have invested in health technology assessments of the value and effectiveness of prescription drugs, for use in their coverage and payment policies.⁹

One recent strategy that garnered public attention was Massachusetts’ attempt to establish a closed Medicaid formulary. The state sought a waiver from Medicaid’s requirement to cover all approved drugs, as it was concerned by varying evidence on effectiveness for new therapies. CMS denied the waiver request in June 2018 on grounds that the Medicaid statute required coverage of all drugs for which manufacturers were willing to meet Medicaid pricing and other requirements.¹⁰ The state has pivoted to a strategy (already adopted by New York) of establishing drug utilization reviews. The goal of such strategy is to increase the fraction of drugs prescribed and purchased under Medicaid judged to be appropriate, medically necessary, and not likely to result in medication-related problems.¹¹ In New York, the Drug Utilization Review Board may also recommend an additional rebate for drugs that increase overall spending, have had significant or unjustified price increases, or are disproportionately priced compared to the state’s assessment of their relative benefit.¹²

Other states, following the examples of Maryland and Vermont, have shown interest in laws that require manufacturers to report large price increases, particularly for products that have had price increases without a new indication for treating another condition or without new evidence of its effectiveness in real world settings.¹³ These transparency policies are not limited to Medicaid, but have often included all purchasers and insurance companies in the state. In their implementation, these approaches have encountered legal challenges.¹⁴

The level of policy activity, number of states implementing new approaches, and variety of policy strategies being tried underscore state interest in controlling Medicaid prescription drug spending. However, several of these approaches, such as preferred drug lists, utilization review, and other restrictions, may introduce unintended consequences, such as potential reductions in access. Given these potential unintended consequences, a growing number of states are exploring new drug payment reforms that link payments to health care quality, health outcomes, and population health.

KEY TAKEAWAYS

- States are implementing various strategies aimed at prescription drug spending, including price transparency, pooled purchasing, utilization reviews, health technology assessments, and other steps to increase negotiating power and reduce drug prices.
- A growing number of states are complementing these efforts with drug payment reforms, such as linking drug payments to health care quality, health outcomes, or broader population health.

Alternative Payment Models for Drugs in Medicaid Programs

States are not alone in implementing new payment models for prescription drugs; commercial payers have been using value-based payment models for drugs and other medical products.¹⁵ For example, a survey found manufacturers implementing an average of 9 value-based payment contracts and payers averaging 11 such contracts between 2014 and 2017.¹⁶ However, alternative payment models for drugs in Medicaid have distinct features due to the unique characteristics of the Medicaid program.

One reason Medicaid drug payment models differ from those offered by commercial payers is that Medicaid programs already receive substantial price discounts. The Medicaid Drug Rebate Program mandates that Medicaid programs receive minimum rebates for their prescription drugs ranging from 13% of the Average Manufacturer Price (AMP) per unit for non-innovator drugs (generally generic drugs) to 23.1% of the Average Manufacturer Price per unit for innovator drugs (generally “brand-name” drugs). In addition to these mandatory minimum rebates, states are entitled to the “best price”* of a product— the lowest unit price that almost any payer paid for that product.^{17,18} States can then negotiate with manufacturers for even lower prices through Supplemental Rebate Agreements,¹⁹ often in exchange for placing products on preferred tiers of their drug benefit and with limited or no prior authorization.²⁰

Another consideration for Medicaid payment models is that there are federal statutory and regulatory constraints on Medicaid programs. States generally need federal review and approval before implementing a new alternative payment

model for drugs, as the models change Medicaid payment rates, benefits, or administrative aspects of the state’s program. One pathway is for states to file a State Plan Amendment, which will be approved as long as CMS determines the proposed change is allowed under existing law and regulation. This pathway has the added benefit that the review process is relatively fast (within 90 days). States could try more novel payment approaches by filing a Medicaid waiver with CMS. Many states have used a particular type of waiver (section 1115 waivers) for care delivery payment reforms, but none have used them to date to tie payment for a drug to successful outcomes or to implement population-level payment models. While providing more flexibility, these waivers have to be cost neutral; require a more intensive application, review, and evaluation process; and CMS has more discretion in approving (as illustrated by the Massachusetts example earlier). Given the very limited experience with how an alternative drug payment model could succeed as an 1115 waiver, most states have sought to implement new drug payment approaches using State Plan Amendments.

Currently, states are focused on two types of alternative drug payment models: outcomes-based and population-based payment models. Outcomes-based models are a type of value-based payment arrangement that ties Medicaid payment, through the Supplemental Rebate, to a particular measured outcome, such as medication adherence, health care utilization, total cost of care, or a health outcome. Currently-implemented population-based payment models seek to expand access to a therapy by setting an expenditure cap for the drug, and states pay a much reduced per-unit price of the drug after it has spent more than the cap. The following sections illustrate examples that states have implemented, along with lessons that have been learned to date.

KEY TAKEAWAYS

- Drug payment models look different in Medicaid programs because of statutory and regulatory constraints, as Medicaid programs already receive the “best price” paid for a drug and state Medicaid programs require approval before implementing new payment models for drugs.
- Medicaid programs have started to implement payment reforms for drugs in two categories: outcomes-based contracts and population-based models.

* In the commercial sector, manufacturers cite these federal requirements in limiting their willingness to offer deep discounts to commercial sector payers, as the companies would then need to offer those prices to all Medicaid programs across the country. This also impacts manufacturers’ willingness to participate in specific alternative payment models with commercial payers, such as a subscription model where the per-unit price could be very low depending on the population size or a warranty-type model where the manufacturer offers deep discounts when a patient does not achieve certain clinical outcomes, as these models may effectively set a new best price for Medicaid. These challenges should not apply to Medicaid alternative payment models, as negotiations with Medicaid programs, through the approaches highlighted in this brief, do not count toward the Medicaid “best price” calculation.

Outcomes-Based Payment Models: Oklahoma, Michigan, and Colorado

Oklahoma, Michigan, and Colorado have been granted federal approval to implement outcomes-based payment models for prescription drugs. Massachusetts has also submitted a revised State Plan Amendment to implement these contracts alongside their drug utilization review process. These outcomes-based contracts have been operationalized using Supplemental Rebate Agreements negotiated with manufacturers, and the additional rebates vary based on agreed-upon metrics.^{21,22,23}

Several current outcomes-based contracts have incentives based on utilization or adherence. The adherence approach has similarities to the population-based payment models discussed in the next section in that it enables more people to get treated and makes it easier for states to afford the treatment for people who adhere. Future outcomes-based contracts may focus more on sharing the gains of better adherence, such as better mental health or fewer medical costs for complications, and moving incentives to be based on metrics that better quantify the full impact of a drug on health outcomes and cost.

In addition, the current iteration of these agreements adjust overall drug spending according to the specified outcome measures, but spending continues to increase if utilization increases. Future models could delink payment from utilization or link payments to additional outcomes more closely related to lowering total cost of care.

This section describes Oklahoma's and Michigan's experience as they were furthest along at the time of this brief's writing.

Oklahoma's Experience to Date

The state of Oklahoma has four outcomes-based contracts in place with several pharmaceutical companies for therapies that address schizophrenia, bacterial skin infections, and epilepsy. Oklahoma's initial contracts allow rebates to increase or decrease based on outcomes, with the contracts using outcomes measures such as medication adherence, reduced emergency department visits, and impact on total cost of care.

The state's initial goal for outcomes-based contracts is to improve patient outcomes based on similar or lower pharmacy spending. However, the state's longer-term goal is that with enough experience implementing outcomes-based contracts, they can better target the most appropriate pharmaceutical intervention for particular patients to achieve lower overall program costs.

Oklahoma has encountered multiple challenges in implementing outcomes-based contracts, such as engaging larger manufacturers in the new models and reliably measuring meaningful outcomes with timely data. The state has met with 40 manufacturers to date and has had more success with small companies with smaller market share in a

given therapeutic area; companies with a larger market capitalization and more diversified product portfolios and pipelines have not yet expressed much willingness to enter into outcomes-based contracts.

A measurement challenge is that few meaningful outcomes can be assessed through readily available health care claims data, as claims data can show health care utilization or prescription refills but includes little information about clinical assessments (such as blood pressure or lab values), a person's functional status, or a person's overall health status. To assist in identifying appropriate outcome metrics, Oklahoma collaborated with the University of Oklahoma School of Pharmacy and the Center for Evidence-Based Policy's State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) initiative. In order to move to better and more outcome measures, particularly those that might show whether a therapy had its intended effect beyond changes in health care utilization, state Medicaid programs will need access to clinical or patient-reported data, capabilities to construct reliable measures from these data sources (either in house or through their managed care plans), business processes and contracting for reporting (especially if analyses are conducted through managed care plans), and potential new partnerships. While these capabilities are being developed in commercial and Medicare Advantage plans, they have been applied less so far in Medicaid plans. Though Oklahoma is encountering this measurement challenge sooner than other states, it is generalizable to most other states' programs.

In an early example of one of their contracts, Alkermes has promised the state of Oklahoma steeper rebates for sustained patient adherence to their long-acting antipsychotic drug Aristada. Under the one-year contract, the rebate amount increases every other month, as long as the prescription is refilled, since the cumulative effect of this product is most clinically meaningful when maintained over time.²⁴ This example differs from how these contracts are offered in commercial settings, where the payer reimburses for a medical product at a lower point until an outcome (like adherence or reduced ED visits) is achieved. This model also has similarities with population-based payment models that expand access to a given therapy. Nonetheless, it is a promising example for how states and manufacturers can collaborate and develop new contracts that better align state and manufacturer incentives for better population health management of high-cost patients.

Michigan's Experience to Date

In November 2018, Michigan became the second state to receive approval from CMS to develop outcomes-based contracts with manufacturers in its Medicaid program. The state plans on using outcomes-based contracts to address pricing uncertainty, given the rising number of high-cost orphan drugs recently approved or in the development pipeline, and to ensure more appropriate use of high-cost, specialty drugs. Since receiving approval, Michigan has had preliminary conversations focusing on prospective contracts including specific drug classes or categories of drugs.

Michigan faces several challenges in standing up its outcomes-based contracts. Like Oklahoma, Michigan anticipates similar challenges in defining and constructing the metrics used by the program, and it is considering how to use data beyond health care claims. Another challenge Michigan faces is that its law prohibits prior authorization for specific protected drug classes. For drugs in these classes, negotiations with manufacturers are more difficult as the state cannot offer the incentive of waiving prior authorization and placing drugs in a preferred tier.

KEY TAKEAWAYS

- **Some states are pursuing outcomes-based contracts to ensure Medicaid spending is linked to measurable outcomes for its patient population, and their goal is mostly about improving the value of prescription drug spending versus reducing costs.**
- **States are challenged in implementing outcomes-based contracts by the limited number of appropriate outcome measures that can be assessed using available data.**

Population-Based Payment Models: Louisiana and Washington

At a conceptual level, population-based arrangements mean that a manufacturer agrees to accept responsibility for providing therapies to a group of patients in exchange for a set payment. This may be operationalized as a per-patient capitation model, with fixed spending amounts per patient, or it may be a fixed fee for an entire population.

One way to implement population-based approaches is through the “subscription” model, which has been called the “Netflix” model,²⁵ and is conceptualized as multi-year agreements which enable access to an unlimited volume of a particular drug based on a fixed, predictable payment (that is not tied to the amount of the drug used). While the term “subscription” has been used widely by policy professionals and media to describe these new payment models, the proposed approaches are not generally paying manufacturers a guaranteed, flat rate regardless of drug utilization, as would be implied by the analogy to subscription services such as Netflix.

Louisiana and Washington are the initial states seeking to implement ‘modified’ subscription models, with both states focused on expanding access to Hepatitis C direct-acting antiretroviral treatments without substantial increases in state spending. In order to implement a ‘true’ subscription model where payment is structured in a flat, subscription-style fee de-linked from volume, states would likely be required to obtain a Section 1115 Medicaid waiver or obtain additional flexibility from CMS. Moreover, if utilization were to decline under a true subscription model, that would amount to a unit price increase. Instead, the two states have begun implementing a subscription-like approach through an expenditure cap, where the per-unit price becomes substantially lower after spending for the drug exceeds the cap amount.

To achieve substantial population health improvement, these population-based models would need to be complemented by medical screening and treatment, public health education, and assistance in identifying people already diagnosed with the condition. Manufacturer activities like promotion and data sharing could support these goals.

Future versions of population-based payment models could tie reimbursement to access and successful performance measures (like lower population rates of Hepatitis C). This more comprehensive population health care reform might be challenging given the current rules on Medicaid Supplemental Rebate Agreements, although some commercial plans are exploring the feasibility of such arrangements.

Modified subscription models are in an early stage of implementation, but present a promising approach to improving population health while ensuring budget certainty for the state government. State leaders emphasized modified subscription models may work best under the following conditions with:

1. Competitive markets with multiple therapeutic options,
2. Curative drugs as opposed to chronic therapies,
3. Conditions and treatments that have substantial unmet population health needs, and
4. Clinical contexts where providers do not have set preferences on which therapy to prescribe.

Early state contracts focus on Hepatitis C because it meets all these conditions. Both states are significantly affected by the disease - Louisiana has the 5th highest estimated Hepatitis C prevalence in the country, and Washington is 16th. About 35,000 people in Louisiana’s Medicaid program

and prison system have Hepatitis C, but only 384 were treated in 2017. In Washington State, approximately 65,000 residents live with Hepatitis C, and Hepatitis C-related hospitalizations cost taxpayers \$114 million between 2011 and 2014. From a public health perspective, Hepatitis C may spread further since many people with Hepatitis C are undiagnosed and the disease is highly infectious. Further, the focus on Hepatitis C was motivated by the introduction of the antiretroviral curative treatments that had large financial impacts on Medicaid budgets.

Lastly, for either state—or others—to eliminate Hepatitis C fully, the model will eventually need to extend beyond Medicaid and the incarcerated population to the larger public.²⁶ While some commercial insurers and manufacturers have expressed interest in subscription payment models, manufacturers are wary of entering into agreements with multiple payers involved that could impact the Medicaid “Best Price,” as they would then have to offer the same prices to every Medicaid program across the country. In order to truly align with commercial payers over an extended engagement, states likely would require new 1115 waivers to implement true subscription approaches with payments delinked from utilization and with greater data-sharing and support from participating manufacturers.

Louisiana’s Experience to Date

Given the challenge with Hepatitis C prevalence, Louisiana sought to expand access to Hepatitis C treatment, and CMS recently approved Louisiana’s State Plan Amendment to implement a modified subscription model. It will be implemented using the state’s historical spending as a reference point in determining a cap on total expenditures.²⁷ The Supplemental Rebate Agreement will apply to both Managed Care Organizations and fee-for-service Medicaid, though all supplemental rebates will be reaped by the state.

To operationalize the modified subscription concept, the Louisiana Department of Health needs two state expenditure caps: one relating to the Medicaid population and a parallel system for a participating public safety net organization (or “340B entity”) who would provide the therapy to incarcerated populations. In Louisiana and Washington’s early efforts, the designated 340B entities are safety net entities already engaged in caring for incarcerated populations. Both the Medicaid program and the 340B entity will then pay up to a negotiated cap and receive subsequent, nearly unlimited doses for very low prices for their Medicaid and incarcerated populations.²⁸ This approach, with parallel expenditure caps and a 340B entity for its incarcerated populations, is necessary since federal statute prohibits the use of Medicaid funds for incarcerated populations.²⁹

Louisiana received bids from all manufacturers of Hepatitis C direct-acting antiretroviral treatments (AbbVie, Merck, and Gilead). In March 2019, the state announced its intention to contract with Gilead’s subsidiary Asegua Therapeutics as its

partner. The program started in summer 2019, and negotiations have been completed.³⁰ This model will potentially allow the state to spend approximately the same amount annually on Hepatitis C treatment for Medicaid and incarcerated populations (about \$35M in FY2018) while accessing far more doses of curative treatment.

While payments are not linked to performance metrics or shared risk, Louisiana’s model represents a pathway for how such a population-based model could be further developed and demonstrates how states can collaborate with manufacturers on population health or public health goals.

For the modified subscription model to translate into substantial successes in eliminating Hepatitis C, Louisiana must also expand provider and public health capacity to identify people with Hepatitis C and treat them. This may include increased efforts to diagnose individuals, conduct outreach to screen difficult-to-reach patients, connect diagnosed individuals with treatment, monitor and track people during treatment, and manage complications. The state will also need to develop public and provider education and implement a public health strategy to prevent re-infection.

Washington’s Experience to Date

Washington State has taken a similar approach with the goal of eliminating Hepatitis C in Medicaid and its incarcerated population. Washington announced that it would partner with AbbVie to provide direct-acting antiretroviral for Hepatitis C patients in Medicaid, state prisons, state employees, retirees, and teachers.³¹ Reflecting the Medicaid Supplemental Rebate Agreement structure, Washington negotiated to pay a significantly reduced unit price up to a set spending threshold, and all doses provided after the threshold is met will be rebated nearly 100%.

To highlight the future of Washington State’s value-based approaches, CMS recently approved Washington’s State Plan Amendment to link payment to patient outcomes in Supplemental Rebate Agreements, and the state is interested in using this authority for other contracts outside of Hepatitis C.³² Washington became the fourth state to receive the new authority, but one of the first, alongside Louisiana, to implement an expenditure cap program primarily focused on Hepatitis C elimination.

With a directive from Washington’s governor to eliminate Hepatitis C in the state by 2030, health leaders are including a public health component in negotiations with manufacturers. Not only is the state looking to secure a low price for treatment, but it is also working to garner support for screenings, education, care coordination, and preventative services, aided by their manufacturing partner.

While the Washington Healthcare Authority has sought to remove barriers to treatment, the state has had difficulty treating larger populations of individuals and has called for an active public and provider education campaign when releasing its bid. While the final terms, financing, and model (such as shared risk or performance measures) are not yet publicly available, and the state has not worked out the details of its supplemental medical and public health activities to support the reform, Washington has sent a clear signal that it will be defining success by how well the drugs eliminate the disease in the state.³³

KEY TAKEAWAYS

- **Early population-based payment models, which are based on “subscription” models, have focused on increasing access to therapies for a given condition. They are implemented through a negotiated expenditure cap and the per-unit price becomes significantly lower after spending for the drug exceeds the cap amount.**
- **To meet their goal of expanded access, modified subscription models depend on having additional clinical and public health capacity available to diagnose, prescribe, track, and manage the treatment as well as public and provider education on the importance of screening, prevention, and treatment.**

Operational Challenges in Implementing New Drug Payment Models

The models discussed above are early in their implementation, and their overall impact and implementation will be determined over time. However, there are several early implementation challenges states will face when standing up these types of programs.

Difficulty Identifying and Producing Outcome Measures

Outcomes-based contracts depend on having specific metrics that can be included in the contracts with manufacturers, while future subscription models may choose to incorporate disease elimination metrics or other outcome measures. Currently, meaningful measures are limited, so

most programs are assessing whether patients are filling their prescription medications or whether treatment is associated with avoiding costly complications (such as emergency department visits). States are not unique in this challenge—commercial payers also routinely use claims-based measures, such as medication refills or utilization for complications, for their value-based payment contracts for prescription drugs and other medical products.

Looking forward, some commercial contracts have included lab-based measures such as cholesterol levels or viral loads, and reliable clinical outcome measures are being implemented in certain contexts, such as Spark Therapeutics’ gene therapy Luxturna. As electronic data systems and interest in value-based payment for drugs increases, there is interest in capturing a patient’s outcomes, from intermediate clinical outcomes (such as blood pressure or blood cholesterol), to improvements in functional status, to overall health outcomes. As states and manufacturers look to improve on early contracts, there is significant opportunity for states to contract with manufacturers for products where the specific outcome of interest (whether disease remission, a particular complication, or health improvement) can easily be identified in claims and linked to total cost of care. In these contracts, states and manufacturers can partner to explore how to develop better data infrastructure to report clinical and patient-reported measures that can be worked into these contracts. Ultimately, both states and manufacturers should seek to demonstrate improvements in overall state Medicaid costs and patient outcomes. However, the existing gaps in available metrics and data sources will be an ongoing challenge as states consider value-based payment arrangements for prescription drugs.

Limited Clinical and Public Health Capacity to Ensure Treatment Is Successfully Provided

For subscription models, the goal is to expand access to treatment for a condition, which requires expanded access to clinicians and public health resources to support increased case-finding, prescribing, and patient management. This can be challenging for states where Medicaid beneficiaries face access challenges to begin with, particularly in rural or other underserved areas. There is likely to be a need for sustained education and awareness campaigns that let clinicians and the affected populations know of the new treatment opportunity, supporting providers in providing diagnosis and treatment, and data analyses that can identify “hot zones” of untreated individuals. There may also be a need to provide incentives to providers to support the additional care they will be responsible for, especially if the additional patients are harder to reach or manage.

Increases in Administrative Complexity and Management

These contracts require additional administration to implement. Discussions with state leaders working to implement new drug payment initiatives indicate states may lack the in-house expertise to negotiate, monitor, and report measures. Given these challenges, states may, in some cases, need additional resources to build this human capital. States may need different data resources to operationalize the contracts, such as the ability to identify populations who would benefit from the therapy (in a subscription model) or calculate the outcome measures in the contract (especially in an outcomes-based contract model). Administrative expenses can be limited by simplifying contracts, especially in the metrics used to track performance and encourage plans and providers to focus on, and by sharing resources and expertise across states and across other payers.

As state value-based payment arrangements gain traction, there will be important differences if the model is implemented by state agencies or by Medicaid managed care plans. In either scenario, there are more capabilities required to make sure that the right data infrastructure is in place to track longitudinal patient outcomes. State agencies may or may not have the negotiating expertise in house for working with manufacturers, which may depend on whether the pharmacy benefit is entirely carved out from managed care. In managed care settings, states will need to invest more resources in administering a managed care contract that requires value-based payment models for drugs and for evaluating the plans' success under those contracts.

States have differing access to the data needed to administer new alternative payment models for drugs. In some states, managed care plans may have already negotiated with providers, third-party entities, or a pharmacy benefit manager (PBM) to receive laboratory results or clinical data reported in an EHR; in other states, the state Medicaid agency may have access to expanded data sources beyond health care claims as well. In addition, sometimes the Medicaid managed care plan or their PBM have additional experience with these contracts in other settings where new payment arrangements are being implemented, such as the commercial market.

A final challenge is that states are not used to holding discussions with pharmaceutical manufacturers in this new way. Since Supplemental Rebate Agreements are strictly confidential, states are limited in their ability to learn emerging best practices from one another with respect to new payment models. While more transparent evaluation through an 1115 waiver would be greatly beneficial for cross-state learning, there are also

opportunities for states to strengthen relationships with specialty pharmacies that provide similar services or commercial plans that have more experience in these contracts. Additional learning would be especially helpful from those organizations that have greater capacity to track longitudinal outcomes. In addition, the overall process is new for manufacturers, which are themselves having to understand how to bid and negotiate these new types of contracts.

KEY TAKEAWAYS

- **State implementation of alternative payment models for drugs depend on reliable and timely mechanisms to assess the impact of drugs on people's health outcomes. Such alternative payment models would benefit from additional outcome measures in several areas and by improved state data systems to collect such data.**
- **For drug payment reforms to improve people's health, they often need to be coupled with greater or different access to care. This can mean new clinical and public health capabilities to diagnose, prescribe, and manage care, which may be particularly challenging in underserved areas.**
- **As there is a lack of well-established contracting models, Medicaid programs face additional administrative costs for implementing new alternative payment models for drugs. This is true whether the model is operationalized through the state agency or through their managed care plans.**
- **Manufacturers and states have limited experience with discussing new models and finding new ways to collaborate with one another, so identifying and spreading best practices is an important consideration.**

Policy Implications: Overcoming Regulatory and Legal Barriers

Although bipartisan political will at the state level is growing, there are legal and regulatory barriers to implementing new payment arrangements, such as subscription models and outcome-based contracts, for prescription drugs.³⁴

State Guidance and Flexibility for Medicaid

States have a variety of mechanisms to incorporate new payment arrangements in their Medicaid program, including limited reforms through State Plan Amendments and more fundamental ones through Section 1115 waivers.

To date, states have used the State Plan Amendment pathway to implement new value-based payment arrangements for drugs. Current State Plan Amendments have enabled progress, such as the examples described in this brief. However, there are limitations as the State Plan Amendment cannot waive any Medicaid legal or regulatory restriction. This limits the ability of states to implement true subscription models, where cost is fully delinked from the volume of drugs administered, or a truly dynamic outcomes-based contract, such as when a drug is essentially free if the patient does not achieve a designated health outcome or if the state increases the price per unit of drug if the drug improves outcomes while lowering total cost of care.

Without these restrictions, states might also be able to propose even bolder ways to cover prescription drugs. One promising approach would be for CMS to provide a “model” section 1115 Medicaid waiver template that helps states adopt more advanced value-based payment models. A component of this model 1115 waiver template might require some level of payment at risk in all contracts, such as 30-40% of payment, which would be reasonably above the statutory rebate of 23.1%. A model waiver, critically, can be a transparent opportunity to assess the impact of value-based payment arrangements for medical products, and the terms of the waiver could include specific evaluation questions on whether the new payment model improves patient access and reduces total cost of care.

A final implementation concern is supporting states in sharing their learnings or successful contract strategies with one another. Some groups, such as the Center for Evidence-Based Policy at Oregon Health and Science University, have provided early technical assistance with states in this new form of contracting. However, there is limited support for such activities, and specific Supplemental Rebate Agreement terms are confidential. This can be improved through additional supports for model contracts (without disclosing confidential negotiations) and sharing best practices.

Anti-Kickback Rules

Another potential barrier to state payment reforms are federal and state anti-kickback statutes, which prohibit payment for referrals or induced demand of health care services.³⁵ The federal anti-kickback statute broadly prohibits any remuneration, which can include cash, in-kind services, or anything of value, to induce an individual to refer services or products that may be reimbursed by Medicare, Medicaid, or another federal health care program. In addition, many states have adopted their own anti-kickback laws, which can vary significantly in the acts that they define as prohibited.

Anti-kickback statutes could be challenging for implementing value-based payment arrangements for medical products since such payment models depend on some degree of coordination and sharing of resources between the manufacturer and payer. For example, there are some concerns that a manufacturer’s assistance with promoting the payment model to patients, data sharing, or other supports could constitute anti-kickback violations. However, in early modified subscription models, the state has taken on the tasks of identifying, treating, and tracking patients, which has mitigated anti-kickback concerns. Because states are currently receiving limited additional support from manufacturers, the state and national leaders who provided input for this brief did not find the anti-kickback rules stop states from exploring new models, but the uncertainty could limit their ability to spread to other states.

Integrating Payment Reforms for Care Delivery and Pharmacy Benefits

While no currently known models incorporate both pharmacy and medical spending, there is potential for integrating prescription drug contracts with the payment reforms for care delivery that states are now implementing more widely. State Medicaid programs have multiple payment reforms underway for health care services, including episode-based payments, accountable care organizations (ACOs), or population-based payments. Prescription drug payments that are volume-based are not well aligned with provider payment reforms, potentially blocking opportunities for providers and manufacturers to align more effectively around goals of improving health outcomes and reducing total costs of care for Medicaid populations. Moreover, common measures between the two types of payment reforms would reduce administrative costs and provide stronger incentives for reforming care.

Conclusions and Next Steps

New payment models for prescription drugs are still in their early stage, and states are still learning what works. In our analysis, implementation considerations were the biggest barrier states were facing, with some legal or regulatory issues that inhibit spread. There are several short and long-term steps that can accelerate states piloting new approaches to advance value-based payment arrangements for prescription drugs, illustrated in the table below. This can include getting greater clarity on what is possible, additional authority to implement new types of contracts, and improvements in the negotiation culture between manufacturers and states. States will likely continue to lead and work to drive their programs towards greater value.

States Policy Strategies to Manage Prescription Drug Costs and Align Value-Based Efforts		
<i>Policy Intervention</i>	<i>Short-term</i>	<i>Long-term</i>
States can request authority (through State Plan Amendments) to experiment with outcomes-based contracting or subscription models.	✓	
Manufacturers should actively work with states, especially with products that impact Medicaid populations.	✓	
CMS should write a Dear State Medicaid Director letter encouraging states to apply for new authority and provide a template State Plan Amendment for these requests.	✓	
CMS should propose a model 1115 waiver for value-based payment arrangements that proposes specific criteria, such as a threshold percentage of payment at risk, for participation.	✓	✓
States can convene manufacturers, Medicaid managed care plans, and private payers to align ongoing population health care transformation efforts with new payment models for medical products.	✓	✓

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