

MEDICAID PREFERRED DRUG LIST OPTIONS FOR STATES

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



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The SMART-D Initiative

State Medicaid programs must navigate the complicated landscape of drug purchasing. To help states make informed drug coverage decisions, the State Medicaid Alternative Reimbursement and Purchasing Test for High-Cost Drugs (SMART-D) initiative was launched in February 2016 by the Center for Evidence-based Policy at Oregon Health & Science University, with financial support from the Laura and John Arnold Foundation, now Arnold Ventures. The initiative is a collaborative effort to support states in the development of alternative payment models (APMs) for prescription drugs and pharmacy policy interventions.

From 2016 to 2018, the SMART-D initiative focused on helping states identify potential APMs for managing Medicaid prescription drug costs. These APM options are designed to improve access to evidence-based therapies for Medicaid enrollees, while helping policymakers predict and manage prescription drug costs in a manner that connects price, payment, value, and health outcomes. Drawing upon international and U.S. commercial market models, our research identified a series of alternative payment options and existing legal pathways for state Medicaid programs to use when paying for high-cost drugs.



In 2019, SMART-D began a new phase of work on pharmacy policy interventions. This phase will run until September 2021 and provide research and technical assistance to states on 2 focus areas: multi-payer purchaser partnerships involving Medicaid, other public purchasers, and private insurance carriers; and single and aligned preferred drug lists (PDLs) for Medicaid managed care states.

This brief on preferred drug list options compiles our survey of the existing evidence and blends it with states' experiences to date. The analysis will serve as the basis of the SMART-D team's technical assistance to a selection of states as they seek to innovate in the areas of multi-agency purchasing and preferred drug lists. Both the multi-agency purchasing and PDL options brief will be posted at <http://smart-d.org/research-and-reports> when final.

The Phase 1 SMART-D reports are listed below and can be found at: <http://smart-d.org/research-and-reports>.

- [SMART-D Phase 1 Summary Report, September 2016](#)
- [Medicaid and Specialty Drugs: Policy Options, June 2016](#)
- [SMART-D Economic Analysis, September 2016](#)
- [SMART D Alternative Payment Model Brief, October 2016](#)
- [SMART-D Legal Brief, September 2016](#)

Contents

- The SMART-D Initiative 2
- Executive Summary 2
- Purpose and Scope 3
- Introduction 4
- State PDL Structural Options 4
- Regulatory and Policy Framework for State Medicaid PDL Decisions 6
- Problems States are Trying to Address Through PDL Structure..... 9
 - 1. Administrative Efficiencies 9
 - 2. Patient Access and Care Management..... 11
 - 3. Managing Drug Cost Growth and Transparency 13
 - 4. Population Health and Reform Efforts 16
- Key Questions When Considering a Shift to Single or Aligned PDLS 17
- Conclusion 19
- Sources 21
- Appendix A. List of Interviewees and Advisors 26
- Appendix B. Overview of Key Considerations by State Medicaid PDL Structures 28

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Executive Summary

Introduction

State officials across the country are looking for ways to control Medicaid drug costs. One cost control lever is the preferred drug list (PDL), which creates preferred or open access for outpatient drugs deemed to be medically appropriate and cost effective. PDLs are developed and deployed in states within their fee-for-service (FFS) and managed care delivery systems.¹⁻³ States are exploring how to leverage the PDL tool in new configurations, such as the use of single or aligned PDLs that would span a state's FFS and managed Medicaid enrollees.

There is a lack of independent policy analysis on Medicaid PDL structures to guide state decision making. This brief provides a resource by highlighting states' experiences with various PDL approaches, as well as the perspectives of key stakeholders, such as managed care organizations and pharmacists.

State PDL Structures

State Medicaid agencies use 3 PDL structures:

- 1) Multiple PDLs:** A multiple PDL structure allows each managed care organization (MCO) to develop and maintain its own PDL, and the state also maintains a PDL for its FFS program. Multiple PDL models operate within a managed care structure where customarily the MCOs are financially at risk for its enrollees' drug costs.⁴
- 2) Aligned PDLs:** Under an aligned PDL structure, MCOs are at financial risk for the cost of drugs for their enrollees. In contrast to a multiple PDL model, an aligned PDL approach selects the same preferred drugs for MCOs and the state's FFS program.⁴ The state and MCOs typically use a collaborative process to establish alignment criteria on a class-by-class basis.⁴
- 3) Single PDL:** Under a single PDL structure, there is one PDL used by the state's FFS program and any contracting MCOs. Financial risk for a single PDL can be

either carved out of or carved in to MCO capitation rates.⁴

The overall PDL structure has implications for how pharmacy benefit management functions are organized. Some key takeaways include:

- A Medicaid single PDL allows for the most alignment of pharmacy benefit functions across the entire Medicaid population, but may work against MCOs' efforts to align benefit functions across their broader book of business (Medicaid, Medicare Advantage and commercial).⁵
- Conversely, multiple PDLs allows the most flexibility for MCOs to align functions across their public and private lines of business but diminishes a state's direct ability to align drug selection across their entire Medicaid population.³
- Under multiple or aligned PDL approaches, the state will always have a parallel duplication of pharmacy benefit management functions for its FFS population.⁴
- Aligned PDLs provide the possibility for a middle ground to coordinate preferred status and other drug management elements, while allowing MCOs to continue to directly manage the pharmacy benefit for their enrollees. While this alignment is beneficial for patients and providers, there is no streamlining of benefit management functions, and the state and MCO continue to have duplication of pharmacy benefit functions.⁶

Problems States Are Trying to Address Through PDL Structure

Interviews with state policy leaders (see Appendix A) identified several concerns that drive decision making to a single or aligned PDL structure. These concerns include:

- Streamlining the administration of the pharmacy benefit at multiple levels, providing a single PDL for providers, prescribers, and consumers to navigate.
- Ensuring common access to medications and supporting care management needs

through minimizing disruption and confusion, particularly when enrollees change managed care plans.

- Managing drug cost growth through leveraging the purchasing power of both managed care and FFS lives, and gaining transparency on rebate collection, pharmacy benefit manager payments, and other financial transactions.
- Providing a common base to support population health and reform efforts across all Medicaid lives and perhaps other public health, public employee, or other programs.

Key Questions When Considering a Shift to Single or Aligned PDLs

This brief lays out questions for states to explore, in collaboration with provider, pharmacy, managed care, and consumer stakeholders, when considering changes to their PDL structure.

These include:

- 1) What are the state's goals for health care reform and how does its Medicaid program and the role of pharmacy fit into the picture?
- 2) What is the current situation across MCO PDLs and pharmacy benefit managers (PBMs)?
- 3) What impact would a new structure have on Medicaid program costs?
- 4) How are MCO capitation rates affected by the PDL structure being considered?
- 5) What implementation approach is appropriate for your state given all other considerations?
- 6) How will the state's administrative structure need to be changed or expanded?
- 7) What data exchange and analytic support will be needed under the new structure?

Conclusion

States need to weigh a wide range of interacting variables when determining the best PDL structure for their Medicaid program. This brief seeks to draw out key themes, experiences, and considerations based on a range of state agency and stakeholder perspectives. There is no one right decision; rather PDL structures offer

tradeoffs for a state and its constituents when trying to manage escalating drug costs.

Purpose and Scope

State Medicaid officials are looking for new ways to control drug expenditures as costs continue to soar. Since 2003, Medicaid programs have implemented preferred drug lists (PDLs) for their outpatient drug benefit in an attempt to shift utilization to more cost-effective products, control expenditures and improve patient outcomes. Preferred drug lists identify outpatient drugs deemed by payers as medically appropriate, cost effective, and not generally requiring prior authorization. This brief explores options for PDL structures by drawing on states' experiences and available literature to identify key considerations and decision points. The brief gives state Medicaid officials a resource for working with policymakers, executive leadership, and stakeholders as changes in PDL structure are considered.

There is a lack of independent evaluation on the topic of PDL structure as most studies, analyses, and policy documents are put forward by a particular stakeholder perspective. This brief provides a range of perspectives, including those of key stakeholders such as managed care organizations (MCOs) and pharmacists, on the use of single PDLs where possible, and highlights current state experiences with this approach to pharmacy management. The focus of the brief is on outpatient drugs, but we recognize that many states are increasingly concerned about the cost of clinician-administered drugs not typically included on state PDLs.

This report is based on a review of publicly available reports, policy literature, and key informant interviews with state leaders, including state Medicaid agency directors, medical directors, pharmacy directors and program managers, as well as executive branch health policy advisors. Participating states represented a range of Medicaid program sizes and benefit design structures (fee-for-service, administrative service organizations, and managed care) and included: Connecticut, Delaware, Louisiana,

Michigan, Missouri, New Mexico, Ohio, Oregon, South Carolina, Texas, Virginia, Washington, and Wisconsin. (See Appendix A for a detailed list of interviewees.) Any concepts not specifically cited with published literature are based on the authors' synthesis of information obtained through interviews of state representatives.

Introduction

The Medicaid program is one of the largest payers for health care services in the nation, covering an estimated 65 million people as of August 2019.⁷ Medicaid spending grew 2.9% from the previous year, totaling \$581.9 billion, equal to 17% of U.S. health care spending in federal fiscal year (FY) 2017.⁸ Medicaid enrollees are more likely to have chronic health conditions, be disabled, and have lower incomes compared to those in private insurance.⁹

Also, in federal FY 2017, Medicaid spent approximately \$64 billion on outpatient prescription drugs, an increase of 40% from \$43.2 billion in FY 2014.¹⁰ The primary reasons cited for the increase in spending are the introduction of new high-cost drugs and price inflation for existing drugs.¹⁰ The average expenditure for these high-cost drugs has increased from \$2,600 per claim in FY 2014 to more than \$3,100 in FY 2017.¹⁰ A principal way states attempt to contain drug costs is requesting discounts from drug makers under the Medicaid Drug Rebate Program (MDRP).¹¹ Congress created the program in 1990 to ensure state Medicaid agencies receive the lowest price available for all prescription drugs.¹¹

Under the federally managed program, drug manufacturers pay a rebate based on a set formula to state Medicaid programs for each of the manufacturer's drugs.¹¹ For most brand-name drugs, the minimum rebate amount is 23.1% of the average manufacturer price (AMP) and 13% of AMP for generic medications.¹¹ In FY 2014, states collected \$19.9 billion in rebates, and by FY 2017, states almost doubled that amount, collecting \$34.9 billion.¹⁰

Because the federal rebates are based on a formula, states do not negotiate rebate levels, but may shift utilization to drugs with higher rebates. Some states invite drug manufacturers to provide "supplemental rebates," which are additional rebate dollars to encourage the state to prefer their products. Supplemental rebates are not set based on a formula but instead are negotiated by states or their vendors.

States leverage placement on their PDL to obtain supplemental rebates.¹² States have begun to explore the use of centralized single PDLs to span all Medicaid enrollees, both those in FFS and managed care.^{13,14} Medicaid officials theorize making such a change could increase rebates from drug manufacturers by negotiating on behalf of the entire enrolled population, resulting in overall lower or more controlled growth in drug costs, while reducing administrative burden for health care providers, increasing access for beneficiaries, and supporting population-based health initiatives.^{15,16}

State PDL Structural Options

State Medicaid agencies currently employ a range of PDL structures that go hand-in-hand with their managed care approaches as noted in Table 1: Overview of Medicaid PDL Continuum. While each state's structure and histories are unique, there are 3 overarching PDL arrangements based on the authors' synthesis of information obtained through interviews with state representatives:

- 1) Multiple PDLs:** A state has a multiple PDL structure when it allows each MCO to have its own PDL.⁴ In addition, the state typically runs its own separate PDL for the FFS population.⁴ MCOs establish their own PDLs privately, using their own prior authorization criteria and utilization review processes.⁴ Multiple PDL models operate within a managed care structure where customarily the MCOs are financially at risk for its enrollees' drug costs.⁴
- 2) Aligned PDLs:** Under an aligned PDL structure, MCOs are at financial risk for

Table 1: Overview of Medicaid PDL Continuum

Multiple PDLs Carved In to MCOs	Aligned PDLs Carved In to MCOs	Single PDL Carved In to MCOs	Single PDL Carved Out of MCOs
<ul style="list-style-type: none"> Each MCO and the FFS program set their own PDLs Pharmacy is included in MCO Risk 	<ul style="list-style-type: none"> MCO PDLs are aligned with FFS on a class-by-class basis or % of classes basis. May be a “floor”— MCO variation allowed that is not more restrictive (e.g., generic substitution) Pharmacy is included in MCO risk 	<ul style="list-style-type: none"> MCOs and FFS program use the same single PDL set through state’s P&T and DUR processes Pharmacy is included in MCO risk 	<ul style="list-style-type: none"> MCOs and FFS program use the same single PDL set through state’s P&T and DUR process Pharmacy is carved out of MCO risk

Abbreviations. DUR: drug utilization review; FFS: fee-for-service; MCO: managed care organization; P&T: Pharmacy and Therapeutics; PDL: preferred drug lists.

the costs of drugs for their enrollees. In contrast to a multiple PDL model, an aligned PDL approach seeks to coordinate MCOs and the state’s FFS PDLs by selecting the same preferred drugs.⁴ The state and MCOs typically use a collaborative process to establish alignment criteria on a class-by-class basis.⁴ The process is made public through the state’s Pharmacy & Therapeutics (P&T) Committee and Drug Utilization Review (DUR) Board activities. The aligned PDL may be viewed as a “floor” and MCO variation is generally allowed as long as these variations are not more restrictive (e.g., generic substitution).⁴ State approaches to clinical criteria used for prior authorization may vary from requiring the use of specific criteria, to fostering voluntary alignment among the MCOs, or allowing MCO autonomy to set clinical criteria.

3) **Single PDL:** Under a single PDL structure, there is one PDL used by the state’s FFS program and any contracting MCOs.⁴ Financial risk for a single PDL can be either carved out of or carved in to MCO capitation rates. The state’s P&T and DUR processes are used to establish and maintain the PDL.⁴ States without managed care delivering services to enrollees and with an all FFS benefit design are by definition single PDL states.⁴

The overall PDL structure has implications for how a state provides pharmacy benefit management functions. Figure 1 on the next page provides an overview of some of the functions either the state and/or the MCOs need to perform under the various PDL structures. Some key takeaways include:

- A Medicaid single PDL allows for the most extensive alignment of pharmacy benefit functions across the entire *Medicaid* population, but may work against MCOs’ efforts to align benefit functions across their broader book of business (Medicaid, Medicare Advantage, and commercial).⁵
- Conversely, multiple PDLs allows the most flexibility for MCOs to align functions across their public and private lines of business but diminishes a state’s direct ability to align drug selection across their entire Medicaid population.³
- Under multiple or aligned PDL approaches, the state will always have a parallel duplication of pharmacy benefit management functions for its FFS population.⁴
- Aligned PDLs provide the possibility to coordinate preferred status and other drug management elements, while allowing MCOs to continue to directly manage the pharmacy benefit for their enrollees.² While this alignment is beneficial for patients

and providers, there is no streamlining of benefit management functions, and the state and MCO continue to have duplication of pharmacy benefit functions.²

Pharmacy benefit managers (PBMs) are key actors in consideration of state PDL structures. PBMs administer prescription drug coverage on behalf of payers such as Medicaid agencies, Medicaid MCOs, private insurance companies, and Medicare Part D.¹⁷ Each MCO has their own contract with a PBM, as often do state Medicaid agencies for FFS populations, so pharmacies must navigate multiple PBMs in most states.¹⁸ The use of PBMs to aid state staff in overseeing their drug benefits has increased over time.¹⁷ As state Medicaid officials seek to better control drug costs with limited state staffing resources, their relationships with PBMs have evolved.¹⁷ Once primarily contracted for administrative support, such as claims processing, PBMs are often now used to negotiate supplemental rebates, to conduct clinical drug class reviews to inform PDL decision making, and for advanced analytics to manage and predict drug spending.¹⁷ Unlike an administrative services organization, a PBM may generate revenue not only from

the administrative services they provide, but also from discounts negotiated with drug manufacturers or the spread in reimbursement to pharmacies.

Table 2 on the next page provides examples of various PDL structures used in state Medicaid programs. In some cases, states may deploy an overall approach, as outlined in Figure 1 below, but also create exceptions for specific access or areas of cost concerns (e.g., carve out hepatitis C medications and utilize a single PDL specifically for that drug category).

Regulatory and Policy Framework for State Medicaid PDL Decisions

State decisions on PDL structure are nested in a complicated framework of federal statutory and administrative guidance. Elements such as best price, consumer price index penalty, and 340B purchasing shape how Medicaid reimburses drugs and, in some cases, creates disparate incentives for Medicaid versus non-Medicaid purchasers. Federal support for the development of state

Figure 1. Typical Locus of Medicaid Pharmacy Benefit Functions by PDL Structure

	Multiple PDLs	Aligned PDLs	Single PDL Carved in to MCOs	Single PDL Carved out of MCOs	
PDL development & maintenance	● ●	● ●	●	●	
Drug utilization review/P&T functions	● ●	● ●	●	●	
Prior authorization & clinical edits	● ●	● ●	● ●	●	● MCOs & their PBMs
Appeals processes	● ●	● ●	● ●	●	● State Medicaid Agency
Analytics & data support to providers/pharmacies	● ●	● ●	● ●	●	
Pharmacy claims processing	● ●	● ●	● ●	●	
Supplemental rebate negotiation	● ●	● ●	●	●	

Note: States are federally required to maintain many of these functions for their FFS population regardless of managed care structure. Abbreviations. FFS: fee-for-service; MCO: managed care organization; P&T: Pharmacy and Therapeutics; PBMs: pharmacy benefit managers; PDL: preferred drug lists.

Table 2: Examples of State Medicaid PDL Structures

PDL Structure	State	Description
Entirely FFS	Connecticut	Medicaid program operates under a FFS self-insured model with a single PDL. ¹⁹ The state oversees and manages the pharmacy benefit. All pharmacy is done in-house with the exception of select prior authorization reviews. ¹⁹
Single PDL Carved out of MCOs	Tennessee	TennCare has a statewide PDL for the pharmacy program that is the same for all members, no matter which MCO they are enrolled in. ²⁰ TennCare has a single PBM to process all TennCare pharmacy claims and respond to all prior authorization requests. ²⁰
Single PDL Carved in to MCOs	Texas	Texas operates a single PDL for both FFS and MCOs. ²¹ The MCO must adopt the state's prior authorization policies unless the state grants a written exception, and the state's approval is required for all clinical edit policies. ²¹
Aligned PDLs	Michigan	Medicaid MCO PDLs may be less restrictive, but not more restrictive, than the coverage parameters of Michigan's central common formulary. ²² Selected drugs are carved out from MCO risk and are paid by FFS. These include HIV, psychotropics, hepatitis C, and hemophilia clotting factor medications. ²²
Multiple PDLs	South Carolina	There are 6 Medicaid PDLs in the state, 1 for the state's FFS program and the 5 MCOs each operate their own. ²³ All drugs used in the treatment of hepatitis C are carved out of MCO risk and paid for by South Carolina's FFS Medicaid program until July 1, 2020. ²³

Abbreviations. FFS: fee-for-service; MCO: managed care organization; PBM: pharmacy benefit manager; PDL: preferred drug list.

Medicaid PDLs, coinciding with the growth of Medicaid managed care, has also affected state pharmacy management decisions. What follows is a high-level summary of these issues.

Medicaid Drug Rebate Program (MDRP) and Best Price

The MDRP, as codified in section 1927 of the Social Security Act, ensures state Medicaid programs receive a discount on a drug's AMP and never pay more than a brand-name drug's best price in the U.S. pharmaceutical market.²⁴ Best price is:

- The lowest price a drug is sold to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government agency²⁴;

- Reported by the drug manufacturer to the Centers for Medicare & Medicaid Services (CMS); and
- Is confidential as per statute and can only be disclosed in limited situations.²⁴

Drug manufacturers are required to report to CMS the best price at which a brand-name drug is sold in the commercial market and must offer this price, plus a statutory rebate, to state Medicaid programs.²⁴ Drug manufacturers will go to great lengths not to set a new best price in the commercial market—which includes corrections, public employees, and other non-Medicaid populations—because this new price will be a discount passed through to all state Medicaid

agencies nationwide and 340B programs (described below).²⁴

Medicaid programs, however, can negotiate voluntary supplemental rebate agreements with drug manufacturers that do not create a new best price threshold because Medicaid supplemental rebate agreements are excluded from best price determinations.²⁵ In addition, the MDRP includes a consumer price index (CPI) penalty intended to protect Medicaid programs from price increases greater than the CPI.²⁴ This penalty can reduce the price of the brand-name drug to the Medicaid program so it is less expensive than a new generic equivalent.²⁴

340B Drug Pricing Program

The 340B Drug Pricing Program provides discounted prescription drugs to certain health care facilities (referred to as “covered entities”) participating in the program and creates drug discounts for government-supported facilities that serve vulnerable populations.²⁴ Covered entities include qualifying hospitals (e.g., children’s hospitals, critical access hospitals, disproportionate share hospitals) and federal grantees from the Health Resources and Services Administration (e.g., federally qualified health centers), the Centers for Disease Control and Prevention (e.g., sexually transmitted disease clinics), the Department of Health and Human Services’ Office of Population Affairs and the Indian Health Services (e.g., tribal/urban American Indian health centers).²⁶ Manufacturers must offer discounts to 340B entities as a condition of Medicaid coverage of the manufacturer’s drugs. The 340B program provides covered entities with statutorily defined drug discounts (340B ceiling prices), and these covered entities can also negotiate with drug manufacturers for further “sub-ceiling” rates.²⁴ 340B prices are often similar to or lower than the Medicaid prices and participating covered entities report savings that range from 25% to 50% of Average Wholesale Price.²⁷

Federal Statutory and Administrative Guidance on Medicaid Pharmacy Benefit Management

Changes in federal requirements and policy guidance have altered the financial incentives for state Medicaid agencies, leading to an evolution in state PDL approaches over time. In 2002, CMS issued guidance regarding development of state Medicaid PDLs and their role in negotiating for supplemental rebates. This guidance spurred state activity and by 2008, 37 states had implemented a PDL.²⁸ CMS guidance in 2004 regarding multistate purchasing pools galvanized another round of state activity, resulting in 29 states participating in such pools as of 2019.²⁹

In 2010, 20 of the 36 states (or 56%) with comprehensive risk-based MCOs had carved the pharmacy benefit into managed care risk.³⁰ Then the Patient Protection and Affordable Care Act of 2010 authorized states to claim federal drug rebates on managed care pharmacy claims, providing an incentive for states to delegate pharmacy benefit management to their MCOs.³¹ By 2017, the number of states with comprehensive risk-based MCOs that carved in the pharmacy benefit had increased to 35 of 39 states, or 95%.³²

In April 2016, CMS issued a Medicaid managed care rule reinforcing the expectation that MCOs are subject to the same prescription drug coverage requirements as FFS.³³ This clarification eliminated some flexibility MCOs used to align formularies across their lines of business, including Medicaid, Medicare Advantage, and commercial insurance.³³ Coupled with the continuing introduction of highly expensive breakthrough therapies for orphan diseases and rising prices for everyday pharmaceuticals, states have increasingly looked to a centralized PDL as a strategic pharmacy management tool.³⁴ By 2018, 14 states reported a single PDL for at least 1 drug class, 3 states indicated plans to implement a single PDL in FY 2019, and 4 states have announcing similar plans in FY 2020.¹⁷

State-level Authority to Shape Preferred Drug Lists

As changes are contemplated to the PDL structure within this federal framework, states need to assess their own regulatory authority, including statutes and administrative rules potentially necessary to make these programmatic changes. Some states will be able to modify PDL structures using their agency decision-making and contracting authority, while other states may need a legislative mandate to generate the necessary political and budgetary support.

In either scenario, states should plan for a concerted education and outreach effort to legislators, affected executive leadership, pharmacies and other health care providers, beneficiaries, managed care organizations, and key stakeholders to gather input, explain the rationale for any change, and articulate the state's plan for a smooth transition.

Effect of State-specific Policy Priorities or Values

As a final note on the context for state PDL decisions, while states operate within broader statutory and regulatory requirements, each state program is unique in structure and culture for a wide range of historical reasons. An overarching state philosophy may play a key role to support or hinder changing PDL structures. For example, a state's legislature may place a higher priority on privatizing services—contracting out services to private MCOs—over operating services from within the agency. Another state may value local community decision making over a centralized state approach.

Connecticut and Oregon provide contrasting examples to illustrate this point. Oregon's coordinated care organizations (CCOs) were designed to innovate at the local level through full-risk global budget payments tied to quality outcome expectations. Currently 15 CCOs manage their own PDLs.

Connecticut, after a significant history of managed care, transitioned to a fully self-insured FFS delivery model in 2012. The state now oversees a

single PDL for its Medicaid program and performs all pharmacy claims adjudication. An administrative service organization is contracted to perform some prior authorization functions.

Problems States are Trying to Address Through PDL Structure

Interviews with state policy leaders (see Appendix A) identified several issues that drive decision making about PDL structure, including administrative efficiencies and simplification, patient access and care management, the need to manage and predict the growth in drug cost, transparency, population-based health initiatives, and reform efforts. Appendix B provides an at-a-glance table of these characteristics by PDL structure.

1. Administrative Efficiencies

States frequently cite improving the administration of the Medicaid drug benefit as a goal for having a single or aligned PDL structure. The administrative improvements may be sought at multiple levels in the administration of the program; from the state Medicaid agency, to the prescribing providers, the pharmacies filling the prescriptions, and the patients accessing needed medications.

Centralizing Prescription Drug Management

By centralizing pharmacy benefit management through a single PDL or aligned PDLs across FFS and MCOs, states have a more significant centralized role in coverage decisions for their entire population.^{3,4,35} A single drug list means all beneficiaries have access to the same medications without the need to go through a prior authorization process if the beneficiary switches managed care plans.^{3,4,35} States report that having one PDL also allows the Medicaid agency to move quickly in making and implementing coverage decisions as new medications gain approval from the FDA, or reports of adverse drug events emerge, rather than needing to work through MCOs to identify and correct emerging concerns. Also, in single PDL states where pharmacy is carved out of MCO risk, the state is not compelled to adjust

MCO capitation rates when new high-cost drugs are added to the PDL.

As outlined above, the state will always have to administer pharmacy benefit functions for its FFS population, so in the case of aligned or multiple PDL structures, many functions are being duplicated between the state and MCOs. When a state moves to a single PDL, the state will likely build on its underlying FFS infrastructure, although the potential increased volume of both drug classes and broader populations may require some increased administrative investment.

Streamlining Pharmacy Management for Prescribers, Pharmacies, and Enrollees

States and proponents of a Medicaid single PDL structure cite a number of benefits for providers, pharmacies, and the patients themselves including:

- Decreasing the number of prior authorization requests providers and pharmacists need to submit each year^{4,18,36-38}
- Reducing the need for providers to stay abreast of varying coverage criteria of multiple PDLs^{4,18,36-38}
- Creating consistency with coverage criteria across enrollees as they change plans³⁹

The reduction of administrative burden for prescribers, pharmacies, and enrollees may be less clear under PDL structures that leave the financial risk and pharmacy benefit management to the MCOs, whether single, aligned, or multiple PDLs. This delegation, even with a single or aligned PDL, may bring variability in implementation. For example, MCOs in Texas are able to make their own clinical coverage criteria, creating variations in access across plans despite the presence of a single PDL.⁴⁰ Texas clinicians report this variation in clinical editing leads to lack of clarity in when drugs can be prescribed, and no standard procedure exists for requesting the deletion or disuse of that edit.⁴⁰

Likewise, in Michigan where pharmacy is carved into MCO risk but is governed by an aligned PDL, the same variability occurs. In Virginia, there

has been some variability in how MCOs' PBMs code their systems for the aligned PDL, creating statewide inconsistencies.

The impact of PDL shifts is largely anecdotally framed in policy discussions, with very little empirical evaluation of administrative burden. For instance, a group of physician practices interviewed by researchers at the Commonwealth Fund revealed they were spending 24 minutes to readjust prescriptions to be compliant with multiple formularies.⁴¹ That is longer than the average patient visit time of 17.5 minutes.⁴²

These modifications typically involve receiving calls from pharmacists who would suggest an on-formulary alternative after doctors attempted to prescribe another medication.⁴¹ These conversations place burdens on both pharmacists and physicians, and delay the drug dispensing process, which can be frustrating to patients.⁴¹ According to their interviews, physicians with a single formulary spent the least amount of time readjusting prescriptions.⁴¹ However, those time differences were not quantified.⁴¹

States should bear in mind that significant changes to PDL structure will create a short-term workload increase for prescribers and pharmacies as preferred drugs are prescribed for enrollees renewing prescriptions. In Louisiana, which moved to a single PDL in May 2019, family physicians who were not aware of the change may have potentially seen an increase in burden and needed to come up to speed on the new PDL list (Louisiana Association of Family Physicians, personal communication).

Washington phased in a single PDL during 2019. The state has heard commentary from pediatric clinicians who appreciate the streamlined process across the Medicaid MCOs for prescribing commonly used drugs for children, such as those for attention deficit hyperactivity (ADHD) disorder.

Historically, the administrative simplification argument has been criticized for looking at PDLs only through a Medicaid lens, whereas the pharmacy community faces a much broader set

Table 3: Characteristics of Pharmacy Administrative Functions by PDL Structure

Multiple PDLs	Aligned PDL	Single PDL
<ul style="list-style-type: none"> • Least centralized for Medicaid administration • Duplication of administrative functions across Medicaid FFS, multiple MCOs and their PBMs • Multiple Medicaid PDLs for prescribers and pharmacies to follow • Allows MCOs to use same PBM and PDL approach across public and private enrollees 	<ul style="list-style-type: none"> • More centralized decision making with aligned criteria • Duplication of administrative functions across Medicaid FFS, multiple MCOs and their PBMs • Allows some alignment across MCOs and FFS for prescribers and pharmacists to follow 	<ul style="list-style-type: none"> • Most centralized and streamlined decision making • Least duplication of effort as all administrative functions are the same for all Medicaid enrollees • One Medicaid PDL for prescribers and pharmacies to follow

Abbreviations. FFS: fee-for-service; MCOs: managed care organizations; PBM: pharmacy benefit manager; PDL: preferred drug list.

of dynamics across public and private providers.⁶ Aligned PDLs across the Medicaid population may only be a small portion of prescriptions in some pharmacy locations. A state needs to weigh the importance of alignment across the Medicaid population against other system-wide goals.³⁴ This consideration may be different in a state that expanded coverage under the ACA, where Medicaid may cover more than 25% of the state’s population, versus states who did not expand.⁴³ Also, states such as Washington that are working to align purchasing across Medicaid and public employees may decide to develop a single PDL to allow greater alignment across programs where possible.³⁴

2. Patient Access and Care Management

Ensuring access to medications and supporting enrollee’s care management needs are commonly cited as reasons to utilize a single or aligned PDL, particularly in states where enrollees can frequently transition between MCOs. However, many of the same reasons are cited for delegating pharmacy benefit management to MCOs. States need to consider a range of issues to determine which PDL structure would best support enrollee access to high-quality care within their state Medicaid program configuration.

Minimized Disruption When Enrollees Change MCOs

States assert that varied formularies and policies have created difficulty for Medicaid patients in obtaining their medications, particularly as they switch between different MCOs.⁴⁴ Medicaid has a higher level of churn than commercial or Medicare coverage, with 1 of 4 beneficiaries experiencing a change in Medicaid coverage within a given year.⁴⁵ Allowing managed care plans to maintain their own PDLs means Medicaid enrollees may be asked to switch to a different but therapeutically equivalent drug if it is preferred by the enrollee’s new managed care plan, or the prescriber will need to obtain a prior authorization for nonpreferred drug.⁴ Ohio Medicaid officials cited variation in prior authorization for medications for treatment of asthma, diabetes, hemophilia, HIV, and seizures as a motivation for its transition to a single PDL.⁴⁶

States that modify their PDL structures may wish to implement phase-in or grandfather policies that give prescribers and enrollees time to manage prescription changes between preferred drugs. Minnesota included a provision in its PDL transition policy that patients with an existing prior authorization will continue to have their

prescription covered until the prior authorization expires.⁴⁷ Washington asked its DUR Board to determine which drugs should be grandfathered during the transition to a single PDL, so prescribers did not need to obtain prior authorization for enrollees to continue the medication.⁴⁸

Clarity of Coverage and Process to Improve Responsiveness to Patient Needs

A range of states, providers, pharmacists, and consumer groups assert a single PDL approach could improve access through a more clear and consistent coverage methodology.^{40,49} In one American Medical Association survey, 69% of physicians report typically waiting several days to receive preauthorization for drugs while 10% wait longer than a week.^{40,49} Likewise, more than 67% of physicians report difficulty determining which drugs require preauthorization by insurers' PBMs.⁴⁹ Clinicians in states moving to a single PDL anticipated the changes would result in eased access to medications for Medicaid enrollees, as there would be universal understanding of which drugs were covered without a prior authorization and a predictable process to access nonpreferred drugs when necessary.⁴⁰

Support Appropriate Care Management

Through minimizing disruption and a clear, centralized PDL process, proponents assert a single PDL structure promises to reduce delay in starting new medications or abandoning medication therapy while improving adherence to

the prescribed regimen resulting in better health outcomes.⁵⁰ Florida Medicaid officials said having a single PDL resulted in a broader range of cost-effective drug choices compared to when there were various MCO PDLs.

Conversely, MCOs assert they have unique insight into their beneficiaries' care needs. Charged with managing both medical and pharmacy costs, MCOs are able to leverage clinical data to ensure access to the least expensive, clinically effective medication.³⁹ MCOs can utilize care coordination teams that work with physicians and pharmacists to manage pharmacy benefits and avoid harmful drug interactions, monitor opioid prescription misuse, avoid unnecessary hospitalizations, and ensure patients take their medications for chronic medical conditions.⁵¹ MCOs fully at risk for pharmacy can integrate drug utilization and claims data with other medical utilization data for their enrollees, providing the ability to apply preferred drug status and other utilization management approaches with the full context of enrollees' needs.⁴ MCOs express concern that they cannot successfully manage this whole person care when pharmacy is carved out because the MCO will not have access to drug utilization and claims data in real time.³⁹ In Missouri, where pharmacy is carved completely out of MCO risk, the state has constructed a real-time portal for MCOs, pharmacies, and prescribers to access real-time pharmacy data to support care management.

Table 4: Access and Care Management Characteristics by PDL Structure

Multiple PDLs	Aligned PDL	Single PDL
<ul style="list-style-type: none"> Multiple PDLs hold potential for disruption as enrollees change plans Allows for maximum amount of MCO control to manage physical health and pharmacy access for enrollees 	<ul style="list-style-type: none"> Reduced potential for disruption within aligned classes Allows some potential for MCO implementation discretion (e.g., safety edits) May result in variability across MCOs that may reduce clarity of PDL 	<ul style="list-style-type: none"> Minimizes access disruptions as patients move between MCOs Creates clear process for providers to understand what is preferred and to ask for nonpreferred only when necessary, reducing PA time

Abbreviations. MCO: managed care organization; PA: prior authorization; PDL: preferred drug list.

3. Managing Drug Cost Growth and Transparency

States cite a range of cost goals for implementing centralized PDLs, including reducing overall net costs to the state or maintaining budget neutrality while enhancing patient access, administrative efficiency, or population health initiatives. Careful analysis is needed to understand the cost and transparency potential of a PDL structure, ensuring the state is making realistic expectations for cost savings or increases over time. (See highlight box on page 15, Financial Analyses to Support Planning for a PDL Shift.)

Cost Impact of Single PDL Implementation

Overall, there is limited published data about the cost impact of states moving from multiple PDLs to a single or aligned PDL. Much of the literature published is prospective analyses about the potential implications of a state move to a single or aligned PDL. There is mixed evidence that moving to a single PDL reduces overall Medicaid spending on drugs.

There are examples of states that have implemented a single PDL structure and experienced savings over time. Tennessee Medicaid officials report that after they carved out pharmacy and instituted a single PDL, their pharmacy costs averaged \$30 per member, per month (PMPM) as compared to \$46 PMPM in states without the carve out (Tennessee Medicaid staff, personal communication). Similarly, Wisconsin reported an average of \$30 PMPM in pharmacy costs for more than 11 years after implementation of a pharmacy carve out and single PDL.⁵²

Conversely, the Menges Group (a consulting firm) found Florida and other states with a single PDL, including Kansas, Texas, and West Virginia, were averaging \$39.26 PMPM, 5% above other states.⁵³ In West Virginia, one study prepared for the state found an estimated \$14 million was saved in 2018 after the implementation of a single PDL, while a follow-up study funded by

America's Health Insurance Plans estimated the same carve out had cost the state a net \$9 million in the same year.⁵⁴

Analyses commissioned by managed care plans consistently indicate the move to a single PDL will increase costs for MCOs.³⁵ A primary concern is whether a state's single PDL will prefer some brand-name drugs over generics because the brand-name drugs' net cost to the state is lower due to the CPI penalty described earlier in this brief.³⁵ If the MCO is at financial risk for drugs, then the MCO will incur greater costs for preferred brand-name drugs on the single PDL because the MCO does not get the benefit of the state's CPI penalty as part of the MDRP.

A study of Florida's single PDL implementation found overall drug costs rose for MCOs, due in large part to increase use of brand-name drugs.⁵⁰ The MCOs experienced an increase of more than 45% in overall plan drug costs in the post-policy period, largely driven by a 49% increase in brand drug costs and a 13% decrease in generic utilization.⁵⁰ This study acknowledged it could not estimate the state's savings because of lack of access to information about federal or supplemental rebate amounts.⁵⁰

Potential Cost Levers with a Single PDL Structure

Proponents of single PDLs point to a number of structural advantages for managing costs through increased leverage for negotiation and collection of rebates, better management of high-cost drugs, and increased cost transparency.

Maximize Rebate Collection and Increase Negotiating Leverage

A single PDL structure allows a state to maximize the rebates and discounts available under the MDRP.^{4,36} States can more easily shift all Medicaid drug purchasing and prefer drugs that garner the lowest net unit cost after considering federal statutory rebates, supplemental rebates, and CPI penalties.^{4,36} A single PDL also creates a platform for states to maximize their negotiating power for

Table 5: Cost and Transparency Characteristics by PDL Structure

Multiple PDLs	Aligned PDL	Single PDL
<ul style="list-style-type: none"> • Enables for MCO level control of total cost of care • Allows MCOs to customize PDLs for local or VBP initiatives 	<ul style="list-style-type: none"> • Allows for some increased transparency and predictability on rebate collection within aligned classes 	<ul style="list-style-type: none"> • Most transparent for collection of drug rebates and PBM fees • Most leverage for rebate negotiation • Control of total cost of care and clinical priorities across Medicaid population

Abbreviations. MCO: managed care organization; PBM: pharmacy benefit manager; PDL: preferred drug list; VBP: value-based purchasing.

supplemental rebates because the manufacturer knows the state reliably controls the PDL decisions and prior authorization processes.^{18,55}

Additionally, many states form drug purchasing pools to combine their volumes for even greater negotiation and purchasing power.¹⁸ A single PDL enables participation in multistate pools for all lives covered under the Medicaid pharmacy benefit.³⁶ In Florida, state officials report maintaining a single PDL provided stability in the state’s ability to negotiate greater supplemental rebate agreements with pharmaceutical manufacturers to offset the retail reimbursement cost of drugs.⁵⁶

Levers to Manage New High-Cost Drugs

A single PDL allows for centralized mechanisms to manage high-cost outpatient drugs as they enter the market. For example, Missouri Medicaid was able to implement a clear approach to coverage of the new high-cost hepatitis C drugs in 2014 because the state had pharmacy carved out of their managed care capitation rates and governed centrally by a single PDL.

For states where MCOs are at financial risk for the drugs, the state can temporarily carve out a new high-cost drug therapy as it develops claims experience for capitation rates. States can also employ a quality-driven payment pool where MCOs are eligible to access additional payments if they meet specific quality thresholds for the overall care, both medical and pharmacy, of the enrollee receiving the high-cost drug. Many

emerging high-cost drugs are clinician administered and these drugs are commonly not governed by a state’s PDL. See the highlight box, Clinician-administered Drugs on page 20, for a discussion and states initial thinking about management strategies.

Increased Transparency for State Medicaid Spending and Reimbursement

Centralizing the PDL structure allows states greater clarity on all transactions, including rebate collection, pharmacy benefit manager payments, pharmacy reimbursement, and total cost of care across all Medicaid lives. As stewards of taxpayer funds, this visibility into spending and reimbursement is a critical tool for stretching state government dollars.

Connecticut had managed care with pharmacy both carved in and carved out before 2011, becoming a self-insured FFS state in 2012. Under their current self-insured FFS model, Connecticut Medicaid officials assess the total cost of care perspective for a condition, weighing both drug and medical costs, and base drug coverage decisions on improved outcomes and greater cost control across the entire benefit. In a state with multiple PDLs, there are also multiple PBMs contracted to manage pharmacy benefit functions.

As states such as Ohio have identified the prevalence of PBM spread pricing, there is growing concern that PBMs are keeping a portion of the amount paid to them by MCOs instead of passing the full payments on to pharmacies.⁵⁷ In response, Ohio eliminated spread pricing

Highlight: Financial Analyses to Support Planning for a PDL Shift

Cost impact associated with a projected shift in the mix of drugs under new PDL scenario, net of rebate collection. A change in PDL structure will shift the mix of drugs the state is reimbursing, so the state should undertake projections for this change and estimate any resulting cost savings or increases. This analysis requires estimating an average unit cost change per claim per drug as well as the shift in the mix of drugs under a new centralized PDL. When estimating the savings, states need to make adjustments, to the extent possible, for population risk factors, cost and utilization trends, and introduction of new therapeutics to be sure the comparisons and calculations are robust. Focusing on selected drug classes that are high cost, high volume, variable, or otherwise high priority will allow states to tailor the analysis more accurately, including understanding how the collection of rebates is likely to change under a proposed scenario.

Impact on total administrative costs (state and MCO administrative costs). Estimates of impact on administrative costs should consider which activities will result in an increase to the state's direct costs versus those built into MCO rates. Estimates should take into account duplication between the state FFS management and MCOs, such as prior authorization and member communications. There may be additional initial costs for processing and managing exception requests if the state PDL is very different from current PDLs. States should also consider analytics and reporting tools that may need to be developed or maintained to support the delivery of care under a new structure. These may be as simple as basic PMPM trend reports, or as complicated and resource intensive as frequently updated predictive models to spot potential high-cost members and/or online portals that need ongoing maintenance.

Impact on MCO capitation rates. States should work with their MCOs to understand the potential operational and financial impact of a new PDL structure. Capitation rates will likely need to be revised to account for projected shifts in the mix of drugs under the new PDL scenario. Careful consideration of the use of carve outs from MCO risk, risk-corridors, or kick payments is key to translating the cost impact assessments outlined above into successful implementation.

Impact on payment to pharmacies. States should assess how payments to pharmacies may be affected under any new proposed single PDL, particularly when pharmacy is carved out of managed care risk. There are multiple dynamics to be weighed in the state's analysis. One dynamic is estimating the spread between what MCOs pay to their PBMs and what pharmacies receive in payment from the PBMs in the current managed care structure. If the state is contemplating a move to a carved-out single PDL structure, the state FFS payment structure to pharmacies will replace this MCO-PBM payment dynamic. Another dynamic involves estimating the average change in dispensing fees paid under state FFS versus the amount previously paid under the MCO-PBM structure. State FFS dispensing fees are commonly in the \$9 to \$12 range and MCO dispensing fees are often significantly lower.

Impact on state tax structures. A number of states have a tax that is applied to managed care premiums or claims, to providers, or a tax applied to pharmacy claims. Thirty-two states use federal rules to administer these taxes to finance Medicaid programs. If a state elects to carve the pharmacy benefit in or out of managed care risk, it will need to forecast the change in revenue generated by these taxes due to the increase or decrease in premiums or number of claims.

Table 6: Population Health Opportunities by PDL Structure

Multiple PDLs	Aligned PDL	Single PDL
<ul style="list-style-type: none"> • Provides platform for community-level population health initiatives • Ensures MCO has full information to participate in total cost of care or VBP initiatives 	<ul style="list-style-type: none"> • Provides potential platform for uniform implementation in aligned classes across FFS and MCOs 	<ul style="list-style-type: none"> • Provides platform for uniform implementation for statewide population health efforts • Allows for potential alignment with other programs and payers

Abbreviations. FFS: fee-for-service; MCO: managed care organization; PDL: preferred drug list; VBP: value-based purchasing.

effective January 1, 2019. In May 2019, CMS issued PBM spread pricing guidance, making it clear that MCO medical loss ratios must include any price concession or discount received by the managed care plan or by its PBM, regardless of who pays the rebate or discount.⁵⁸

Transparency of PBM prices paid to pharmacies may also result in more appropriate reimbursement and/or payment of dispensing fees. Local pharmacies are key to ensuring Medicaid enrollees have access to necessary medications and these pharmacies are also an important employer group in any state. Medicaid FFS, using a single PDL, generally pays a pharmacy dispensing fee of \$9 to \$12 dollars.⁵⁹ Dispensing fees from MCO’s PBMs are often substantially lower, with one state official citing amounts as low as 80 cents.⁵⁹ New York found PBMs were reducing the weighted average cost of common generic drugs below the pharmacy cost to dispense, and simultaneously increasing the fees they were extracting through spread.⁶⁰

Effect on State Revenue Structure

As Medicaid pharmacy is a high cost for most states, there are multiple potential interactions between the state’s revenue structure and its structure for managing Medicaid pharmacy. The interaction between state health care provider taxes and a Medicaid agency’s decisions on PDL and MCO capitation structure is one component of overall financial stability to consider. In 2018, all states except for Alaska had some form of provider tax in place, commonly used to finance a portion of the state share of Medicaid expenditures.³² In

addition, states that rely on public financing from taxes on MCO premiums may need to consider how a potential carve out of pharmacy from MCO risk for a single PDL structure may reduce their tax base and the associated revenue from their current tax program.

4. Population Health and Reform Efforts

An emerging discussion about single or aligned PDLs is providing a common base to support population health and reform efforts across all Medicaid lives as well as other public health, public employee, or other programs.⁴ Delaware Medicaid officials report leveraging their single PDL when addressing opioid use. The state was able to quickly establish quantity limits for opioids and implement this change across their Medicaid population.

In another example, Washington recently implemented a multi-agency purchasing initiative with the goal to eliminate hepatitis C virus in the state through public health outreach, education, preventive services, testing, linkage to care, and the provision of direct-acting antiviral drugs.⁶⁴ Washington officials noted its approach was feasible, in part, because the state had centralized PDL control over Medicaid purchasing for hepatitis C drugs.

When responding to a public or population health concern, states with multiple PDLs will occasionally carve out a drug or issue a policy that requires a single PDL for a specific drug or drug class. South Carolina has initiated aligned PDLs across FFS and MCOs for tobacco cessation

products and medication-assisted therapy as part of a broader state-federal partnership on population health. In addition, South Carolina implemented a focused carve out, single PDL for hepatitis C drugs until July 1, 2020.

On the flip side, multiple PDLs provide MCOs with the latitude to pursue their own population health and value-based programs, while a single or aligned PDL could have a dampening effect on these local efforts. Some MCOs actively engage with both clinicians and pharmacists to find the most efficient and evidenced-based use of pharmaceuticals and try to link appropriate usage to outcome measures, and others do not. Value-based arrangements, such as bundled payments for oncology or rheumatoid arthritis, are examples of when an MCO might link payment and outcomes for both medical and pharmacy claims.

Key Questions When Considering a Shift to Single or Aligned PDLs

The range of considerations in moving to a single or aligned PDL, combined with deciding whether the pharmacy benefit will be carved out of MCO risk, are interrelated and complex. This section lists questions states should ask when analyzing the issues, including assessing stakeholder impact.

1) What are the state's goals for health care reform? How does its Medicaid program and the role of pharmacy fit into the picture?

This brief highlights potential state priorities around administrative structure, access and quality, cost and transparency, and population health or health reform initiatives. States should also consider priorities around payment reform and how those might interact with a PDL change. Drugs can be a component of total cost of care initiatives or payment models that focus on management of particular chronic conditions or high-needs populations. If pharmacy is carved out from MCO risk or preferred drugs are selected at the state level, would this affect successful

payment reform initiatives? Could the state achieve some of its goals by creating a single PDL or carve out for select high-cost drugs?

2) What is the current situation across MCO PDLs and PBMs?

States should look carefully at their MCOs and analyze variation among their PDLs. Knowing MCO populations can vary, states may want to consider whether any of the PDL variation is driven by population differences. There may be local variation in delivery patterns or population needs that are important to understand, or there may be evidence that one MCO PDL process is more effective than others.

3) What impact would a new structure have on Medicaid program costs?

When analyzing the cost impact of a centralized PDL approach, states should work with an actuary and use state-specific data to the extent possible. Some published evaluations of single PDL costs are calculated using broadly applied savings assumptions based upon national data.^{53,65}

A state's actuary can help ensure savings assumptions take into account drug class variations that may be masked in the analysis, such as a small number of prescriptions for specialty drugs driving a large portion of the costs. In addition to working with its own actuary, budget, and program staff, states should reach out to MCOs, pharmacy, and provider associations to augment available data at the state level and to also build broader buy-in for the analyses. The highlight box on page 15 provides a brief overview of some key analyses states can conduct to gauge the financial impact of a shift in PDL structure.

4) How are MCO capitation rates affected by the PDL structure being considered?

A shift in PDL structure may require adjustments to capitation rates to account for variations in MCO risk and responsibilities. States moving to a single PDL may decide to carve the drug benefit out of the MCO risk

completely, requiring a clear and significant shift in the MCO capitation rates. States that leave the drug benefit carved in to MCO risk may need to investigate risk mitigation for specific high-cost drugs or drug classes. Risk corridors and kick payments are 2 options available to mitigate MCO risk in key high-cost or variable instances.

Risk corridors put a floor and ceiling to the potential losses for a health plan. States and MCOs then effectively share in the losses (and gains) across the state, based on these rates. Kick payments allow MCOs to cover stipulated services without assuming the full financial risk. States can also take on full risk through carve outs of specific drugs from MCO risk.

South Carolina's Medicaid program provides an example of employing a risk mitigation arrangement for hepatitis C drugs. As new hepatitis C drug options became available, competition increased the supplemental rebates being offered to states and this competition threw off the alignment of financial incentives between the state and its MCOs. The MCOs continued to prefer a drug with a lower actual acquisition cost that was consistent with their financial incentives.

The state, however, found a different drug to be less expensive in net cost because of the substantial supplemental rebates available to them as a state Medicaid agency. South Carolina officials weighed the range of risk mitigation options and chose to carve out hepatitis C medication from their managed care capitation rates and manage it through a single PDL until the carve out ends on July 1, 2020.

Additionally, states should work collaboratively with their MCOs to understand and make the necessary capitation adjustments for any anticipated shift from generics to brand-name drugs that may occur under a new centralized PDL. As outlined above, a state's single or aligned PDL may prefer some brand-name drugs over generics because the brand-name

drugs' net cost to the state is lower due to the CPI penalty described earlier in this brief. If the MCO is at financial risk for drugs, then the MCO will incur greater costs for preferred brand-name drugs on the single PDL because the MCO does not get the benefit of the state's CPI penalty as part of the MDRP.

5) What implementation approach is appropriate for your state given all other considerations?

If a PDL structure shift is being considered, there are a range of approaches to consider. States have discretion on how they approach a new single or aligned PDL structure. Washington opted to phase drug classes into the single PDL over 18 months and held weekly meetings with MCO staff to ensure open lines of communication. Phasing of classes allows for mid-course correction and can help ensure smooth implementation.

States can also phase in the single PDL, making changes voluntary at first before moving to a mandatory PDL to give MCOs flexibility to adjust to the new requirements on their own timeline.

As part of implementation, states should also consider what strategies will mitigate disruption for enrollees. These strategies include allowing additional time for providers to switch patients to a preferred drug, or for a prescription for a nonpreferred drug to continue until treatment is completed or a previous prior authorization has expired. An outreach and communication strategy with pharmacies, providers, and consumers is a key component for supporting any transition.

6) How will the state's administrative structure need to be changed or expanded?

As mentioned earlier in this brief, state Medicaid agencies are already performing the full range of pharmacy benefit management functions for their FFS population.

The movement to a more centralized PDL structure may require additional administrative capacity. States should consider, for example, whether additional resources may be needed

to support an enhanced state P&T committee process, deliver real-time pharmacy data feeds to MCOs (see #7 below), build additional project management resources to track implementation components, or develop more frequent and detailed communications processes with MCOs, pharmacies, providers, and consumers.

Additional staff capacity may be required to manage drug coverage edits and file updates, increased number of supplemental rebate agreements, additional prior authorization volume, and call center inquiries.

7) What data exchange and analytic support will be needed under the new structure?

A shift in PDL structure may require pharmacy data to be shared differently between the state and MCOs to support care coordination, payment reform initiatives, and other efforts. For single PDL structures with a full carve out from managed care risk, sharing real-time pharmacy data with MCOs will need to be considered if not already a current capability. Particularly under a full carve out of pharmacy from MCO risk, MCOs may require real-time access in addition to cyclical or monthly data feeds for their enrollees' pharmacy utilization to have a whole person view of care management and total cost of care goals. For aligned PDLs or a single PDL carved into MCOs, the state will need an efficient approach to sharing coding for preferred agents, as well as any changes, additions or deletions based on P&T and DUR Board meetings.

Conclusion

States need to weigh a wide range of interacting variables when determining the right PDL structure for its Medicaid program. The currently available evaluative literature on the range of PDL structures—often published to support one stakeholder group's perspective—may hinder rather than support a productive conversation.

The examples highlighted in this brief indicate the need for states to bridge the typical ideological disagreements by including a full range of stakeholders in a balanced assessment of:

- The state's goals for the Medicaid program and the role of pharmacy in meeting those goals;
- What a shift in PDL structure means for administrative, access, cost, and population health components of those goals; and
- How to approach the implementation concerns held by all stakeholders of a new PDL structure.

These decisions are nested within the culture and context of each individual state and the impact on patients, prescribers, managed care organizations and pharmacies will vary according to each state's circumstances.

There is no one right decision, rather PDL structures offer tradeoffs for the state and its constituents when trying to manage escalating drug costs.

Highlight: Clinician-administered Drugs

Clinician-administered drugs (CADs) are drugs administered by a physician or a health care professional operating under a physician's supervision, such as a nurse. The MDRP, and the restrictions it imposes on drug coverage, only apply to "covered outpatient drugs."⁵⁹ The definition of covered outpatient drugs is broad, encompassing all prescription drugs, biologics (other than vaccines), and insulin.⁶¹ However, drugs administered by physicians and clinicians are excluded from this MDRP definition and most, but not all, state Medicaid programs reimburse CADs through the medical benefit.⁶²

Nearly every drug dispensed in retail pharmacy is a covered outpatient drug. As part of the services offered by retail pharmacies, these outpatient drugs are subject to real-time insurance coverage and prior authorization checks before the prescription is filled.⁵⁹ Unlike outpatient drugs, CADs are billed to Medicaid and other insurers after the patient encounter (generally within 180 days) and are much less often subject to prior authorization requirements.

The asynchronous nature of medical benefit billing for CADs makes it harder to manage these high-cost drugs. Clinicians are not accustomed to securing prior authorization approval for CADs and their offices do not have access to the same real-time, point-of-service systems used in a retail pharmacy to check coverage and prior authorization requirements. States have growing incentives

to manage CADs, as these drugs reimbursed through Medicaid's medical benefit comprise more than 28% of overall drug spending, and for many states this category of spending is growing faster than covered outpatient drugs.⁶³

Escalating costs are prompting states to consider taking a more activist strategy to manage CADs. There is no right way to manage CADs in Medicaid since state programs have different configurations that make some approaches a better fit than others. The SMART-D team is compiling a list of potential CAD management approaches Medicaid programs may wish to explore. These ideas include:

- Create a PDL for select CADs and a network of providers to dispense these drugs (e.g., specialty pharmacies or outpatient hospital clinics).
- Implement a maximum allowable cost methodology for CADs.
- Use a risk-sharing pool to create clinical and cost transparency for select high-cost CADs.
- For MCO states, employ a temporary carve out strategy for new high-cost CADs.

These ideas should be seen as an opportunity to explore multiple approaches and fit them to the specific circumstances of a state's Medicaid program.

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Appendix A. List of Interviewees and Advisors

Amick, Bryan, PhD, MBA, MS. Deputy Director, South Carolina Department of Health and Human Services. September 9, 2019.

Appleby, Pamela. Director of Medicaid Benefits Management, Wisconsin Department of Health Services. September 17, 2019.

Archibald, Tracey. Pharmacy Program Manager, Ohio Department of Medicaid. September 3, 2019.

Armijo, Kari, JD. Acting Director, New Mexico Medicaid. October 18, 2019.

Bachhuber, MD. Chief Medical Officer, Louisiana Medicaid. October 25, 2019.

Bachireddy, Chethan, MD, MS. Chief Medical Officer, Virginia Department of Medical Assistance Services. September 26, 2019.

Barran, Scott, RPh. Pharmacologist, Health Innovation and Quality, Ohio Department of Medicaid. September 3, 2019.

Bouck, Trish. Pharmacy Management Division Director, Michigan Department of Health and Human Services. November 4, 2019.

Brundage, Kelsey, JD. Pharmacy Section Chief, Wisconsin Department of Health Services. September 17, 2019.

Bridges, Richard. Vice President, Louisiana Academy of Family Physicians. November 25, 2019.

Citron, Roger, RPh. Pharmacy Program Manager, Division of Medical Assistance Programs, Oregon Health Authority, Oregon State University, College of Pharmacy. September 24, 2019.

Clark, Renee, PharmD. Chief Pharmacy Officer, TennCare Pharmacy. October 23, 2019

Douglass, Trevor, DC, MPH. Director, Oregon Prescription Drug Program and Pharmacy Purchasing, Office of Delivery System Innovation, Oregon Health Authority. September 24, 2019.

Evaskus, Leta. Manager, NW Prescription Drug Consortium Operations, Clinical Quality and Care Transformation, Washington State Health Care Authority. September 16, 2019.

Fliss, Mary. Deputy, Clinical Strategy and Operations, Clinical Quality and Care Transformation, Washington State Health Care Authority. September 26, 2019.

Francioni-Proffitt, Donna. Pharmacy Program Manager, Virginia Department of Medical Assistance Services. September 26, 2019.

Groff, Stephen. Director, Delaware Division of Medicaid and Medical Assistance. September 4, 2019.

Holley, April, PharmD. Pharmacy Manager, Louisiana Medicaid. October 25, 2019.

Irwin, Amy. Medicaid Pharmacy Operations Manager, Washington State Health Care Authority. September 16, 2019.

Kranc, Herman. Manager, Integrated Healthcare, Connecticut Department of Social Services. September 24, 2019.

Moore, Joshua, PharmD. Director of Pharmacy, State of Missouri MO HealthNet. September 6, 2019.

Owens, Rebecca, FSA, FCA, MAAA. Consulting Actuary, HCA Solutions

Pistoresi, Ryan, PharmD, MS. Assistant Chief Pharmacy Officer, Washington State Health Care Authority. September 16, 2019.

Roaseau, Mark, MD. Clinical Pharmacist/Physician, State of Missouri MO HealthNet. September 6, 2019.

Subhedar, Rita. State Assistant Administrator, Michigan Department of Health and Human Services. November 4, 2019.

Sullivan, Donna, PharmD, MS. Chief Pharmacy Officer, Washington State Health Care Authority. September 16 & 26, 2019.

Thomas, Tara. Medicaid Pharmacy Program Manager, Lead for State Programs, Capital District Physicians' Health Plan, October 22, 2019

Wanicha, Burapa, MD, MPH. Medical Director, New Mexico Department of Health, New Mexico Medicaid. October 18, 2019.

Weston, Deborah, JD, MPA. Pharmacy Program Advisor, Director, Office of Delivery System Innovation, Oregon Health Authority. September 24, 2019.

Wilson, Angela. Pharmacy Operations Manager, State of Missouri MO HealthNet. September 6, 2019.

Wishner, Jane, JD. Executive Policy Advisor on Health and Human Services, New Mexico Governor's Office. October 18, 2019.

Wood, Eileen. Senior Vice President, Clinical Integration, and Chief Pharmacy Officer, Capital District Physicians' Health Plan, October 22, 2019

Wynn, William, PharmD. Director of Medicaid Pharmacy, South Carolina Department of Health and Human Services. September 9, 2019.

Zamora-Martinez, Debbie. Acting Director, New Mexico Medicaid. October 18, 2019.

Zavoski, Robert, MD. Medical Director, Connecticut Department of Social Services. September 24, 2019.

Zerzan, Judy, MD, MPH. Chief Medical Officer, Clinical Quality and Care Transformation, Washington State Health Care Authority. September 26, 2019.

Zimmerman, Lisa. Deputy Director, Delaware Division of Medicaid and Medical Assistance. September 4, 2019.

Appendix B. Overview of Key Considerations by State Medicaid PDL Structures

PDL Structure	Multiple PDLs	Aligned PDL	Single PDL
Description	Each MCO and the FFS program set their own PDLs.	MCOs PDLs are aligned with FFS program on a class-by-class or % of class basis. May be a “floor” & MCO variation that is not more restrictive is allowed (e.g. generic substitution).	MCOs and FFS program use the same, single PDL set through state DUR process.
State Priorities			
Administrative Efficiencies	<ul style="list-style-type: none"> • Least centralized for Medicaid administration • Duplication of administrative functions across Medicaid FFS, multiple MCOs and their PBMs • Multiple Medicaid PDLs for prescribers and pharmacies to follow • Allows MCOs to use same PBM and PDL approach across public and private enrollees 	<ul style="list-style-type: none"> • More centralized decision making with aligned criteria • Duplication of administrative functions across Medicaid FFS, multiple MCOs and their PBMs • Allows some alignment across MCOs and FFS for prescribers and pharmacists to follow 	<ul style="list-style-type: none"> • Most centralized and streamlined decision making • Least duplication of effort as all administrative functions are the same for all Medicaid enrollees • One Medicaid PDL for prescribers and pharmacies to follow
Patient Access & Care Quality	<ul style="list-style-type: none"> • Multiple PDLs hold potential for disruption as enrollees change plans • Allow for maximum amount of MCO control to manage physical health and pharmacy access for enrollees 	<ul style="list-style-type: none"> • Reduced potential for disruption within aligned classes • Allows some potential for MCO implementation discretion (e.g., safety edits) • May result in variability across MCOs that may reduce clarity of PDL 	<ul style="list-style-type: none"> • One PDL minimizes access disruptions as patients move between MCOs • Creates clear process for providers to understand what is preferred and to ask for nonpreferred only when necessary, reducing PA time

PDL Structure	Multiple PDLs	Aligned PDL	Single PDL
Cost Management & Transparency	<ul style="list-style-type: none"> • Enables for MCO level control of total cost of care • Allows MCOs to customize PDLs for local or VBP initiatives 	<ul style="list-style-type: none"> • Allows for some increased transparency and predictability on rebate collection within aligned classes 	<ul style="list-style-type: none"> • Most transparent for collection of drug rebates and PBM fees • Most leverage for rebate negotiation • Control of total cost of care and clinical priorities from state perspective
Population Health & Reform Initiatives	<ul style="list-style-type: none"> • Provides platform for community-level population health initiatives • Ensures MCO has full information to participate in total cost of care VBP initiatives 	<ul style="list-style-type: none"> • Provides potential platform for uniform implementation in aligned classes across FFS and MCOs 	<ul style="list-style-type: none"> • Provides platform for uniform implementation for population health efforts • Allows for potential alignment with other programs and payers

Abbreviations. DUR: drug utilization review; FFS: fee-for-service; MCO: managed care organization; PA: prior authorization; PBM: pharmacy benefit manager; PDL: preferred drug lists; VBP: value-based purchasing.

