

*State Medicaid Alternative
Reimbursement and Purchasing Test
for High-cost Drugs (SMART-D)*

Summary Report

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Preface

This report analyzes the options available to state Medicaid agencies to purchase and pay for high-cost specialty drugs under current federal law. Drug prices are set by manufacturers, and Medicaid price and coverage regulation is most clearly within the domain of federal policy and legislation, so this report cannot offer a quick solution to high drug launch prices. Rather, in this first phase of SMART-D, the Center for Evidence-based Policy has sought to identify tools and techniques that states can use under current law to enable patient access to needed drugs while being an effective steward of scarce public dollars.

Implementing alternate purchasing and payment models for high-cost drugs is not an effort to be taken lightly; it requires time, planning, data, and sustained oversight. This level of effort may, at first, seem off-putting. But state Medicaid programs are already pursuing value-based purchasing strategies more broadly as they struggle with escalating drug costs. Moreover, SMART-D's pipeline forecast has identified more than 110 new high-cost drugs awaiting approval by the U.S. Food and Drug Administration (FDA) in the next 18 months. States cannot wait for some undetermined federal upending of the pharmaceutical market status quo; now is the time for state Medicaid programs to pilot alternative purchasing and payment models that will enable them to better respond as new high-cost drugs are approved.

Executive Summary

Prescription drug costs are the single fastest growing component of U.S. health care spending (Larner, 2015). Spending by Medicaid on prescription drugs increased 14% in overall costs and 3.6% in expense per enrollee (MACPAC, 2015a), with the total expenditures increasing from \$37.1 billion to \$42.3 billion between 2013 and 2014. A major factor in this surge has been the introduction of several high-cost specialty drugs that treat serious conditions such as cancer, hepatitis C, blood disorders, and HIV. These innovative drugs are being introduced at an accelerating pace and present exciting opportunities to improve the health and lengthen the lifespan of patients. At the same time, the high prices of the new therapies pose a challenge for all health care payers' budgets, especially state Medicaid programs that must ensure access to a broad range of health services for low-income individuals and families within state budget parameters and federal requirements.

Many Medicaid enrollees have complex and expensive health needs. These factors contribute to a per capita cost for Medicaid beneficiaries that is more than \$2,000 above the per capita cost in the private insurance market (CMS, 2015d). Patients, providers, and policymakers expect state Medicaid programs to provide ready access to new therapies—a demand that in several states has been enforced by actual or threatened class-action lawsuits (Ollove, 2016). Yet these state programs must operate within finite budgets subject to legislative approval and state constitutional limits, often including a requirement that the state's budget be balanced. Compared to private payers, states have additional challenges. Unlike commercial insurance companies, state Medicaid programs have very limited latitude to increase budgets by shifting costs to Medicaid enrollees through premium obligations or patient cost-sharing. Both are extremely restricted under federal law. Moreover, the Medicaid Drug Rebate Program (MDRP) requires states to provide coverage for all drugs produced by drug manufacturers with federal rebate agreements, with very limited exceptions.

For these reasons, high-cost specialty drugs have put state Medicaid budgets into crisis. For example, in 2016, Missouri had to seek a midyear supplemental appropriation of \$150 million to address escalating drug costs within its Medicaid program. In 2014, Florida's Agency for Health Care Administration needed to provide an additional "kick-payment" to Medicaid managed-care plans for covering hepatitis C drug costs. Faced with increasing drug costs, state Medicaid officials are seeking novel ways to manage their prescription drug purchases. Yet, drug purchasing stakeholders—states, managed care organizations (MCOs), pharmacy benefits managers, drug manufacturers, federal policymakers, and others—are operating in a charged political environment. Scrutiny of drug costs and patient access make it difficult for these stakeholders to collaborate, take risks, and find new solutions. State officials are under intense pressure to balance budgets, improve health, achieve broad patient access to treatment, avoid lawsuits, and deliver on the expectations of the state's executive and legislative branches.

The State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) initiative seeks to clarify this complicated state drug purchasing landscape and identify and test new drug payment options for states to consider. These alternative payment model (APM) options are designed to provide improved access to evidence-based therapies for Medicaid enrollees, while improving state officials' ability to predict and manage prescription drug costs in a manner that connects price, payment, value, and health outcomes. Any models identified through SMART-D are voluntary collaborations between a drug manufacturer, prescribing stakeholders, and a Medicaid program. They build upon the substantial contracting experiences that drug manufacturers have in international and U.S. commercial markets. Through the SMART-D initiative, the Center seeks to enable states to achieve four aims: provide access to effective drug therapy for Medicaid enrollees, develop payment strategies for innovative drugs, enhance patient health outcomes, and improve state fiscal status.

Scope and Objectives of the SMART-D Project

The SMART-D initiative is envisioned as having three-phases. Phases I and II include the following key objectives:

- **Map the landscape of Medicaid drug purchasing.** Drug purchasing by Medicaid programs is extraordinarily complicated. State program officials must navigate federal statutes and regulations, state budget frameworks, complex market incentives, and nontransparent rebates and pricing. SMART-D's Phase I research explores these complexities in a way that will help states more easily develop alternate purchasing models.
- **Identify payment options for states.** Drawing upon models used in international and U.S. commercial markets, this project identifies a series of alternative payment options and legal pathways for state Medicaid programs to use when paying for high-cost drugs. Phase I of SMART-D identifies the best practices. Phase II will develop concrete proposals for state Medicaid programs.
- **Increase patient access and outcomes.** State Medicaid directors want to reach more people within their existing budgets and connect patients with drug therapies that improve health outcomes and minimize side effects and toxicity. SMART-D will support state officials in their efforts to use budgets in a way that maximizes these benefits to patients. This goal guides the entire SMART-D initiative but will specifically drive the development of APMs in Phase II.
- **Identify specific opportunities to collaborate with drug manufacturers.** SMART-D supports engagement with drug manufacturers for the joint development of voluntary, financial, or health outcome-based alternative payment arrangements with Medicaid programs. Opportunities exist to enable broad patient access to critical drug therapies while operating in the context of state budget constraints.
- **Provide implementation technical assistance and support to states.** As state officials develop models with drug manufacturers, the Center will support their efforts with technical and other assistance in Phases II and III. When viable models are developed that produce improvements in patient outcomes, the health of populations, and/or the per capita cost of

care, the Center will disseminate information about these best practices among participating states.

Findings of SMART-D Phase I Research

This summary report includes the results of SMART-D's Phase I research, which consists of four components: a review of current Medicaid prescription drug coverage and purchasing practices, a financial analysis of Medicaid drug spending, identification of alternate payment models used in international and U.S. commercial markets, and an analysis of key federal and state laws relevant to Medicaid drug purchasing. The research encapsulates complex issues, addresses the current status of state Medicaid program high-cost drug coverage and purchasing, and identifies new opportunities to integrate value into purchasing.

Medicaid Best Practices to Manage Specialty Drugs

State Medicaid directors are actively managing prescription drugs, with an added focus on high-cost specialty drugs, to reach the most patients despite limited budgets. Management tools include Medicaid drug payment and pricing strategies (340B and actual acquisition cost), utilization management (prior authorization, preferred drug lists, and care management), and managed care coverage of prescription drugs (carving-in the pharmacy benefit and MCO care management). To date, prescription drugs have mostly been excluded from broader value-based payment model discussions and delivery system transformation initiatives developed for other Medicaid-covered health care services. Yet, there is growing interest among Medicaid policymakers to deploy drug pricing and payment models that reflect the underlying clinical value a drug provides and move drug purchasing into the realm of value-based purchasing.

Economic and Pipeline Analysis

The SMART-D analysis found that 64 high-cost specialty drugs accounted for 32.6% of Medicaid drug reimbursement spending and 3.1% of overall Medicaid spending in 2015. These 64 drugs all had reimbursements of more than \$600 per prescription and an annual Medicaid expenditure of \$72 million or more per year. There are at least 110 additional drugs in the pipeline in the next two years that are likely to meet this same criteria and have a similar budget impact. These trends reinforce state officials' interest in strategic alignment of drug reimbursement with overall payment reform efforts and, specifically, the possibility of implementing APMs for high-cost specialty drugs.

Alternative Payment Models

Alternative payment models (APMs) are used by private and public-sector payers to manage drug utilization and costs in the United States and Europe. APMs are widely used in Europe and their use appears to be increasing in the U.S. commercial market. An APM is a contract between a payer

and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure; it is generally either financial or health outcome-based.

Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. In health outcome-based APMs, payments for drugs are tied to predetermined clinical outcomes or measurements, or conditional coverage is provided while data regarding a drug's effectiveness is being collected and assessed. Financial-based APMs, which focus on lowering costs and expanding patient access, have proven to be easier to administer. APMs based on health outcomes require additional planning and data collection, but have the potential to increase the quality, value, and efficacy of treatments.

Legal Analysis

Although the federal Medicaid Drug Rebate Program constrains state Medicaid purchasing flexibility in return for guaranteed statutory rebates, states still have latitude to pursue APMs. The SMART-D legal analysis has identified seven potential legal pathways that states can employ to implement financial and outcome-based payment arrangements with drug manufacturers and other health care providers.

In summary, APMs could be one of many levers that a state needs to create changes in patient outcomes or prescription drug spending. States should be cautioned about anticipating net savings with their first APM implementation; the immediate state-level outcomes are likely to be better patient access and budget predictability. Initial APM implementation will require an investment of time and resources to design, implement, and monitor, but if APMs are viewed in terms of the Triple Aim, states could see important advancements including improvements in patient outcomes and the health of populations, with reductions in the per capita cost of health care over time.

Next Steps for the SMART-D Initiative

The above section summarizes research conducted during Phase I of the SMART-D initiative. Phase II will involve planning and producing a detailed tool through which states can assess their level of interest in and readiness to develop and implement APMs. For Phase II, the Center has identified four areas to focus its work with states on:

- Determine the strategic fit, scope, and potential design of APMs within state Medicaid programs and identify stakeholders that must be engaged in the planning process.
- Assess technological readiness to identify, manage, and track health, drug, or cost outcomes related to APMs, while ensuring appropriate patient confidentiality.
- Establish or build upon a professional relationship between the state and one or more drug manufacturers to facilitate good-faith discussions about APM opportunities.
- Identify legal pathways that pair with the targeted APM and state Medicaid program design.

During the final phase of the project, Phase III, the Center anticipates supporting a small number of implementing states and drug manufacturers by: 1) providing technical assistance, 2) convening meetings to share implementation experiences and address challenges, 3) evaluating pilot projects, and 4) developing a consistent framework to capture results. When viable models are developed and produce improvements in patient outcomes, the health of populations, and/or the per capita cost of care, the Center will disseminate information about these best practices among participating states.

Section I: How Medicaid Pays for Drugs

Overview of the Medicaid Drug Rebate Program

Under the Medicaid program, states have the option of providing coverage for outpatient drugs as part of state plans (in practice, all states provide such coverage). In 1990, Congress responded to reports that Medicaid was overpaying for prescription drugs by enacting the Medicaid Drug Rebate Program (MDRP). Enactment of the MDRP, codified as section 1927 of the Social Security Act,¹ ensures that states receive a discount on a drug's average manufacturer price and never pay more than a brand name drug's best price (Best Price) in the U.S. pharmaceutical market. Under the MDRP, for states to receive federal Medicaid matching funds for expenditures on a covered outpatient drug, the manufacturer of the drug must have entered into a rebate agreement with the Secretary of the Department of Health and Human Services. In exchange for entering into a federal rebate agreement, manufacturers are guaranteed Medicaid and Medicare coverage of their drugs, subject to reasonable limits (SSA § 1927(a)). The MDRP directs state Medicaid programs to collect statutorily prescribed rebates from manufacturers on covered outpatient drugs; a portion of the rebates is shared with the federal government.

The rebate amount under the MDRP is the greater of either: (1) a statutory discount off the drug's average manufacturer price, or (2) the difference between that price and Best Price. Average manufacturer price is "the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer" (42 C.F.R. § 447.504(a)). Best Price is generally the lowest price at which a given drug is sold to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity (SSA § 1927(c)(1)(C)(i)). Average manufacturer price and Best Price are reported by the drug manufacturer to the federal Centers for Medicare and Medicaid Services (CMS); these data are confidential and can only be disclosed in limited situations (SSA § 1927(b)(3)(D)).

The statutory discount on an average manufacturer price, called the rebate percentage, varies with the type of drug. The rebate percentage is currently set at 23.1% for single-source or innovator drugs (i.e., brand name drugs), 17.1% for innovator blood-clotting factor drugs and drugs approved by the FDA only for pediatric care, and 13% for non-innovator or multisource (i.e., generic) drugs (SSA § 1927(c)(1)(B), (c)(3)(B)). Congress increased the statutory discount percentages as part of the Affordable Care Act. The rebates attributable to this increase belong entirely to the federal government (SSA § 1927(b)(1)(C)). Whether the rebate is provided as a percentage discount or as a difference between average manufacturer price and Best Price, manufacturers owe additional rebates if the average manufacturer price increases faster than the consumer price index (SSA § 1927(c)(2)). Rebates are calculated based on a drug's national drug

¹ 42 U.S.C. § 1396r-8.

code (NDC), an 11-digit number that identifies the drug’s manufacturer, product type, and package size.

Although states are entitled to receive rebates on the prescription drugs they cover under the MDRP, it is difficult for them to exclude any FDA-approved drug from Medicaid coverage. States are required to reimburse all drugs from any manufacturer that has signed a rebate agreement, unless a state committee of pharmacists and physicians determines that a drug “does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome... over other drugs in the formulary.”² Regardless, states are empowered to establish preferred drug lists and use prior authorization as a way to negotiate rebates that supplement the statutory rebates required under the MDRP. Manufacturers are often willing to pay supplemental rebates for placement of their drugs on the state’s preferred drug list, which in turn protects them from prior authorization requirements and the related administrative burdens that tend to discourage providers from using non-preferred drugs. Prior authorization programs have broader applications. They can be used to ensure evidence-based prescribing and to support patient adherence programs. For this reason, even drugs on a state’s preferred drug list can be subject to prior authorization.

Recently, CMS issued a rule updating and modifying the agency’s prior Medicaid managed care regulations.³ The rule explicitly requires that MCOs with contracts that include prescription drug coverage must provide coverage of covered outpatient drugs that meets the coverage standards imposed by section 1927.⁴ Thus, all of the MDRP requirements applicable to covered outpatient drugs subject to fee-for-service reimbursement are equally applicable to covered outpatient drugs subject to managed care contracting.

Dynamics Created by the MDRP

For many in health care, the workings of drug purchasing and the MDRP in particular are difficult to decipher. The SMART-D Phase I research has yielded some insights about the incentives and market behaviors fostered by the MDRP. These insights could be useful to state Medicaid leaders and other policymakers as they craft alternative and value-based payment approaches.

- **Medicaid Best Price provisions do not always apply to Medicaid itself.** Drug manufacturers participating in the MDRP are required to give CMS and Medicaid access to the Best Price offered elsewhere. But, within certain bounds, Medicaid programs have latitude to negotiate voluntary agreements with drug manufacturers that do not create a new Medicaid Best Price threshold (CMS, 2016b). For example, supplemental rebates negotiated by or for the state are excluded from Best Price determinations. See *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)* for a more detailed discussion.

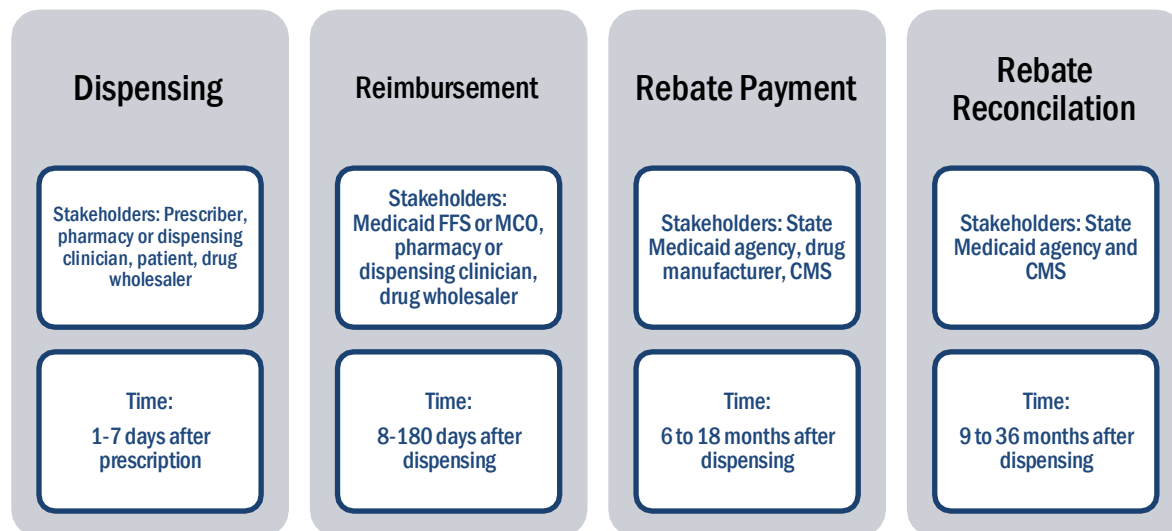
² SSA § 1927(d)(4)(C).

³ Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27,498 (May 6, 2016).

⁴ 42 C.F.R. § 438.3(s) (effective July 5, 2016).

- **The consumer price index penalty provision has an impact on price and purchasing behavior.** The consumer price index penalty provision in the MDRP is intended to protect Medicaid programs from price increases above the index. This provision, however, creates an incentive for drug manufacturers to set a high price upon entering the market because they cannot achieve price increases from Medicaid that are larger than the index after a drug enters the program. The consumer price index penalty can apply when a generic equivalent is first introduced, and in certain situations the penalty can reduce the price of the brand name drug to Medicaid so that it is less expensive than a new generic equivalent.
- **Federal rebates and state supplemental rebates are interdependent.** The Affordable Care Act increased the federal statutory rebate amount, with the increase allocated only to the federal government and not shared with states. This federal-only share interacts with state supplemental rebate agreements when supplemental agreements are negotiated to include a price floor. In essence, the states may lose a portion of their supplemental rebate to the federal government (OIG, 2014). Moreover, states bear the administrative burden and cost of billing drug manufacturers for the federal rebates, resolving any disputes regarding these rebates and then reconciling these amounts with CMS. In addition, states must share their supplemental rebates with the federal government based upon the federal Medicaid matching fund percentage set for each state.
- **Drug purchasing, reimbursement, rebates, and reconciliation are separate processes.** Three years or longer can elapse between dispensing a drug and reconciling rebates. There are four distinct stages to this process—dispensing, reimbursement, rebate payment, and reconciliation of rebates—each with a distinct set of stakeholders. Medicaid programs do not purchase drugs per se, rather they reimburse for drugs and then undertake rebate collection and reconciliation. This extended time horizon makes it difficult to calculate the financial impact of rebates because reconciliation occurs long after the patient receives the drug in question.

Figure 1: Time Horizon for Drug Dispensing to Medicaid Rebate Reconciliation

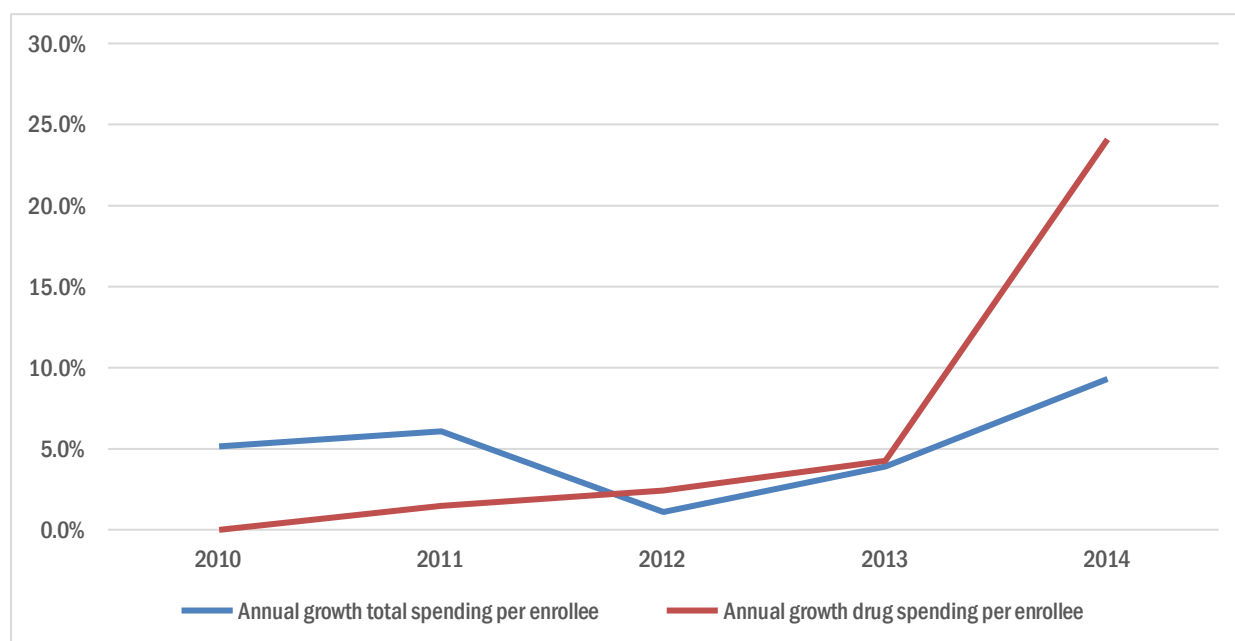


Section II: Medicaid Drug Spending and Cost Analysis

Overview of Medicaid Prescription Drug Spending

Between 2013 and 2014, the U.S. as a whole experienced a 12.2% increase in outpatient prescription drug costs—the largest increase in more than a decade. In this same yearlong period, spending by Medicaid on prescription drugs increased even more rapidly—14% in overall costs and 3.6% in expense per enrollee, with the total expenditures jumping from \$37.1 billion to \$42.3 billion (MACPAC, 2015a). CMS identified several drivers for the sudden growth in spending, including “increased spending for new medications (particularly for specialty drugs such as hepatitis C), a smaller impact from patent expirations, and brand-name drug price increases” (CMS, 2015d).

Figure 2. Percentage Change in Medicaid Spending per Enrollee



Source: MACPAC, 2015a

State Medicaid budgets have been drastically affected by the introduction of a small number of expensive specialty drugs. In a recent 50-state budget survey, a majority of states identified specialty and other high-cost drugs as a major factor in increasing financial outlays (NCBI, 2015). These high-cost therapies include hepatitis C antivirals, oncology drugs, cystic fibrosis agents, hemophilia factor drugs, and cholesterol medications (Smith et al., 2015).

Increases in Medicaid prescription drug expenses are also caused by spikes in prices and acquisition costs for certain kinds of generic drugs (Smith et al., 2015). Although there has been tremendous price escalation for some generic drugs, thus far the issue appears to be limited to

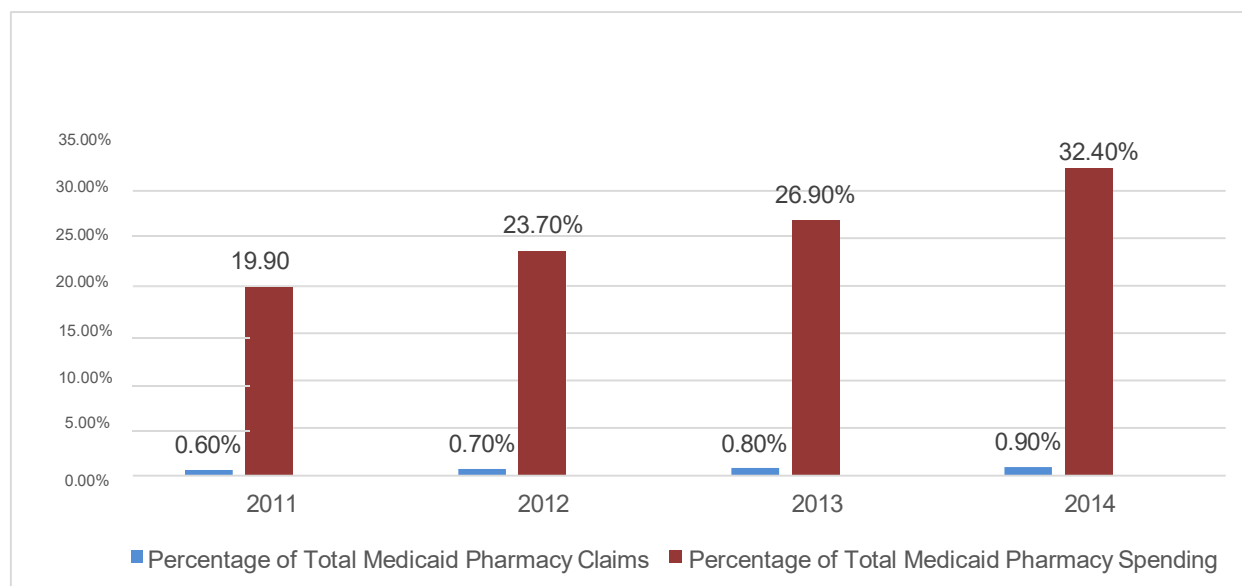
certain small market segments. A recent Department of Health and Human Services report (DHHS, 2016) attributes the rising costs in generic drugs to low competition in the market stemming from high barriers to market entry, mergers and acquisitions of pharmaceutical companies, or drug producers having exited the market. Yet, the costs of generic drugs remain small compared to brand-name drugs. In the Medicaid program, generic drugs accounted for 81% of prescriptions, but only 26% of expenditures (DHHS, 2016).

State Medicaid programs can pay directly for prescription drugs for some of their enrollees through fee-for-service delivery systems, but the programs increasingly rely on capitated arrangements with MCOs. Of the almost 64.8 million people covered by Medicaid in 2014, 43 million were enrolled in some kind of managed care, up 24% from 2013 (CMS, 2014). In a Medicaid state budget survey in October 2015, 35 states indicated that they “carve-in” prescription drugs to some degree in their contracted managed-care arrangements (Smith, et. al., 2015). According to the Medicaid and CHIP Payment and Access Commission (MACPAC), almost 60% of Medicaid prescription drug costs (\$14 billion) are covered through Medicaid managed-care plans.

Impact of High-Cost Specialty Drugs on State Medicaid Costs

High-cost specialty drugs are typically used to treat complex, often rare diseases. Many of these medicines require ongoing assessments of the therapeutic response and patient adherence, complex patient or provider training, specialized handling by pharmacy or individualized distribution networks, and continuous monitoring of side effects.

Figure 3. Medicaid Prescription Drugs over \$1,000 per Claim



Adapted from MACPAC, 2016

State Medicaid programs have spent billions of additional dollars on high-cost specialty drugs. A recent report on prescription drug spending indicates that high-cost specialty drugs accounted for

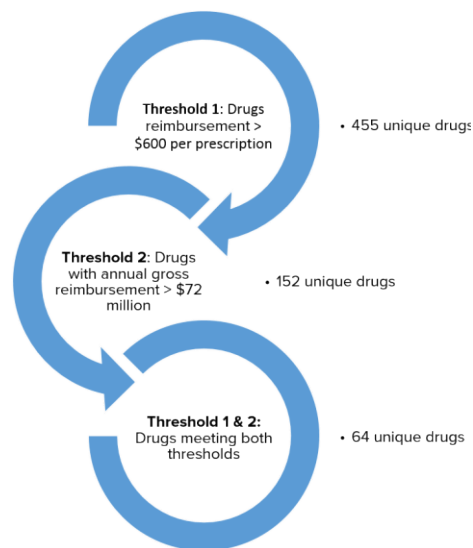
0.9% of claims but resulted in 32% of total spending (before rebates) in 2014 (See Figure 3: *Medicaid Prescription Drugs over \$1,000 per Claim*). Between 2011 and 2014, prescription drug expenditures by Medicaid grew by 12.2%, with prescription drugs accounting for \$42.3 billion in total spending in 2014 before rebates (CMS Drug Utilization Dataset, 2015).

SMART-D Analysis of “High-Cost” Specialty Drugs

Although there is anecdotal information about specific drugs driving up costs, this effect has not been isolated to a list of drugs or to Medicaid programs in particular. To that end, the SMART-D team developed a definition for “high-cost” drugs and undertook an analysis of these drugs. For the purposes of this study, high-cost, specialty drugs are defined as having the following characteristics:

- Reimbursement of more than \$600 per prescription; and
- Total Medicaid reimbursements of \$72 million per year.

After aggregating the CMS Medicaid State Drug Utilization Data across packaging, dosages, and labelers, the study team found 455 drugs for which average total reimbursements exceeded \$600 per prescription and 152 drugs for which Medicaid reimbursement, gross of rebates, exceeded \$72 million in the most recent four quarters for which data were available. There were 64 drugs



that met both criteria. See the Appendix for a list of the 64 drugs, their average total reimbursement per prescription, and their cost to Medicaid in fiscal year 2015.

In fiscal year 2015, these 64 drugs accounted for 9.3 million prescriptions or 1.5% of Medicaid prescriptions nationally. However, this group of drugs comprised a much larger share of

prescription drug spending: 32.6% of Medicaid drug reimbursement dollars or \$16.9 billion in Medicaid drug reimbursements (before rebates). This spending was for covered outpatient drugs and those that physicians administer. To contextualize this, consider that the Medicaid program spent an estimated \$538.4 billion for all services in 2015 (Kaiser, 2015b). **The estimated \$16.9 billion spent on these 64 high-cost drugs accounts for 3.1% of total national Medicaid spending for all services.**

This analysis demonstrates that a small number of high-cost specialty drugs are driving Medicaid drug spending and having an impact on states' Medicaid budgets. In the near future, there are at least 110 additional drugs in the pipeline that are likely to be high-cost and could have large effects on state Medicaid budgets. See the *SMART-D Economic Analysis* for details on the economic analysis and pipeline forecast.

Section III: Current Medicaid Environment and Drug Management Strategies

Importance of State Medicaid Program Configuration

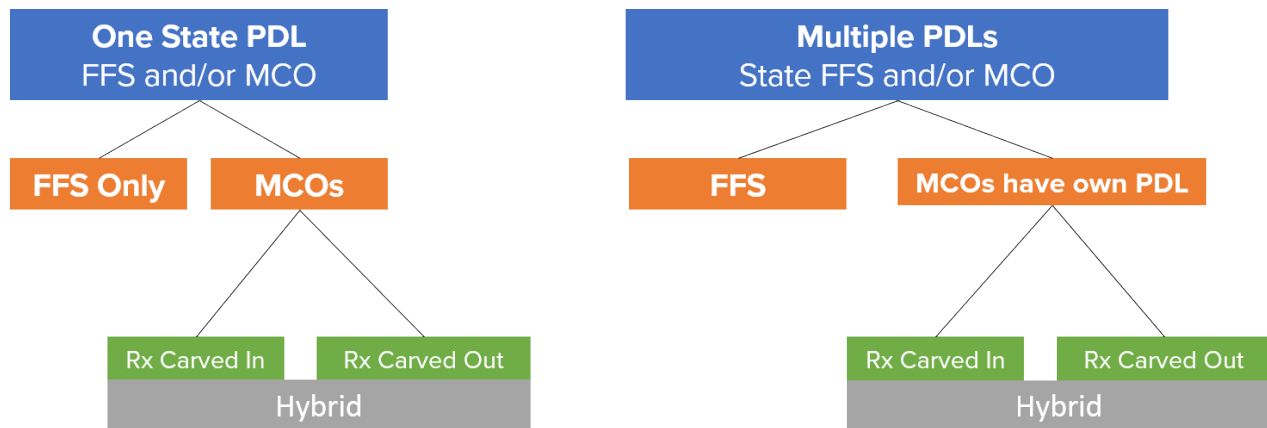
State Medicaid programs have different approaches to prescription drug coverage and payment, making it difficult for drug manufacturers and policymakers to identify a single intervention that is applicable to all states. This variability in approach is not limited to prescription drug purchasing. During stakeholder interviews conducted by SMART-D team members, drug manufacturers described state Medicaid program design as confusing and said that APM-centric classifications would help drug manufacturers approach individual states with more specific models.

Medicaid programs have many design elements that vary by state, but three elements are particularly important when considering alternative drug payment models:

1. *Preferred drug list.* Does the state have one Medicaid preferred drug list or multiple lists?
2. *Fee-for-service and managed care.* Does the state provide Medicaid benefits only through a fee-for-service program? Or does the state use fee-for-service and managed care?
3. *Pharmacy benefit configuration.* For states with Medicaid managed care, is the pharmacy benefit included (carved-in), excluded (carved-out), or a hybrid?

Figure 4, *State Categories for Alternative Drug Payment Models*, depicts how these elements occur across states. In SMART-D's Phase II planning process, the Center will work with state officials and drug manufacturers to design APMs that fit with these varying practices.

Figure 4: State Categories for Alternative Drug Payment Models



PDL = preferred drug list; FFS = fee for service; MCO = managed care organization;
RX = drug coverage; Hybrid = combination of carve-in and carve out

Other Program Attributes Affecting Drug Purchasing

State Medicaid programs have drug purchasing programs and pricing tools that must be figured into the development of alternative and value-based models, which include the 340B Drug Program, membership in prescription drug purchasing pools, management of clinician-administered drugs, and actual acquisition cost pricing.

340B Drug Program

The 340B Drug Program provides reduced-price prescription medications to certain health care facilities (referred to as “covered entities”) participating in the program. Drug manufacturers must offer discounts to 340B entities as a condition of Medicaid coverage of the drugs. Drugs included in the 340B program generally include outpatient prescription drugs and drugs administered by physicians in an outpatient setting (HRSA, n.d.).

State Medicaid programs could try to maximize drug savings through 340B prices, however, the program can be burdensome to administer. Most states’ program administrators expect 340B entities to bill the state at their actual acquisition cost for 340B drugs, which is generally lower than Medicaid drug prices. But because 340B prices are proprietary, states’ program administrators must rely on post-payment reviews to determine payment accuracy. In addition, it can be challenging for state officials to determine whether to submit claims from 340B providers for federal rebates or to exclude them to avoid duplicate discounts. Some states have created programs to take advantage of drug pricing offered through 340B and offer “whole person care” approaches, such as centers of excellence used to establish hemophilia treatment centers. In these states, Medicaid beneficiaries with hemophilia are required to receive care through these providers.

Purchasing Pools

States can negotiate supplemental rebates as a single state, through multistate purchasing pools, or both individually and through a purchasing pool, depending upon the drug(s) being purchased. As state Medicaid program directors seek to implement APMs, these purchasing pools are a key stakeholder. According to a CMS survey from December 2015, almost all states (47) participate in some type of supplemental rebate agreement (CMS, 2015b); 31 states have single-state supplemental rebate agreements with an effective date ranging from the 1980s through 2015. More than half of states (28) participate in multistate supplemental rebate agreements with effective dates ranging from 2004 through 2015; 12 of those states participate in both single-state and multistate supplemental agreements.

Clinician-administered Drugs

Clinician-administered medications often fall outside of states' (and other payers') traditional pharmacy management systems and are reimbursed through the payer's medical, rather than pharmacy, benefit. Because of the significant number of high-cost specialty drugs that are clinician-administered, states have undertaken efforts to more closely manage these drugs. These efforts include management and payment of clinician-administered medications through state pharmacy systems, as well as state efforts to expand pharmacy management of clinician-administered medications that continue to be billed and reimbursed as a medical benefit (Pinson, 2016). Nationally, across payer types, it is estimated that clinician-administered medications reimbursed through the medical benefit amount to 28% of overall drug spending, although many estimates of prescription drug spending omit these figures (ASPE, 2016a). An even greater proportion of specialty drug spending (55%) is estimated to be reimbursed through the medical benefit. Forecasts for the drug approval pipeline show significant activity for clinician-administered drugs, meaning that growth in this area is likely to continue.

Actual Acquisition Cost

In February 2016, CMS released a final rule requiring states to shift to actual acquisition cost reimbursement for drugs provided through outpatient pharmacies that are reimbursed on a fee-for-service basis. This rule covers only outpatient drugs, not physician-administered drugs. This shift to actual acquisition cost is intended to establish Medicaid pharmacy payments that more accurately reflect the amount that pharmacies pay for drugs. With the new federal rule, many states are now in the process of evaluating and determining plans to comply with these actual acquisition cost requirements by April 2017 (CMS, 2015a and 2016d).

Medicaid MCOs and the Pharmacy Benefit

Since 2011, many states with Medicaid managed care programs have shifted the pharmacy benefit into managed care. This shift has been driven by the new opportunity, authorized by the Affordable Care Act, for states to claim federal drug rebates on managed care pharmacy claims. Some states that had previously retained pharmacy as a fee-for-service benefit have begun to carve pharmacy into their managed care contracts. In addition, states have further increased pharmacy spending through managed care plans by expanding populations covered through

managed care (Pinson, 2016). Between 2011 and 2014, managed care drug spending grew from 14% to 47% of total gross Medicaid drug spending (MACPAC, 2016).

Increased responsibility for pharmacy expenditures has also generated greater scrutiny for MCOs in the areas of MDRP compliance, preferred drug lists, and care management. In recently issued Medicaid managed care regulations, CMS recognized the variability in how MCOs have implemented the pharmacy benefit for covered outpatient drugs, and therefore clarified that the requirements of the MDRP apply equally to both Medicaid fee-for-service and MCO prescription drug purchasing (42 C.F.R. § 438.3(s)). Historically, states have allowed some variability of preferred drug lists between their fee-for-service programs and MCOs. Some states might continue to allow this variability in preferred drug lists, while others might tighten alignment between the managed care and fee-for-service components of their programs (or among their contracted MCO's). In addition, state Medicaid programs are starting to hold MCOs accountable for care management to support adherence to drug regimens, particularly for high-cost drugs (Pinson, 2016).

Medicaid administrators have maximized the use of existing drug utilization management tools in their fee-for-service programs, particularly the use of prior authorization and preferred drug lists. To further align efforts to support patients with complex care needs, through health homes or primary care case management, state officials are exploring the use of drug case-management programs and centers of excellence to improve patient outcomes when using complex and high-cost drug regimens (Pinson, 2016). These tools are well-known to states, commercial payers, drug manufacturers, providers, and pharmacies and are described in more detail in the *Medicaid and Specialty Drugs: Current Policy Options* report (Pinson, 2016).

As Medicaid directors have maximized the use of current management tools, their interest in alternative drug payment models is increasing. In individual interviews, state Medicaid leaders expressed interest in adopting alternative payment models. Reasons for this interest include garnering better value for tax dollars spent, improving health outcomes and quality of care for patients, reducing waste, achieving better cost predictability, and meeting state budget requirements.

State Medicaid Political Environment

Drug purchasing stakeholders—states, MCOs, pharmacy benefit managers, drug manufacturers, federal policymakers, and others—are operating in a politically charged environment. Scrutiny of drug costs and patient access make it difficult for stakeholders to collaborate, take risks, and find new solutions. State officials are under intense pressure to balance their budgets, achieve broad patient access to treatment, avoid lawsuits, and deliver on the expectations of the state's executive and legislative branches. Alternate drug purchasing and payment models will not address all of these concerns. But APMs can be one of the tools states use to create fiscal predictability for high-cost drugs and to support patient access.

As the Center for Evidence-based Policy, state Medicaid programs, drug manufacturers, and other stakeholders navigate the process of developing APMs for Medicaid drug purchasing, it is critical to bear in mind the following sensitive dynamics:

- *Medicare has proposed changes for clinician-administered drugs.* A draft proposal from Medicare to test new models for reimbursing clinician-administered drugs within the Part B program has received both criticism and support (CMS, 2016c). The controversy associated with this Medicare proposal could make drug manufacturers, providers, pharmacies, and others more sensitive about changes to drug purchasing within state Medicaid programs.
- *Congress is making inquiries about rising drug costs.* The National Association of Medicaid Directors (NAMD) released a letter in March 2016 to the U.S. Senate Finance Committee underscoring Medicaid agency concerns with the limits of Medicaid's existing policy levers to negotiate drug prices and the need to move toward value-based payment models (NAMD, 2016). The Senate Finance Committee has been actively investigating pricing for hepatitis C drugs, and 14 members of the Committee have opposed the Medicare Part B test for clinician-administered drugs (U.S. Senate, 2016).
- *High-cost drugs have strained state Medicaid budgets.* The new drugs, such as hepatitis C drug therapies, have created midyear or mid-biennium Medicaid spending deficits for several states. In response to financial concerns from Medicaid managed-care plans, California, Florida, and Pennsylvania are among states that needed supplemental funds to support state and MCO expenditures for these drugs. These supplemental budget appropriations attract legislators' attention—and are an unsustainable method of managing drug costs.
- *State legislatures are scrutinizing drug cost and access.* A search of the National Council of State Legislatures prescription drug state database for calendar year 2016 found 183 bills in 40 states related to pharmaceutical pricing and payment and 81 bills in 30 states related to Medicaid drug use and cost (NCSL, 2016a). State Medicaid program directors know that state legislators are worried about drug costs and are under pressure from patient groups, MCOs, pharmacies, providers, drug manufacturers, and others.
- *Lawsuits against state Medicaid programs.* Numerous states are contending with class action lawsuits, or threats of such lawsuits, to expand patient access to hepatitis C drugs (Ollive, 2016). These lawsuits make state officials risk averse, whether the state has been sued or not, because the lawsuits allege violation of federal Medicaid statutory provisions that are applicable to all states. State Medicaid programs could end up in an adversarial position to patients and drug manufacturers, and efforts to collaborate could be hampered while lawsuits are active. Patients expect access to drugs they believe may improve and better manage their condition, but state Medicaid programs—and state governments as a whole—might not have the funds to meet this demand or the tools to ensure that the drugs deliver the results patients expect.

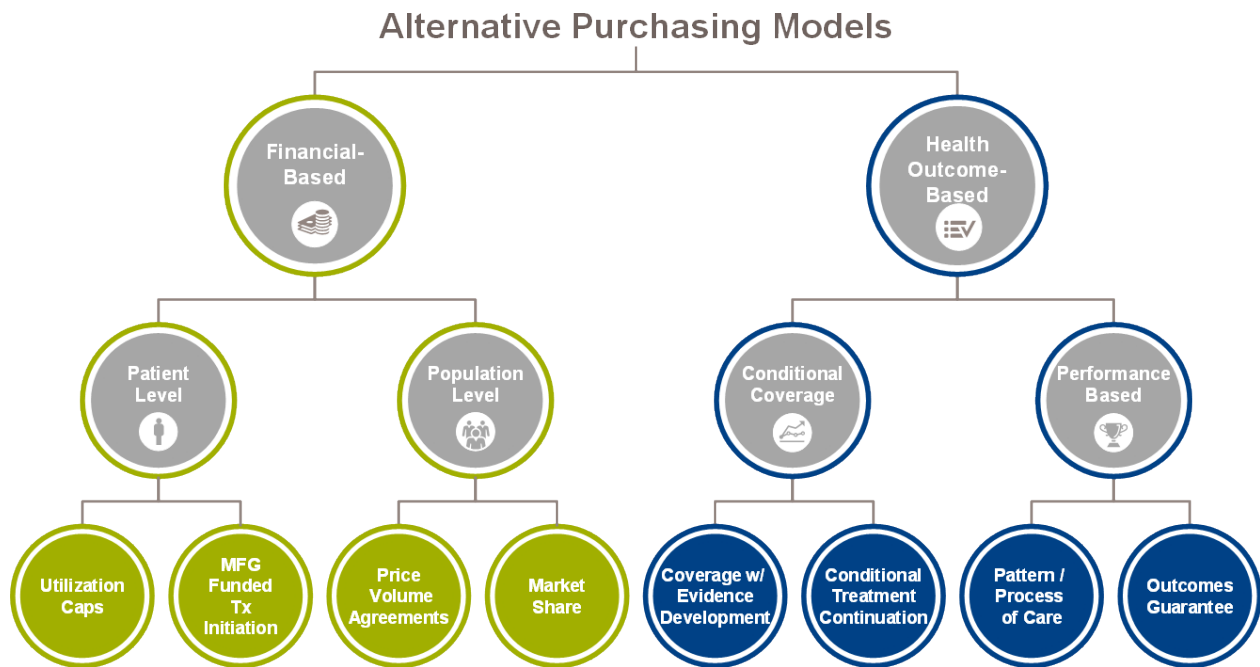
Section IV: Alternative Payment Models Used in U.S. Commercial and International Markets

To address the issues outlined above, state officials are exploring the potential of alternative payment models. An APM is a contract between a payer and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure. Currently, in Medicaid drug purchasing, the manufacturer sets a price for the drug wholesaler, pharmacy, or provider, and Medicaid reimbursement is based upon that price, with a subsequent, time-delayed reconciliation for rebates. An APM changes the price-setting dynamic and creates shared risk between the manufacturer and payer for an agreed-upon outcome measure.

APMs are generally financial- or health outcome-based. (See Figure 5: *Alternative Payment Models Taxonomy*.) Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. In health outcome-based APMs, payments for drugs are tied to predetermined clinical outcomes or measurements, or conditional coverage of the drug is offered while data regarding its clinical effectiveness is being collected. Financial-based APMs, which focus on lowering costs and expanding patient access, have proven to be easier to administer. APMs related to health outcomes require additional planning and data collection, but have the potential to increase the quality, value, and efficiency of treatments.

This summary report provides a short overview of APMs. An in-depth analysis of European and U.S. commercial market APMs, including examples and lessons learned, is provided in the *Alternate Payment Model Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)*.

Figure 5: Alternative Purchasing Models Taxonomy



Adapted from Garrison, 2014; INSEAD, 2014

APMs are less common in the United States than in many other parts of the world because purchasing power is distributed among a large number of entities rather than being centralized, as it is in most other developed countries. The extent to which APMs are used in the U.S. is not well-known because most programs involve confidential contracts between pharmaceutical manufacturers and MCOs or their pharmacy benefit managers. However, there are indications that the use of APMs might be growing.

APMs have been used in numerous European Union (EU) countries for many years and in some, such as Italy, they have become relatively commonplace. APMs in the EU have developed into a valuable tool for financial management, patient access, quality improvement, and successful negotiations with drug manufacturers. The types of APMs utilized in the EU vary across markets; currently, the majority of APMs in effect are financial-based. In Italy, outcomes-based agreements are more frequent. In some EU markets, the purpose of an APM is to take a drug that is deemed not cost-effective and make it cost-effective by reducing the price of the drug (e.g., a simple price-volume discount). In other markets where cost-effectiveness is not the primary criterion, outcomes-based APMs are used to limit coverage to specific indications while coverage evidence is gathered. See Table 1 for a summary of European APMs.

Table 1: Types and Percentage of Total APMs in Europe

Type	% of APMs	Description
Price-Volume	39.2%	The price of a drug is tied to the volume of utilization. Thresholds may exist where the price would gradually decrease (e.g., \$100 per patient for the first 10,000 patients; above that, \$80 per patient).
Data Collection	29.2%	Additional data collection is required for coverage so that either (a) a more thorough analysis of a health intervention can be conducted at a later time or (b) claimed cost savings can be validated in the real world.
Limited Access	13%	Access to a drug is more restrictive than the regulatory label. The covered group might include special populations perceived to receive the highest value from a treatment. Or certain health centers or specialists may be tasked with acting as “gatekeepers” of prudent use.
Conditional Coverage	5.6%	Coverage is provided under pre-specified conditions such as running additional clinical trials or publication of outcomes studies.
Results-based	5.4%	The price corresponds to an economic, clinical, or humanistic outcome, for example, if the price was only paid for patients who achieved the agreed-upon outcome.
Simple discounts	4.6%	A typically nontransparent price is provided to bring the affordability, cost-effectiveness, or value to an acceptable level. Generally used in markets that utilize cost-effectiveness-based coverage decisions, such as in the UK.
Price or dose cap	2.2%	The price may be capped per patient or dose. For instance, the payer would pay the same, singular, standard price for all patients, including those who remain on treatment for extremely long durations or require significantly higher doses.
Price match	0.8%	The price of a health technology is tied to a comparator benchmark for any given setting. Typically done when products are widely available but there is a large variation in price depending on the technology used.

(Fessario, 2013)

APM options that are available in other countries, where one entity negotiates for all citizens, are likely not directly transferable to the U.S., in either the private or public sectors, although these options have elements to borrow and experiences to learn from. In addition, state Medicaid programs have less leverage over manufacturers than private U.S. payers because of the requirements of the MDRP. They also encounter significant regulatory and technical challenges in the implementation of APMs. However, SMART-D interviews with a range of Medicaid officials showed a distinct interest in these programs, especially those related to health outcomes. Please see the SMART-D *Alternate Payment Model Brief* for an in-depth analysis of European and U.S. commercial market APMs, including examples and lessons learned. During Phase II of the project, concrete APM proposals will be developed for consideration by state Medicaid programs.

Section V: Legal Analysis and Pathways

To enable states and other interested stakeholders to move forward with APMs, SMART-D analysts conducted a detailed legal analysis of the MDRP and other federal and state laws relevant to Medicaid drug coverage and payment. SMART-D analysts identified seven legal pathways for developing APMs that appear to offer significant value-based opportunities for states: supplemental rebate arrangements, MCO contracting, MCO/340B covered entity partnerships, hospital-dispensed covered outpatient drugs, physician-administered drugs that fall outside the definition of a “covered outpatient drug,” Section 1937 alternative benefit plans, and Section 1115 waivers.

This summary report provides an overview of these seven pathways. Any state or stakeholder considering moving forward with APMs should review the entire SMART-D legal analysis: *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)*. This detailed report provides an overview of the MDRP and analyzes federal and state laws, including those associated with the MDRP, that affect a state Medicaid agency’s opportunity to establish an APM. It also provides a detailed discussion of the seven pathways and their strengths and weaknesses.

Seven Pathways

The approach taken in each of the legal pathways described below varies significantly. Pathway One builds upon supplemental rebates, a tool currently used by almost all Medicaid programs to gain additional rebate revenue from drug manufacturers. Pathway Two offers opportunities to implement payment pathways through managed care contracting. In states that include prescription drug benefits in managed care contracts, the ability to implement prescription drug APM opportunities under Pathway One or Pathway Two depends heavily on the ability of state officials and their MCO and pharmacy benefit manager partners to bring manufacturers to the negotiating table, unless state officials choose to carve one or more therapeutic drug classes out of their managed care contracts in order to negotiate directly with manufacturers. The remaining five pathways take a different approach. They are structured to allow states to negotiate value-based arrangements outside of the MDRP, either in whole or in part. Pathways Three and Four are based on explicit statutory exceptions to the MDRP. The MDRP statute only applies to “covered outpatient drugs,” so Pathway Five focuses on opportunities related to prescription drugs that fall outside the statute’s definition of a “covered outpatient drug.”⁵ Pathway Six relies on the Secretary of Health and Human Service’s authority to approve differing benefit packages for certain groups of Medicaid enrollees. Pathway Seven relies upon the Secretary’s authority to waive MDRP requirements or to interpret them more narrowly when in conflict with other Medicaid provisions.

⁵ SSA § 1927(a), (k)(2)-(3).

The seven pathways are not necessarily mutually exclusive. Some are more appropriate for a narrow class of drugs and others can be used more broadly. For example, Pathways One and Seven could be applied to virtually any group of drugs covered by a state plan, whereas Pathways Two and Three are limited to MCO-covered drugs, and Pathway Five applies only to physician-administered drugs. In designing a specific prescription drug APM, state officials could choose to combine two or more of the pathways detailed below or limit the APM to only one of the pathways.

Pathway One: Supplemental Rebate Arrangements

States, either individually or through multistate purchasing groups, are expressly authorized under the MDRP to enter into supplemental rebate agreements with manufacturers. Under these negotiated agreements, manufacturers pay rebates that supplement the statutory rebates they are obligated to pay as part of their MDRP participation. Apart from being subject to CMS approval, supplemental rebate arrangements are largely unregulated, allowing states and manufacturers to negotiate terms and conditions designed to implement health outcome-based and financial-based APMs. Pathway One capitalizes on this opportunity by using the tools underlying supplemental rebate arrangements (including prior authorization, preferred drug lists, generic and therapeutic substitution, among others) to launch APM's. CMS expressly encourages use of value-based arrangements as part of supplemental rebate agreements between Medicaid and drug manufacturers in a July 2016 program notice (CMS, 2016b).

Since enactment of the Affordable Care Act, states have been entitled to receive MDRP statutory rebates on covered outpatient drugs paid by Medicaid MCOs, not only those reimbursed on a fee-for-service basis. Extension of the MDRP to drugs purchased through MCOs, most of which are reimbursed by pharmacy benefit managers on behalf of MCOs, means that states now have an opportunity to negotiate supplemental rebates on such drugs.

Pathway Two: MCO Contracting

Pathway Two is designed to take advantage of the greater flexibility and experience that Medicaid MCOs offer in negotiating alternative payment or value-based arrangements with manufacturers and providers. Because actual acquisition cost reimbursement under the covered outpatient drug rule does not apply to drugs purchased through MCOs, they have more leeway than states in reimbursing covered outpatient drugs so that pharmacies are rewarded for engaging in outcome-based best practices. Such authority allows MCOs to establish alternative payment models for retail drugs that states are precluded from pursuing in the fee-for-service setting. Pathway Two is also structured to capitalize on the significant experience that pharmacy benefit managers have in negotiating with manufacturers on behalf of private non-Medicaid payers, to the extent that an MCO has subcontracted with a pharmacy benefit manager. Under Pathway Two, states would delegate to the pharmacy benefit managers the task of negotiating the states' supplemental rebates in lieu of the pharmacy benefit managers' own rebates, and these arrangements could mirror the structure of financial- or health outcome-based APM's that a pharmacy benefit manager might negotiate for a commercial health plan. This approach would require delicate

negotiations in contracting with MCOs because the terms of an MCO-based supplemental rebate program would have to be incorporated into the MCO's subcontract with the pharmacy benefit manager.

In considering the viability of an APM based on Pathway Two, a state must consider at the outset how to structure the pharmacy benefit managers' supplemental rebate arrangement in a manner that does not adversely affect a manufacturer's Best Price. Pharmacy benefit manager rebates are historically included in a manufacturer's Best Price calculations, so it would be understandable if most manufacturers hesitated to entertain a pharmacy benefit manager supplemental rebate proposal for fear of setting a new Best Price. In this case, though, the rebates would be passed through to the Medicaid program, either directly to the state Medicaid agency or indirectly through the MCO. The rebates would therefore qualify for the explicit Best Price exemption applicable to pharmacy benefit manager rebates that are not designed to adjust prices at the retail or provider level.

Pathway Three: MCO/340B Covered Entity Partnerships

Section 1927(j) of the Social Security Act establishes two explicit MDRP exemptions for covered outpatient drugs that, in the absence of the exemptions, would be subject to the full range of MDRP requirements. The first exemption, found in 1927(j)(1) (hereafter the (j)(1) Exemption), was created to protect drug manufacturers from providing both a discount and an MDRP rebate on a drug purchased through the federal 340B drug discount program. It states that manufacturers are not required to pay an MDRP rebate on drugs purchased through the 340B program and paid for by an MCO.⁶ The (j)(1) Exemption covers the entire MDRP statute, not only the rebate requirements.⁷ The second exemption was established under Section 1927(j)(2) (hereafter the (j)(2) Exemption) and serves as the basis of Pathway Four, which is discussed in the next section.

The (j)(1) Exemption only applies to drugs purchased through the federal 340B drug discount program, and therefore the scope of Pathway Three is limited to this cohort of 340B activity. The 340B program allows certain types of safety net providers, called "covered entities," to purchase covered outpatient drugs at substantially discounted prices. Often these providers pay less than the amount that state Medicaid agencies pay, even after the MDRP rebate is factored in. 340B covered entities include federally qualified health centers, disproportionate-share hospitals (which serve a high proportion of Medicaid and uninsured patients), children's hospitals, clinics funded by the Ryan White HIV/AIDS Program, and hemophilia treatment centers, among other safety net providers. Some of these providers treat large and diverse Medicaid populations, some focus on specific conditions, and some do both.

Importantly, besides protecting manufacturers from the duplicate discount risk associated with 340B drugs paid for by MCOs, the (j)(1) Exemption removes such drugs entirely from regulation under the MDRP. The (j)(1) Exemption therefore creates an opportunity for state Medicaid

⁶ SSA § 1927(j)(1).

⁷ *Id.*

agencies to experiment with alternative payment models outside of the MDRP's constraints. The (j)(1) Exemption is triggered when two events coincide: (1) a covered entity purchases a drug through the 340B program, and (2) the drug is "dispensed" by a Medicaid MCO.⁸ CMS has interpreted the word "dispensed" to mean "paid for."⁹ If the exemption is triggered, the drugs in question "are not subject to the requirements" of the MDRP statute.¹⁰

Perhaps the most significant advantage of Pathway Three is that the drugs in question are already purchased at discounted prices that approximate, and in many cases are less than, the prices the state pays after receiving the MDRP rebate. In that sense, the pathway is less dependent on replacing the MDRP rebate revenue. States can therefore focus their negotiations with manufacturers on patient outcome and quality of care measures and worry less about the size of their rebates. This pathway should also reduce the state's administrative costs in seeking the rebate and managing manufacturer rebate disputes.¹¹

Pathway Three offers several additional advantages. As a result of the (j)(1) Exemption, MCO 340B drugs are not regulated under the MDRP. State Medicaid program directors are therefore liberated from the MDRP requirements preventing them from setting different prescription limits, varying rebate amounts based on indication, linking payment to a drug's clinical performance, or establishing closed formularies. States and manufacturers have broad latitude to negotiate creative and mutually beneficial agreements. There is an explicit Best Price exemption for 340B drugs, so the risk of establishing a new Best Price should not interfere with negotiations.¹² The pathway also allows for innovative pharmacy payment models because the drugs would not be subject to actual acquisition cost reimbursement standards. Lastly, CMS approval would not be required unless the state chooses to couple the pathway with broader reforms requiring a state plan amendment or waiver.

Pathway Four: Hospital-Dispensed Covered Outpatient Drugs

In the same way that Pathway Three is built around the (j)(1) Exemption, Pathway Four is based on the second MDRP exemption, the (j)(2) Exemption. The exemption applies to hospitals that dispense covered outpatient drugs using formulary systems and bill Medicaid at no more than the hospital's purchasing cost for the drug.¹³ The statute specifies that the state's Medicaid plan "shall provide" that a hospital billing such drugs "shall not be subject to the requirements of this section."¹⁴ Although the statute could be read to exempt hospitals from the MDRP rather than the drugs billed by hospitals, CMS has interpreted the (j)(2) Exemption to mean that the drugs

⁸ SSA § 1927(j)(1).

⁹ See Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,546.

¹⁰ SSA § 1927(j)(1).

¹¹ Note that some administrative burden would remain to remove the 340B claims from the other rebate claims. Also, the availability of the model would be both payer-dependent (only when an MCO is the payer) and drug-dependent (only when 340B drugs are used).

¹² Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,256.

¹³ SSA § 1927(j)(2).

¹⁴ *Id.*

themselves are not subject to the rebate requirement.¹⁵ Virtually every hospital buys drugs using a formulary. As long as hospitals bill the drugs at no more than their purchasing costs—a requirement states could add to their state plans—such drugs would appear to fall within the (j)(2) Exemption.

The scope of the (j)(2) Exemption is not entirely clear, and CMS has only interpreted it in response to litigation.¹⁶ On the one hand, the (j)(2) Exemption is a clean slate, and CMS is not restricted by how it has viewed the provision previously. On the other hand, the public has no way of knowing whether CMS might be willing to allow states to employ the exemption.

Subject to clarification with CMS, Pathway Four has the potential to offer many of the advantages of Pathway Three described above, but only for drugs obtained through a hospital formulary. Because the manufacturer rebate arrangements would not be governed under the MDRP, rebates could be indication-specific and adjustable. Value-based provider payment innovation would also be possible for hospital physician-administered drugs. Importantly, most of the hospitals serving large numbers of Medicaid beneficiaries are likely to be enrolled in the 340B Program. By only having to pay hospital purchasing costs, states could reduce their drug expenditures to levels comparable to or below their current expenditures under the MDRP, which in turn would allow them to pursue health outcome-based arrangements with drug manufacturers that do not involve paying large rebates.

Pathway Five: Physician-Administered Drugs That Fall Outside the Definition of “Covered Outpatient Drug”

The MDRP, and the restrictions it imposes on drug coverage, only apply to “covered outpatient drugs.” The definition of covered outpatient drugs is broad, encompassing all prescription drugs, biologics (other than vaccines), and insulin.¹⁷ The definition, however, is narrowed by a “limiting definition,” which excludes physician- and clinician-administered drugs. This limiting definition provides a potential opportunity for Medicaid agencies to experiment with APM arrangements, free of the constraints of the MDRP.

The scope of Pathway Five is narrower than that of the other six pathways because it only applies to drugs that are not separately billed and reimbursed within a state’s Medicaid program. Virtually every drug dispensed in the retail setting is separately billed and paid for by Medicaid, so Pathway Five would be limited to drugs administered by a physician or a professional operating under a physician’s supervision such as a nurse. States have a strong incentive to consider these physician-administered drugs as covered outpatient drugs because they would then become eligible for rebates under the MDRP. For this reason, Pathway Five might be

¹⁵ See CMS, MDRP Release No. 153 (Oct. 16, 2009), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/state-rel-153.pdf> see also Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

¹⁶ Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

¹⁷ SSA § 1927(k)(2).

appealing for only a small group of physician-administered drugs, although that category of drugs may be growing. A state would have to be willing to surrender its MDRP statutory and supplemental rebates in exchange for the right to negotiate an APM arrangement outside the limitations of the MDRP. State Medicaid officials would have to feel confident that, by applying a closed formulary or using promising payment strategies not permitted under the MDRP, they could negotiate rebates comparable to those available through the MDRP and/or establish health outcome-based arrangements that are sufficiently attractive to justify lower rebate amounts.

As far as the SMART-D team knows, Pathway Five is untested, probably because it runs counter to the prevailing practice (among states and CMS) of trying to qualify as many drugs as possible as covered outpatient drugs in order to apply clinical prior authorization criteria and maximize rebate revenue under the MDRP. The approach proposed in Pathway Five works if the drugs in question can be paid for as part of a broader set of services. The most suitable drugs might be those for which the value of the forfeited MDRP rebates is outweighed by the potential benefits of improving patient outcomes, avoiding waste, reducing the use of costly health services such as hospitalizations, or achieving other value-based goals. This pathway could therefore be used in conjunction with provider payment models centered on specific disease states or episodes of care involving the administration of drugs that generally have low rebate value but high patient-outcome potential. Provider payments could be structured to create an incentive for value-based patient care because they would not be subject to actual acquisition cost limitations.

Pathway Six: Section 1937 Alternative Benefit Plans

Enacted under the Deficit Reduction Act of 2005, and amended in 2010 by the Affordable Care Act, section 1937 of the Social Security Act provides states with the flexibility to develop Medicaid benchmark or benchmark equivalent coverage, now referred to by CMS as “alternative benefit plans” (ABPs).¹⁸ States are required to provide Medicaid expansion populations with a benefit package in accordance with ABP standards,¹⁹ and in addition, may develop ABPs for targeted populations or geographic regions of a state.²⁰

¹⁸ SSA § 1937(a); CMS, State Medicaid Director Letter 12-003 (Nov. 20, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf>; CMS, *Alternative Benefit Plan Coverage*, <https://www.medicaid.gov/medicaid/benefits/alternative-benefit-plan-coverage/index.html> (last visited June 20, 2016). The following coverages are considered to be benchmark coverage: (1) The standard Blue Cross/Blue Shield preferred provider option service benefit plan offered under the Federal Employee Health Benefits program; (2) a coverage plan that is offered and generally available to the state’s employees; (3) a health insurance coverage plan that is offered by an health maintenance organization (HMO), and “has the largest insured commercial, non-Medicaid enrollment of covered lives of such coverage plans offered by such a [HMO] in the State involved”; and (4) a “Secretary-approved” plan. SSA § 1937(b)(1); 42 C.F.R. § 440.330.

¹⁹ SSA § 1902(k)(1).

²⁰ CMS, State Medicaid Director Letter 12-003 (Nov. 20, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf>; CMS, *Alternative Benefit Plan Coverage*, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html> (last visited June 20, 2016).

Alternative benefit plans must cover essential health benefits (EHBs) as defined by 10 categories of health care services, including prescription drugs.²¹ For prescription drugs, Medicaid ABP/EHB standards are defined in reference to EHB standards for health insurance exchange plans requiring coverage of the greater of (1) one drug in every United States Pharmacopeia category and class; or (2) the “same number of prescription drugs in each category and class as the EHB-benchmark plan.”²² In addition, to the “extent states pay for covered outpatient drugs under their [ABP’s] prescription drug coverage, states must comply with the requirements under section 1927 of the [Social Security] Act.”²³ In the comment and response preamble to the final Medicaid EHB rule, there is a lengthy discussion of the application of section 1927 of the Social Security Act to Medicaid ABPs and EHB coverage standards for prescription drugs.²⁴ Initially, in the proposed Medicaid EHB rule, CMS suggested a blanket application of Medicaid section 1927 outpatient drug requirements to Medicaid ABPs.²⁵ In the final rule, however, CMS retracted this position, explaining that it was “over-inclusive,” and clarified that “section 1927 requirements do not apply to ABPs to the extent that they conflict with the flexibility under section 1937 of the Act for states to define the amount, duration, and scope of the benefit for covered outpatient drugs.”²⁶

Therefore, unlike traditional Medicaid, Medicaid ABPs are not required to cover all drugs from manufacturers that have signed a federal rebate agreement. The flexibility for ABPs allowed under section 1937 trumps section 1927 requirements, and ABPs can design a formulary in

²¹ SSA § 1937(b)(5). The 10 categories of health care services are:

- (1) Ambulatory patient services;
- (2) Emergency services;
- (3) Hospitalization;
- (4) Maternity and newborn care;
- (5) Mental health and substance use disorders, including behavioral health treatment;
- (6) Prescription drugs;
- (7) Rehabilitative and habilitative services and devices, except that such coverage shall be in accordance with § 440.347(d);
- (8) Laboratory services;
- (9) Preventive and wellness services and chronic disease management; and
- (10) Pediatric services, including oral and vision care, in accordance with section 1905(r) of the Act.

42 C.F.R. § 440.347; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302(b), 124 Stat. 119, 163-65 (2010). The state must also adhere to other applicability and coverage requirements. SSA § 1937(a)(2)(B), (4), (6), (7); 42 C.F.R. §§ 440.315, 440.320, 440.335, 440.345, 440.350, 440.360, 440.365, 440.390, 440.395.

²² 42 C.F.R. § 440.347(a); 45 C.F.R. § 156.122(a)(1).

²³ 42 C.F.R. § 440.345(f).

²⁴ Medicaid and Children’s Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. 42,160, 42,219-24 (Jul. 15, 2013).

²⁵ Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 Fed. Reg. 4,594, 4,631 (Jan. 22, 2013).

²⁶ Medicaid and Children’s Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. at 42,219.

compliance with the EHB standards noted above for health exchange plans. After a drug has been put on the formulary for an alternative benefit plan, then the plan and the drugs covered must comply with the MDRP as laid out within section 1927.

Pathway Seven: Section 1115 Waivers

Section 1115 of the Social Security Act grants the Secretary of the Department of Health and Human Services the authority to approve experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid and children's health insurance programs.²⁷ Under section 1115 authority, the Secretary can waive federal Medicaid requirements set forth in section 1902 of the Social Security Act governing the state plan.²⁸ This authority also allows the Secretary to provide federal financial participation for costs of the demonstration project that would not otherwise be included as matchable expenditures under section 1903 of the Social Security Act.²⁹

Pathway Seven seeks to take advantage of the opportunities authorized under section 1115 of the Social Security Act to implement various APM initiatives. The most significant advantage of Pathway Seven is that the states are afforded considerable flexibility in designing an APM that furthers value-based goals and the objectives of the Medicaid program. Notably, section 1115 authorizes the Secretary to waive section 1902(a)(54) of the Social Security Act, which specifies that any state providing medical assistance for covered outpatient prescription drugs through its Medicaid program must comply with the applicable requirements of section 1927 of the Social Security Act.³⁰ The reference to section 1927 in section 1902 provides the authority for the Department of Health and Human Services to waive provisions of the MDRP in Medicaid demonstration projects.

To date, Department of Health and Human Services waivers of section 1927 through section 1115 demonstration waivers have been limited. A March 2016 search of state section 1115 demonstration waivers identified only six states—Arizona, Arkansas, Iowa, Michigan, New Hampshire, and Tennessee—whose waivers extended to a provision within section 1927. An advantage of Pathway Seven is that it could complement other pathways presented in this report, providing authority to implement an innovative arrangement that wouldn't otherwise be permissible. However, this Pathway does have one considerable disadvantage: the state must first apply for and obtain CMS approval of the section 1115 waiver. The state must ensure that its demonstration application contains all of the required elements,³¹ including a requirement that

²⁷ SSA § 1115.

²⁸ SSA § 1115(a)(1).

²⁹ SSA § 1115(a)(2)(A).

³⁰ SSA § 1902(a)(54).

³¹ *Id.* § 431.412; CMS, State Medicaid Director Letter 12-001 (Apr. 27, 2012), <https://www.medicaid.gov/federal-policy-guidance/downloads/sho-12-001.pdf>.

the proposed demonstration be budget-neutral, such that “during the course of the project Federal Medicaid expenditures will not be more than Federal spending without the waiver.”³²

³² CMS, *Section 1115 Demonstrations*, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html> (last visited June 19, 2016).

Section VI: Barriers and Practical Constraints

In addition to the MDRP, there are some practical constraints that state Medicaid agencies might encounter when developing or implementing alternative prescription drug purchasing and payment programs. These constraints relate to state officials' ability to solicit stakeholder engagement and cooperation, navigate regulatory approvals, and deploy the data and analytics infrastructure necessary to assess APM-related outcome measures.

Stakeholder Engagement and Cooperation

To successfully implement APMs, state Medicaid agencies need to work with stakeholders to gain their buy-in, as with other delivery system or payment reform initiatives. This buy-in helps create a sufficient volume of Medicaid enrollees for any APM, which is important to generating drug manufacturer interest. States may need to negotiate with the prescribers, providers, pharmacies, hospitals, pharmacy benefit managers, and MCOs to adjust their operations. They might also venture into fields in which stakeholders already have complicated arrangements among themselves, such as those between an MCO and its contracted pharmacy benefit manager. Organizations representing Medicaid enrollees will need to be consulted as well.

Managed care organizations (MCOs) are a key stakeholder. Many state Medicaid programs contract with MCOs to manage the pharmacy benefit for their enrollees. Some states have strict pharmacy coverage and management policies that must be followed; others provide MCOs with more flexibility to manage pharmacy benefits. As MCOs take more responsibility for managing the pharmacy benefit, their input to any potential APM becomes a larger consideration. For example, an agreement between a state Medicaid program and a manufacturer that provides a drug preferred access status could potentially clash with the utilization management efforts of MCOs (e.g., the MCO's preferred drug list), creating challenges for the state and the MCOs in managing the pharmacy benefit.

States that participate in multistate purchasing pools must also consider whether engaging in an APM with a manufacturer would conflict with or support the efforts of the purchasing pool program. The SMART-D legal analysis has found pathways that would work both within and outside of existing supplemental rebate constructs. A consistently cited concern of state Medicaid agency staff members was whether an APM would be able to accommodate the supplemental rebates negotiated through the purchasing pools; that is, would states have to choose between receiving the supplemental rebate and engaging in an APM? In the latter case, many state Medicaid representatives expressed reluctance to forgo supplemental rebate revenue because programs rely upon that revenue and APM fiscal results are less certain.

Health care providers are another stakeholder group that must be engaged with APM development. Medicaid program staff members interviewed by SMART-D were understandably concerned about successfully engaging providers, especially if APMs require physicians to submit clinical data. In a health outcome-based agreement, in which rebates or payments from the

manufacturer might be tied to a predefined clinical outcome, physician involvement is most likely a necessity. Physicians might not be willing to collect and send data regarding patient outcomes unless an incentive were provided. States can use existing prior authorization tools and the Healthcare Effectiveness Data and Information Set (HEDIS) quality measures, but both approaches have some limitations well-known to state officials.

Regulatory Approvals

As publicly funded government entities, state Medicaid programs are constrained by certain legal statutes and regulations at both the federal and state level. An in-depth analysis of these legal constraints, including potential legal pathways to implement APMs, is provided in the *Medicaid Policy Options to Manage High-Cost Specialty Drugs* issue brief. Two issues should be emphasized: CMS approvals and state-specific statutes and regulations.

The Medicaid program is jointly administered by states and the federal government, so federal support is important when pursuing new models. Depending on the value-based or alternate payment approach, implementation will likely require varying levels of federal oversight and/or approval. Many APM strategies will need approval from CMS through the submission of a Medicaid state plan amendment or waiver. Prior authorization programs, purchasing pools, payment changes, and manufacturer-risk sharing arrangements generally need approval from CMS through a state plan amendment. Regardless of formal approval, the political reality is that states will need a high degree of confidence that CMS will not reject an APM strategy or render their pursuit of APMs moot.

State statutes and regulations will need to be considered when implementing an APM. If a state has an “any willing pharmacy” or “dispense as written” law that prevents certain alternative payment arrangements, new legislation could be necessary to dismantle implementation barriers.

Lack of Clinical Data and Other Information

Medicaid program administrators might be constrained by the lack of clinical effectiveness and outcomes data available to implement and track APMs and their outcomes. Medicaid agency interviewees had mixed opinions on whether health outcome-based APMs were feasible given their current data and analytics capabilities. In contrast to EU countries with centralized registries, state Medicaid programs are potentially less able to track and analyze patient outcomes, making administration of health outcome-based APMs challenging. In addition to possible deficiencies in data collection, other issues include disconnects between various data systems, limited data analysis capabilities, and potential legal hurdles to storing and sharing data.

Some state Medicaid agencies contend with Medicaid management information systems that were implemented more than 30 years ago. These systems may not be able to record, codify, and report needed data for an APM. Moreover, these systems sometimes have limited ability to integrate data from external data sources such as electronic health records, laboratory information systems, and health information exchanges. Important health outcome data is often collected by external

systems, so administrators could encounter significant delays in gathering and aggregating the data and in conducting analyses.

There is a possibility that capabilities for collecting and tracking patient data can be improved through upgraded IT infrastructure, but the ability to analyze, store, and share data within the confines of regulatory requirements remains a concern. Some state Medicaid representatives interviewed have the necessary analytics teams in place, whereas others rely on third-party vendors. Still others anticipate encountering issues in securing the appropriate resources for rigorous data analysis.

Section VII: Concluding Remarks and Next Steps

APMs are an intriguing tool, but they are only one of many levers that a state needs to create changes in patient outcomes or prescription drug spending. APMs can support and reinforce a state's strategic direction toward value-based payment. However, states will need to ensure necessary capacity to implement APMs, negotiate agreements, track outcomes, and identify high-yield opportunities. When thoughtfully deployed, APMs can help states align incentives between their medical and pharmacy benefits. APMs can catalyze change within an existing framework by including drugs in total cost of care models, capitation arrangements, and care management models.

Realistically, states may not save money with their first APM implementation. An initial APM will require an investment of time and resources to design, implement, and monitor; the immediate state level outcomes are likely to be improved patient access and budget predictability. But if APMs are viewed in terms of the Triple Aim—improving the experience of care, improving the health of populations, and reducing per capita costs of health care—states could see important potential benefits, including improvements to patient outcomes and the health of populations, along with reductions in per capita costs of health care over time (Berwick, 2008). APMs can also provide a measure of control over prescription drug spending. States can engage in voluntary agreements with drug manufacturers that fit their state's goals, their Medicaid program configuration, and specific patient populations. Financial-based APMs will give state budgets a level of predictability that they currently lack.

This report summarizes the findings of research conducted under Phase I. Phase II of the SMART-D Initiative will seek to develop an APM implementation plan for participating states that includes the following:

- *Development of alternative purchasing models.* Drawing on international and commercial APMs and following the legal pathways identified in Phase I, the Center will work with states to develop a strategic approach and an APM implementation plan for their state. Some APMs will likely be narrow in focus, looking at one drug or drug class and a simple health outcome measurement approach. Some might be bundled into larger value-based reform efforts.

- *Readiness assessment tool.* APM implementation will require states to develop new capabilities or extend existing capacities. To enable states to evaluate their readiness for this work, the Center will develop an assessment tool, which could include the categories of data gathering and outcome tracking, stakeholder relations, state political environment, state budget situation, current value-based work, number of PDLs, MCO contractual arrangements, and Medicaid agency staffing.
- *Legal and policy tools.* APM implementation within a given state will require specific policy analysis and legal support. The Center anticipates that state Medicaid officials may need assistance to assess which legal pathways best accommodate the APM strategies they would like to pursue, develop model contract language and confidentiality agreements, prepare a Medicaid state plan or waiver amendment for submission to CMS, engage in ongoing communication with CMS, and analyze state-specific statutes and regulations.
- *Outreach to and engagement with drug manufacturers.* Successful, voluntary models require that drug manufacturers feel enfranchised in the model's development and see a value proposition for their companies and their drugs. Outreach is necessary to other stakeholders as well, including health care providers, MCOs, pharmacy benefit managers, and state legislators.

APMs hold strong promise as a tool to support Medicaid value-based reform efforts, but not every state will be able to undertake such a project. The Center will work with State Medicaid Officials to help them identify APMs, assess readiness, and develop the legal and policy structures for implementation. These Phase II efforts will result in identification of several states that are ready to implement APM pilots with drug manufacturer partners in Phase III.

Appendix

High-cost specialty drugs are typically used to treat complex, often rare diseases. Many of these medicines require ongoing assessments of the therapeutic response and patient adherence, complex patient or provider training, specialized handling by pharmacy or individualized distribution networks, and continuous monitoring of side effects. For the purposes of this study, high-cost, specialty drugs are defined as those that have reimbursement of more than \$600 per prescription and total Medicaid reimbursements of \$72 million per year. The 64 drugs listed below meet this two-part definition.

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription ³³	FY 2015 Gross Cost to Medicaid	New Since 2012?
1	Abilify	900	2,746,712,000	NO
2	Harvoni	28,300	1,540,228,000	YES
3	Humira	3,500	693,300,000	NO
4	Truvada	1,400	667,395,000	NO
5	Sovaldi	24,400	643,446,000	YES
6	Atripla	2,200	596,965,000	NO
7	Latuda	800	555,665,000	NO
8	Omnitrope, Genotropin, Humatrope, Zomacton, Serostim, Saizen, Norditropin	3,500	485,258,000	NO
9	Invega	1,500	472,003,000	NO
10	Stribild	2,600	413,342,000	NO
11	Enbrel	3,000	396,948,000	NO
12	Prezista	1,200	336,474,000	NO
13	Complera	2,200	293,270,000	NO
14	Copaxone, Glatopa	5,300	276,151,000	NO
15	Advate	19,100	270,617,000	NO
16	Neulasta	3,600	248,221,000	NO
17	Reyataz	1,300	240,591,000	NO

³³ Prescriptions are most commonly written for 30 days. In some circumstances, prescriptions can be 15, 60, or 90 days. The dataset used for this analysis does not provide data regarding days per prescription.

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription ³³	FY 2015 Gross Cost to Medicaid	New Since 2012?
18	Synagis	2,300	240,280,000	NO
19	Invega	1,000	221,648,000	NO
20	Novoseven	81,500	219,484,000	NO
21	Isentress	1,200	219,434,000	NO
22	Pulmozyme	3,300	202,733,000	NO
23	Tecfidera	5,300	199,262,000	YES
24	Vimpat	700	184,365,000	NO
25	Viread	900	183,553,000	NO
26	Gleevec	9,100	173,214,000	NO
27	Tivicay	1,400	166,653,000	YES
28	Remicade	3,500	150,666,000	NO
29	Herceptin	3,100	150,052,000	NO
30	Avastin	1,300	148,259,000	NO
31	Jadenu, Exjade	6,400	147,722,000	NO
32	Gammaplex, Flebogamma Dif, Vivaglobin, Gammagard, Bivigam, Privigen, Carimune, Gammagard S/D, Hizentra	3,100	146,327,000	NO
33	Kogenate Fs, Novoeight, Kovaltry, Nuwiq, Xyntha	21,500	142,953,000	NO
34	Creon, Ultresa, Viokace, Pertzye, Zenpep, Pancreaze	1,000	140,508,000	NO
35	H.P. Acthar	43,700	138,727,000	NO
36	Epzicom	1,200	137,677,000	NO
37	Onfi	900	135,133,000	NO
38	Revlimid	9,800	131,926,000	NO
39	Avonex, Rebif, Rebif Rebidose	5,200	131,275,000	NO
40	Triumeq	2,400	127,545,000	YES
41	Xolair	2,500	121,190,000	NO
42	Xifaxan	1,400	119,251,000	NO

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription ³³	FY 2015 Gross Cost to Medicaid	New Since 2012?
43	Sabril	9,400	114,468,000	NO
44	Remodulin, Tyvaso, Orenitram	12,200	114,006,000	NO
45	Viekira Pak	25,400	111,334,000	YES
46	Zortress, Afinitor	7,900	104,599,000	NO
47	Rituxan	4,700	98,123,000	NO
48	Makena	2,700	97,899,000	NO
49	Eligard, Lupron Depot	1,800	94,554,000	NO
50	Implanon, Nexplanon	700	90,423,000	NO
51	Sprycel	8,800	89,670,000	NO
52	Gilenya	5,400	89,594,000	NO
53	Banzel	1,400	83,923,000	NO
54	Humate-P, Alphanate	21,800	83,737,000	NO
55	Feiba	50,100	83,540,000	NO
56	Cinryze, Berinert	32,300	80,357,000	NO
57	Xeloda	2,300	77,078,000	NO
58	Renvela	1,100	76,998,000	NO
59	Letairis	7,200	75,603,000	NO
60	Neupogen	1,300	75,602,000	NO
61	Stelara	11,700	75,180,000	NO
62	Olysio	19,900	73,568,000	YES
63	Saphris	600	72,472,000	NO
64	Renagel	1,300	72,398,000	NO

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