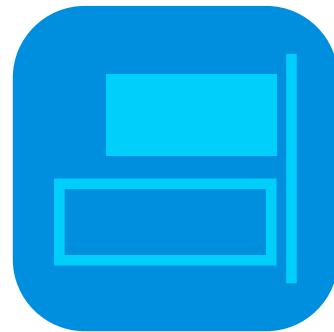*State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)*

Multi-agency Purchasing Framework for States

January 2020

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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 commercial insurance carriers; and single and aligned preferred drug lists (PDLs) for Medicaid managed care states.

This paper on multi-payer purchasing 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 papers 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.
>
> - Medicaid and Specialty Drugs: Policy Options, June 2016
> - SMART-D Phase 1 Summary Report, September 2016
> - SMART-D Economic Analysis, September 2016
> - SMART-D Legal Brief, September 2016
> - SMART D Alternative Payment Model Brief, October 2016

Background

State governments fund health care through a range of programs including Medicaid, public employee health benefits, retiree benefits, workers compensation programs, state hospitals, and corrections facilities. Across the country, states report difficulty in balancing and predicting the budgets of many of these programs as health care inflation continues to exceed state general fund revenues. Prescription drug costs account for approximately 10% of overall health care spending, yet have had several years of double-digit increases in the rate of growth.[1]

Controlling prescription drug spending remains a focus for state policymakers.[2] Prescription drugs account for a growing percentage of expenses and are expected to grow over the next 10 years at one of the fastest rates to date, due in part to the anticipated growth of new high-cost treatments.[3] From 2010 to 2015, average Medicaid spending for brand drugs increased by 40% and spending on specialty drugs almost doubled, growing from $4.8 billion to $9.9 billion.[4] This trend is expected to continue. In addition, state corrections departments spend more than 15% of their health care budget on drugs, with some spending as much as 32%.[5]

To combat the rise of prescription drug spending, states have been searching for legislative solutions. In 2019, 33 states enacted a record 51 laws to address drug prices, affordability, and access.[6] Many laws focus on increased transparency of pharmacy benefit managers (PBMs), Canadian importation programs, and the creation of boards or commissions focused on drug affordability.

Many state Medicaid agencies and departments of corrections have historically tried to manage or reduce pharmacy spending by leveraging their purchasing power with other states through interstate purchasing pools. These pools are specific to both Medicaid and corrections, and are designed to maximize drug discounts and rebates.[7]

However, given the growing concerns about drug spending and the maturity of many preferred drug lists, states are now interested in leveraging their intrastate purchasing portfolio across agencies as a way to better manage pharmaceutical expenditures.[7]

There are a few states with early multi-agency purchasing experience and several others are exploring possible opportunities. These examples provide valuable lessons regarding structure and implementation of such arrangements, and present state leaders with potentially viable pathways to alleviate some of the current pressure of the rising drug spend.

The goal of this policy brief is to provide a framework for states when considering multi-agency drug purchasing approaches. (See next page.) It will describe suggestions and highlight key elements for state leaders in planning multi-agency purchasing.

This brief is based on 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, and executive branch health policy advisors. Participating states represented a range of program sizes and structures (fee-for-service and managed care), and include: Connecticut, Delaware, Louisiana, Michigan, Missouri, New Mexico, Ohio, Oregon, South Carolina, Texas, Virginia, Washington State, and Wisconsin. (See Appendix A for a detailed list of interviewees.)

Any concepts not specifically cited in this document with published literature are based on the authors' synthesis of information obtained through the interview of state representatives.

Framework for Multi-Agency Purchasing	
State goal and support	Develop an overarching state goal and secure strong support from the executive and/or legislative branches.
Drug class selection	Identify drug classes that: (1) link to the state's goal, and (2) have competition within the drug class.
Agency alignment	Ensure alignment exists among participating agencies and designate one lead agency.
Budget and analytics	Align budgets and data analytics among state agencies.
Purchasing strategies	Establish purchasing strategies to solicit required information from manufacturers for both Medicaid and non-Medicaid pricing.
Future considerations	Develop a "future state" scenario to allow the program to expand with additional participating payers and states.

Framework for Multi-Agency Purchasing

State Goal and Support

Step 1: State Goal and Support
Develop an overarching state goal and secure strong support from the executive and/or legislative branches.

- What is the state's health care goal(s) and how does a multi-agency purchasing initiative fit into its strategic plan?
- What does the state hope to achieve with multi-agency purchasing? How does the state intend to measure its goal(s)?
- What is the political support, either through the legislative or executive branches, to pursue a multi-agency purchasing initiative?
- Who will serve as champion(s) for achieving this goal?
- What process will be used to align or coalesce agencies, stakeholders and champions?

A critical first step to effectively mobilizing state resources and stakeholder support for multi-agency drug purchasing is to develop an overarching state goal. Goals could include increasing access, lowering costs, or improving health outcomes, or a combination of all three. Articulating at least one clear goal is necessary for governors and state legislators to solidify support, produce the necessary executive orders or other authorizing documents, pass legislation, or convene public bodies.

Executive Branch Examples

Like many states dealing with the high cost of hepatitis C medications, both Louisiana and Washington State initially set clinical criteria that triaged and effectively reduced the number of patients eligible for treatment, based on clinical criteria. To create broader access, both states subsequently developed public health-driven, statewide approaches for hepatitis C that allowed treatment of more individuals with a parallel goal of controlling costs.

In 2016, Louisiana, under the leadership of Governor John Bel Edwards and State Health Secretary Rebekah Gee, developed a multiyear plan to make hepatitis C drugs more accessible to the most vulnerable populations and provide more budget predictability. This approach involved: (1) obtaining stakeholder buy-in, (2) soliciting philanthropic support, (3) using

national expertise and, (4) securing the first drug manufacturer contract in the nation with a fixed price that is delinked from volume.[8]

Washington Governor Jay Inslee issued a directive in September 2018 to provide the necessary direction and authority for state agencies to mobilize and begin work on eliminating hepatitis C by 2030.[9]

> *I direct my health sub-cabinet and the health and human service state agencies under my authority to begin immediately to work with tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide HCV elimination plan.*

Through this directive Washington State: (1) launched a state coordinating committee, (2) deployed resources to analyze data between agencies, (3) created a state-wide elimination plan and, (4) developed a procurement process that solicited proposals from drug manufacturers aimed at reducing costs and incorporating key public health strategies.

Much attention has also been given to California where Governor Gavin Newsom issued an executive order in January 2019 directing the Department of Health Care Services to use the state's market power and "take all necessary steps to transition all pharmacy services for

Medi-Cal managed care to a fee-for-service benefit by January 2021."[10] This is a significant step since California Medicaid covers 13 million beneficiaries. In addition, the executive order also provided the following direction:

> To the fullest extent permitted under law, all agencies under my direct executive authority shall cooperate with providing data and other information to the Department of General Services to assist the Department in developing a list of prescription drugs that could appropriately be prioritized for future bulk purchasing initiatives. Agencies not under my direct executive authority are requested to do the same.

With the goal of reducing prescription drug prices, Wisconsin Governor Tony Evers issued an executive order in August 2019 creating the Governor's Task Force on Reducing Prescription Drug Prices to advise the governor on possible strategies and actions.[11] Governor Evers similarly directed all state agencies to assist the task force with technical assistance on an as-needed basis. These executive branch directives have proven effective in reducing bureaucratic barriers and aligning state agencies around a common agenda and outcome.

Legislative Branch Examples

The New Mexico Legislature passed Senate Bill 131 in March 2019, establishing the Interagency Pharmaceuticals Purchasing Council with a goal of maximizing the state's purchasing power of pharmaceuticals among certain state agencies.[12] The council is comprised of officials representing state agencies, school and public employee health insurance, and retiree benefits. The council will provide the legislature with annual updates on opportunities for leveraged purchasing strategies between agencies to help lower costs.

Similarly, in April 2019, the Delaware House of Representatives passed House Concurrent Resolution 35 that created the Interagency Pharmaceuticals Purchasing Study Group to review and make recommendations to leverage the state's bulk purchasing power to negotiate lower prices.[13] The study group is comprised of state legislators and state department officials, and is expected to issue its final report no later than December 31, 2019.

Delaware and New Mexico are just 2 examples of state legislation driving exploration and strategy development around multi-agency purchasing. Several other states have legislatively created boards focused on reducing pharmaceutical drug costs.

Maine, Maryland, Massachusetts, and New York have all established boards to review drug costs, increase transparency, investigate drugs that increase in price by certain percentages each year, and/or set annual spending targets.

Table 1. Summary of executive or legislative directives by state

State	Executive or Legislative Directive
California	Direct state agencies to review opportunities to expand existing bulk purchasing efforts for state, local and private sector entities and transition Medi-Cal pharmacy services from managed care into the fee-for-service delivery system to create significant negotiating leverage and substantial savings for the state.
Delaware	Create an Interagency Pharmaceuticals Purchasing Study Group to review and make recommendations to leverage bulk purchasing power of the state to negotiate lower prices.
Louisiana	Make hepatitis C drugs more accessible to Louisiana's most vulnerable populations and provide for more budget predictability.
New Mexico	Create an Interagency Pharmaceuticals Purchasing Council to assist in the coordinated procurement of drug among certain state agencies.
Washington	Direct state agencies to work with partners across the state to develop and implement a statewide hepatitis C elimination plan.
Wisconsin	Create a Governor's Task Force on Reducing Prescription Drug Prices to advise the governor on possible strategies and actions to reduce prescription drug prices.

Articulation of a clear goal is critical in all these efforts. In the absence of such a "North Star," different interpretations of process and outcomes can lead to a lack of alignment between state agencies, policymakers, and stakeholders, leading to gridlock and project delays. In addition, the more a state establishes clear and compelling goals, especially those not limited to reducing cost, the more it can leverage the motivation of drug manufacturers.

There are important differences when initiatives are launched by the executive branch versus legislative branch. Louisiana and Washington State's executive-led efforts picked a specific and compelling public health goal, since nearly all state agencies report directly to the governor. Effective and efficient progress is made when a governor provides strong directives and leadership.

Legislative directives are effective at compelling agencies to assess a topic and make recommendations, as opposed to setting a specific goal. Since the legislative branch is responsible for executive branch oversight, it can be more difficult to establish trust and remove any key barriers between agencies because the legislative and executive branches are not always aligned with one another.

Drug Class Selection

Step 2: Drug Class Selection
Identify drug classes that: (1) link to the state's goal, and (2) have competition within the drug class.

- Which drugs or drug classes align with the state's goal?
- Based on the structure of the state's drug benefit, what process will be used to obtain authority to pursue multi-agency purchasing?

Once a state goal has been established, the selection of a drug class or classes is the next step. The following areas should be taken into consideration when selecting a drug class for a multi-agency purchasing initiative:

- Alignment with state goal(s)

- Medicaid program structure: fee-for-service vs. managed care

- Competition within the identified drug class(es)

Alignment with State Goal(s)

State officials interviewed for this brief cautioned of exclusively focusing on drug costs and advocated for focusing on total cost of care and value whenever possible, since increased spending on the right drug for a patient may reduce downstream medical costs.

States expressed strong interest in public and population health interventions, such as drug classes that treat hepatitis C, hemophilia, HIV, oncology, medication-assisted treatment for opioid addiction, gene therapies, and diabetes.

Ultimately, a comprehensive analysis of drug cost, utilization and outcome data (if possible) among agencies should be performed. This analysis can determine areas of greatest overlap and opportunity for leveraged purchasing between agencies.

States pursuing a comprehensive cost control approach may find it useful to limit the scope of analysis to the top cohort of drugs—perhaps the top 25 or 50—that are *both* high-cost (by unit price) and high spend (by overall volume).

Medicaid Program Structure: Fee-for-Service vs. Managed Care

Drug class selection can be impacted by how states structure their Medicaid programs: as either fee-for-service or managed care.

States that administer Medicaid pharmacy benefits in a fee-for-service (FFS) environment or have specific drug classes "carved-out" from managed care contracts are in a stronger position to coordinate and partner with other state agencies for leveraged purchasing. When the drug benefit (or a drug class) is under the state's direct control, it is generally easier to analyze data between agencies, develop a unified procurement process if desired, and ultimately negotiate with manufacturers.

States that contract with managed care organizations (MCOs) and have prescription drugs carved in to the MCO contracts can also pursue multi-agency arrangements using the Centers for Medicare & Medicaid Services (CMS) 2016 rule explicitly requiring MCOs to abide by the Medicaid Drug Rebate Program (MDRP), thus ensuring the state receives any additional supplemental rebates the state negotiates, even if the drugs are paid for through an MCO.[14] Louisiana's hepatitis C initiative used this CMS rule.

As states have struggled to contain costs within their Medicaid programs, 39 states now have risk-based contracting with MCOs with the goal of increasing budget predictability, constraining Medicaid spending, and improving access to care and value.[15] Nearly 70% of Medicaid beneficiaries nationwide currently receive care through an

MCO.[15] Beginning in 2011, state Medicaid programs began a significant shift of pharmacy benefits into managed care delivery systems. Many states that previously retained pharmacy as a FFS benefit began to carve pharmacy in to their contracts with MCOs.[16] As a result, managed care drug spending grew from 14% to 47% of total gross Medicaid drug spending from 2011 to 2014.[17]

States are now reconsidering the pharmacy benefit as part of managed care for many reasons, including:

- As more high-cost specialty and orphan drugs come to market, many MCOs have advocated that specific drug classes be carved out of their contracts due to extraordinary costs coupled with high unpredictability. In response, several states have carved out or developed partial risk-sharing arrangements with MCOs for drugs treating such conditions as hepatitis C, hemophilia, multiple sclerosis, and cystic fibrosis. Based on interviews with state officials, this trend is expected to continue as more high-cost gene therapies enter the market.

- The rise in high-cost drugs has prompted many states to look at bringing the Medicaid prescription drug benefit entirely under state control (i.e., carve it out from MCO contracts) to maximize the state's supplemental rebates and increase transparency.[16] State officials expressed concern over spread pricing that occurs when PBMs keep a portion of the amount paid to them by MCOs for prescription drugs instead of passing the full payments on to pharmacies. The prescription drug benefit carve-out has become a controversial issue between many states and their MCOs. For example, in February 2019 West Virginia produced a Medicaid pharmacy cost-savings report detailing the cost benefit of carving out the Medicaid prescription drug benefit from their MCO contracts. The report highlighted savings (largely through decreased administrative expenses) of more than $54 million in 2018 by carving out prescription drug coverage.[18] This report was quickly refuted by America's Health Insurance Plans (AHIP) whose research showed an opposite effect, with an overall increase in costs to the state.[19]

- States are focused on improving the patient and provider experience. States with multiple MCOs often operate with different PDLs and clinical coverage criteria. Patients who transition to a different MCO may experience breaks in continuity and/or be forced to switch drugs. These differences also impact providers who must learn to navigate and expend time navigating the different PDLs and clinical criteria in order to prescribe for their Medicaid population. A prescription drug carve-out scenario can improve the portability of a patient's prescription drug benefit and greatly reduce the administrative burden to clinicians, as they would only have a single PDL and one set of clinical criteria to navigate.

Competition

A multi-agency purchasing approach should focus on drug class(es) with competition between manufacturers. Competition creates the basis for negotiation between leveraged state purchasing volume and competing manufacturers.[20] The importance of competition also suggests a multi-agency approach is not the perfect solution for every drug class, especially with the emergence and growth of orphan drugs with a sole manufacturer and where no competition exists.

A key factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity and the absence of competition. There is a decline in drug prices to approximately 55% of brand-name drug prices when two generic manufacturers make the product, 33% with five manufacturers, and 13% with 15 manufacturers.[21] There are some recent high-profile examples of sharp increases in the costs of some older generic drugs. Turing Pharmaceuticals raised the price of pyrimethamine (Daraprim), a 63-year-old treatment for toxoplasmosis, by 5500%, from $13.50 to $750 a pill in 2015.[21] The company was able to set the high price despite the absence of any patent protection because *no other manufacturer was licensed to market* the drug.

Agency Alignment

- What are the current relationships among key state agencies (e.g., Medicaid, corrections, public employees, public health) and what is the likelihood of those agencies working collaboratively toward a common goal of aligned pharmaceutical purchasing?
- What forum or setting will be used for multi-agency collaboration and discussion?
- Under what authority will agencies collaborate?
- How will agency discussions be convened and led? Who is responsible and accountable, and to whom?

Aligning multiple agencies around leveraged drug purchasing requires collaboration and trust. Interviews with state leaders highlighted the need for a collaborative forum between agency leadership, including state pharmacy and medical directors. Currently most states use informal discussions between agencies to share their concerns about trends and future planning, but do not have a formal venue to plan and align their work.

Establishing a formal setting (such as a multi-agency task force), as well as designating a lead agency with the authority to make critical decisions can provide the necessary infrastructure and traction to move forward.

Multi-agency venues should also have clear authority, such as a directive from a governor or the legislature, as it is extremely difficult to have agencies mobilize such a task force on their own. Once the setting is established, clear roles and responsibilities should be developed for all agency members to ensure the necessary resources to implement a multi-agency initiative.

For example, a department of public health may be responsible for public messaging, community programs and coordinating with local county health departments. A Medicaid agency may be responsible for provider outreach and education, data collection and analytics. An administrative services department may be responsible for contract procurement and contract oversight.

Depending on the scope and size of the project, securing project management resources can provide needed bandwidth for successful implementation.

There can be significant challenges in aligning efforts due to myriad operational issues and regulations within each agency. The following overview of potential key agencies is designed as a primer for considering potential alignment opportunities, roles and responsibilities.

Medicaid

The Medicaid drug benefit is a voluntary benefit which, in practice, all states offer. States must comply with the regulations of the MDRP when agreeing to participate in the Medicaid drug benefit. The federal MDRP, however, is often seen as a major impediment to statewide purchasing. Under the MDRP, in return for offering a best price, manufacturers are guaranteed Medicaid coverage of their drugs. This open formulary can present challenges as non-Medicaid agencies generally develop a closed formulary and have tighter control and decision-making authority around which drugs are covered. State Medicaid programs can attempt to mitigate this through use of a PDL selection to align with other agencies' closed formularies.[16]

Twenty-nine states participate in one of three multistate Medicaid purchasing pools (National Medicaid Pooling Initiative [NMPI], Top Dollar Program [TOP$], and Sovereign

States Drug Consortium [SSDC]).[22] These pools provide assistance in managing state PDLs by negotiating supplemental rebates on behalf of the participating states.

Other states choose to negotiate and manage their PDLs on their own. States face a challenge in trying to understand the net benefit gained in Medicaid supplemental rebates by staying in the pool, requesting permission from the pool to exclude a specific drug or drug class, or deciding to negotiate all rebates on their own.

Department of Corrections

There can be significant overlap between high-cost drugs in Medicaid and departments of corrections (DoC) due to the vulnerable populations each agency serves.

Hepatitis C and HIV are two of the most common overlapping conditions mentioned by state officials, due to both high numbers of patients and high costs to treat them in both DoC and Medicaid. Unfortunately, Medicaid program regulations prohibit correctional facilities from directly accessing the same reduced drug prices negotiated with manufacturers.As a result, many DoCs also use a multistate purchasing pool; the most notable being the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP). States participating in a purchasing pool for DoC face the same challenge as those previously mentioned in Medicaid purchasing pools: trying to understand the net benefit gained in discounts by either staying in the pool, requesting a carve-out or leaving it to pursue a multi-agency approach within the state.

Some correctional programs have also accessed discounted prices by transporting incarcerated adults to hospitals or clinics eligible for the discount available under the 340B Drug Discount Program. The 340B program provides discounts to hospitals and clinics that meet federal standards for serving low-income or uninsured patients.[5] Eligible entities include:

- Qualifying hospitals (e.g., children's hospitals, critical access hospitals, disproportionate share hospitals)

- Federal grantees from the Health Resources and Services Administration (e.g., federally qualified health centers)

- Centers for Disease Control and Prevention (e.g., sexually transmitted disease clinics)

- Department of Health and Human Services Office of Population Affairs and the Indian Health Services (e.g., tribal/urban American Indian health centers).[23]

The 340B program generally requires patients be physically seen in the eligible facility to qualify for drug savings. Bringing incarcerated adults to a hospital or clinic creates substantial logistical and financial hurdles for correctional programs.

The challenge—or opportunity—for state DoCs is determining how to incorporate their 340B approach into a multi-agency purchasing initiative.

Public Employees

In most states, state employees, including school employees, have access to health benefit plans that resemble traditional commercial plans.

There are two ways states commonly purchase these benefits. The first is a self-insured model, in which the state assumes financial risk and contracts with a third-party administrator to manage the plan. The second is a fully insured model, in which the state contracts with an insurer to underwrite financial risk while also administering the plan.

Under a self-insured model for public employees, similar to a Medicaid FFS environment, the state may have more flexibility and control to determine which drugs could be used in a multi-agency purchasing initiative.

Through a fully-insured model, much like in Medicaid managed care, the state must work through an insurer and its respective pharmacy benefit manager, which can create challenges for carving out any specific drug class.

Department of Health

Departments of health are commonly known for working with at-risk and vulnerable populations,

including but not limited to, maternal and child health, seniors, and individuals with substance use disorder.

Generally, these departments can provide valuable insight and expertise when addressing a state goal that requires a state-wide or public health approach. A public health approach examines the big picture; the health outcomes of a group of individuals, including the patterns of health determinants; policies and interventions; as well as the long-term savings vs. short-term costs.[24]

With a receptive audience of state agencies, these departments can help create a meaningful public health framework about a targeted drug class for Medicaid, corrections, and state employees. Departments of health may operate or sponsor direct care services for underserved or high-risk populations in some limited circumstances.

Budget and Analytics

Step 4: Budget and Analytics
Align budgets and data analytics among state agencies

- What is the state's ability to access data across agencies to manage and track health, drug, and cost outcomes related to prescription drugs?
- What processes will agencies use to analyze data and budgets across organizations? Who will be responsible for processes and analytics?
- What will the state do to ensure price confidentiality is maintained?
- What are the values and principles the state wishes to uphold in establishing a target price?

A multi-agency purchasing approach requires significant effort to create a detailed understanding and accounting of the utilization and cost for a targeted drug or drug class, maintain drug price confidentiality requirements, and establish a price benchmark for a request for proposal (RFP) or other purchasing mechanism.

These analyses are important from a budget development standpoint as well as for program tracking and evaluation. The budget development process can vary between agencies, particularly in how drug rebates are accounted for, and may also vary by state. Using an aligned and uniform budget and accounting process among agencies will help provide needed consistency and improve accuracy.

Legislators responsible for overseeing appropriations have an interest in understanding and identifying cost savings initiatives that can be incorporated into the state's budget. It is not uncommon for legislators to target a high cost savings number for each agency without an aligned strategy as a mechanism for framing budget conversations.

An aligned multi-agency budget can help ground budget estimates for legislators as well as make the case for increased patient outcomes and access, cost savings, or budget predictability.

There are at least three critical steps to creating a detailed and shared understanding of cost and utilization across state agencies: 1) analyzing information across agencies; 2) maintaining price confidentiality; and 3) establishing a target price.

Analyze Cost and Utilization Data Across Agencies

In order to analyze cost and utilization data across agencies, states should develop a template to track and report drug class information in a uniform and timely manner. The state should organize a collaborative process in which pharmacy and analytics staff from participating agencies review and provide input to create a uniform template that gathers utilization data and aggregates costs of the drug class(es) being targeted. Participating agencies can complete their data gathering and populate the master template for joint analysis.

There may be stark differences in information technology infrastructure among state agencies. Many states are working on outdated Medicaid Enterprise Systems (MES), which can limit the ability to perform robust data analysis. Some state Medicaid administrators have analytics teams in place, while others rely on third-party vendors. Regardless of infrastructure, analytic capacity is increasingly important, particularly as states look to bring the Medicaid drug benefit (or a drug class) under the state's control (i.e., carving-out from MCOs).

Maintain Price Confidentiality Required by MDRP and Commercial Contracts.

States are required to meet a myriad of confidentiality requirements, necessitating that the net price a specific agency pays for a drug must not be disclosed outside that agency.

These requirements stem from either regulation or confidentiality clauses included in drug reimbursement contracts with the manufacturer. The federal MDRP statute specifies that the average manufacture price (AMP), best price, and unit-level sales information shared by manufacturers or wholesalers with Department of Health and Human Services (HHS) is confidential.[25]

Medicaid agencies have access to information about AMP, but do not have access to best price data. Supplemental rebate agreements between drug manufacturers and a state's Medicaid agency always include price confidentiality requirements. Entities covered by the 340B program are subject to similar restrictions, requiring the 340B ceiling price be kept confidential.

The Patient Protection and Affordable Care Act (ACA) directed the federal Health Resources and Services Administration (HRSA) to share ceiling prices with 340B providers, but did not authorize HRSA to share 340B ceiling prices with states.[26] For commercial purchasing contracts, drug manufacturers insist on price confidentiality clauses and these clauses will similarly be found in purchasing contracts by other government (non-Medicaid) agencies or their designees.

While the requirements for price confidentiality hampers government transparency, they can be navigated when there is more than one drug in the drug class. For example, instead of reporting a specific price, a state and its individual agencies can instead report aggregate spending on a drug class and divide that spending by utilization to arrive at an average price. When there is more than one drug, this average price is an estimate and is not a specific net price for a specific drug. The average price can then be used as a proxy to compare drug class spending across agencies and identify opportunities to leverage state purchasing to decrease costs or improve access.

Establish a Price Target

Outside expertise can be useful when bringing multiple agencies together to look at future pricing. Louisiana and Washington State turned to the Drug Pricing Lab at Memorial Sloan Kettering

Cancer Center to estimate future revenues for pharmaceutical manufacturers from hepatitis C treatment, which were used as benchmarks to inform their RFP bid expectations for a subscription model.

The Drug Pricing Lab used financial analyst reports forecasting a drug manufacturer's stock price over a five-year time horizon based on projections of revenue generated from specific drugs in their portfolio.[27] Combining these forecasts with national and state-level market share and disease prevalence estimates, it is possible to create an estimate of the sales volume of a specific drug from a specific manufacturer. Dividing the forecasted revenue for the drug by the estimate of the drug's volume, it is then possible to estimate a price implied from the stock market analyst reports over five years.

Sales revenue is the reference point a manufacturer has in mind when developing a bid to the state. This bid takes into account the state's willingness to pay, as well as the erosion in sales volume and price that occur with competition.

Importantly, a manufacturer submitting a bid may be willing to accept a discount from this level of revenue in exchange for certainty that they will receive a state's sales volume over a defined period of time. The state can also use the manufacturer's expected sales revenue as a benchmark of reasonableness for the total amount of the bid, as well as the state's existing net prices and treatment volume.

This estimate of reasonableness is particularly important for states developing a multiyear budget, as well as considering a multiyear purchasing agreement with a manufacturer. The state should ensure it is being offered an average price (across Medicaid and non-Medicaid) that is at least as good, if not better than, the price implied in financial analysts' forecast.

The estimated price will also enable the state to forecast for its own agencies and determine if the state can save money and/or expand patient access or outcomes through a multi-agency purchasing effort.

Purchasing Strategies

- How will the state navigate purchasing for Medicaid and non-Medicaid agencies (given differing regulations, etc.)?
- What services do manufacturers perform that would further the state's goal? Will the state consider including these in its purchasing strategy as bona fides?
- How is the state's attorney general office involved?

After a state has completed its due diligence by developing a "North Star" goal, aligning key agencies, developing a budget, and securing the appropriate data analytics, the next step is to finalize a process to solicit bids or information from manufacturers. This most often comes in the form of a direct solicitation, such as a request for information (RFI) or RFP. Considering the myriad regulatory and legal issues, there are at least two areas that deserve consideration as states contemplate purchasing strategies: 1) Medicaid vs. non-Medicaid purchasing; and 2) bona fide services.

Medicaid vs. Non-Medicaid Purchasing

There are many perceived challenges to aligning purchasing strategies between Medicaid and other agencies, including distribution, disparate clinical needs, best price concerns, and inflation penalties.

The distribution of prescription drugs varies greatly between DoCs, state hospitals, Medicaid, and public employee health plans. Generally, DoCs and state hospitals purchase drugs through a manufacturer or purchasing pool, and deliver drugs directly to an individual. Medicaid and state employee health benefit plans typically contract with retail pharmacies, who then deliver the drugs to the member. This difference in distribution channels can create challenges in understanding the flow of rebates and the involvement of any pharmacy benefit managers.

A state's covered populations may also have disparate clinical and social needs that make the route of administration effective in one setting but not in another. For example, a DoC program may find that drugs delivered in a blister pack are a safety threat, as the hard plastic cover can be sharpened to serve as a weapon. Conversely, a Medicaid program may find blister packs work well to encourage daily adherence to a drug regimen in their population.

Manufacturers' best price concerns may also loom large in any multi-agency drug procurement effort. The MDRP, as codified in section 1927 of the Social Security Act, ensures state Medicaid programs receive a discount on a drug's average manufacturer price and never pay more than a brand name drug's best price in the U.S. pharmaceutical market.[28]

Best price is:

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

- Reported by the drug manufacturer to CMS; and

- Is confidential per federal statute and can only be disclosed in limited situations.[28]

Drug manufacturers are required to report to CMS the best price a brand name drug is sold for in the commercial market and must offer this price, plus a statutory rebate, to state Medicaid programs. 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* 340B programs and state Medicaid agencies nationwide.

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.[29] This can create a disparity in net cost between Medicaid and non-Medicaid populations, making the same drug the least expensive option on one PDL and the most expensive option on another.

Disparities in net cost are further exacerbated by the MDRP's consumer price index (CPI) penalty, which is intended to protect Medicaid programs from price increases greater than the CPI. This federal policy may reduce the price of the brand name drug to Medicaid so it is less expensive than a new generic equivalent. A new generic drug might be less expensive than a brand name drug for DoC, but a Medicaid program could find the brand name drug to be the least expensive option because of the CPI penalty.

For multi-agency purchasing, states will also need to consider how to navigate CMS concerns about instances where a state links its Medicaid rebates to non-Medicaid drug purchases. CMS notes in State Medicaid Director letters from 2002 and 2004 that it is concerned about the "efficiency and economy of the Medicaid program" when a state "link[s] a Medicaid prior authorization program to rebates or discounts for non-Medicaid drug purchases."[30]

To navigate these challenges, states may consider three possible routes:

1. Request separate prices for Medicaid and non-Medicaid populations. A competitive procurement process may be the most straightforward and least burdensome for some states. The state of Washington recently completed its hepatitis C drug procurement by negotiating separate Medicaid and non-Medicaid pricing with AbbVie, using one unified procurement process.

2. Pursue 340B pricing for the state's non-Medicaid populations. Currently 16 state DoC programs work with eligible hospitals and other health care providers to obtain some high-cost drugs through the federal 340B drug-purchasing program.[31] However, as previously mentioned, the 340B program generally requires patients be physically seen in the eligible hospital to qualify for drug savings, thus creating logistical and financial hurdles for correctional programs.

   Louisiana is pursuing this approach with their new hepatitis C purchasing model by having DoC facilities qualify as 340B-covered entities since many are qualified through the CDC as testing sites for sexually transmitted diseases (STD). The University of Illinois-Chicago uses a streamlined telemedicine-only model to treat inmates with HIV and hepatitis C, in partnership with the Illinois Department of Corrections.

3. Submit a 1115 waiver request. If a state wishes to involve commercial health plans as part of their multi-agency approach, they may do so on a voluntary basis but may need to seek preapproval from CMS.[32] The state must demonstrate the prior authorization program will further the goals and objectives of the Medicaid program, such as increasing the efficiency and economy of Medicaid. The state could submit evidence demonstrating the prior authorization program sufficiently benefits the Medicaid population as a whole by making medically necessary prescription drugs available to financially needy individuals, making it less likely those individuals will enroll in Medicaid.

   Section 1115 of the Social Security Act grants authority to the Secretary of HHS to approve experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid and Children's Health Insurance Programs.[33] 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.[34] The waiver approach can be lengthy and there is no guarantee on how CMS would view such a proposal.

Bona Fide Services

As part of a multi-agency approach, there is growing interest in understanding how a state might ask a manufacturer to provide bona fide services (bona fides), such as assistance with patient compliance and adherence, or patient or physician education as part of any agreement. Bona fides must avoid any anti-kickback, false claims or related liability concerns. A state should give careful consideration to these issues to avoid creating unnecessary risk and to address potential manufacturer objections.

Bona fides are viewed as an exception to the requirements manufacturers follow in calculating AMP for purposes of the MDRP.[35] While this exception can be viewed as a positive for states to receive needed resources, manufacturers can be reluctant to pursue them due to the worry of potential penalties for misuse.

The federal Anti-Kickback Statute (AKS), criminalizes knowingly soliciting, receiving, offering, or paying, whether directly or indirectly, and whether cash or in kind, any "remuneration" in return for, among other things, purchasing or recommending purchasing any good or item for which payment may be made in whole or in part under a federal health care program.[36]

A state may want to solicit bona fides from a manufacturer in support of the state's public health goals as part of a multi-agency RFP, such as patient screening and education. A manufacturer that responds to such a solicitation and offers to provide such services could be concerned its response to the RFP does not fall within a "safe harbor" to the AKS. Safe harbors are exemptions or exclusions. Without an identified safe harbor, which specifies certain conduct is acceptable, a manufacturer could be concerned its response

to the RFP could constitute a violation of the AKS statute and subject them to criminal, civil, and administrative consequences.

The AKS statute contains a specific discount safe harbor that can be aligned with the bona fide services exception to create viable path forward for provision of these important health services.

To avail itself of the discount safe harbor for bona fides, the state should work with its state attorney general's office to:

- Ensure the agreement between the manufacturer and state agency meets the express terms of 42 U.S.C. §1320a-7b(b)(3)(A) and 42 C.F.R. §1001.952(h);

- Calculate and agree upon the value of the bona fides;

- Apportion the value of the bona fides across the manufacturer's affected products; and

- Disclose apportionment and allocation *as a discount* in all appropriate cost reports and other documentation to both the state and federal government, including disclosing the terms and conditions under which the manufacturer is providing the services.

A key is including a provision that bona fides are services the manufacturer "would otherwise perform (or contract for)" in the absence of the state mandate or contract. If at the state's request, however, the manufacturer offers to provide bona fides beyond what the manufacturer otherwise performs or contracts for, such additional services are *by definition not excluded* from calculation of AMP.

The state's attorney general's office can and should review any state proposals with the legal parameters of bona fides and safe harbor concerns in mind.

Future Considerations

- What is the state's goal 3-5 years from now?
- What stakeholders will need to be involved in achieving this?

Prior to launching a multistate purchasing initiative, states should also identify, understand and prepare for the program in future years, including potential expansion. Doing this before launch allows for the necessary legal and regulatory foresight to avoid future obstacles. Two examples of expansion include other states and/or commercial health plans.

Negotiating with pharmaceutical manufacturers through group purchasing arrangements is a common strategy used by the majority of states to lower the cost of drugs within their respective Medicaid programs and DoCs.

These multistate arrangements have a long history of success in obtaining volume discounts and other favorable concessions from manufacturers. However, state Medicaid programs do not have unfettered discretion regarding design and operation of multistate purchasing pools. The programs must comply with applicable federal statutory law, most notably the MDRP statute.

The MDRP stipulates the federal rebate and precludes the use of closed formularies as a means of negotiating pricing and other terms with manufacturers. The MDRP statute also does not accommodate indication-specific rebate calculations for drugs approved and used to treat multiple conditions.

The MDRP does give states the express authority to negotiate manufacturer payment of supplemental rebates, which is the foundation for all multistate purchasing initiatives. States and manufacturers have broad authority to structure supplemental rebate arrangements and CMS has encouraged states to enter into such arrangements by, among other things,

interpreting the MDRP statute in a way that favors such arrangements. This presents an opportunity for states looking to leverage their purchasing power with other states on targeted drug classes.

A second area of expansion could include commercial health plans. States must be mindful of legal limitations specific to federal preemption and existing state law. For example, states are prohibited from establishing programs that conflict with federal law, a concept known as federal preemption. This could include the MDRP and any effort to involve non-Medicaid populations in a purchasing effort to receive the Medicaid best price.

In addition, a more commonly known federal preemption is the Employee Retirement Income Security Act of 1974 (ERISA), which expressly preempts state laws that "relate to" self-insured employee benefit plans.[37] To address ERISA preemption concerns, states can exclude self-insured health plans from any state mandated program or allow self-insured plans to participate only on a voluntary, opt-in basis.

Any multi-agency purchasing initiative that involves commercial health plans should be designed to comply with relevant state law. Generic and other substitution laws, restrictions surrounding PDL exclusions, and freedom of information laws may affect efforts to involve commercial health plans in a multi-agency purchasing initiative.

These state laws would not necessarily pose barriers to the involvement of commercial payers in a multi-agency purchasing initiative. The laws could, however, influence the way payers participate in the program.

States should also bear in mind that the most innocuous way for states to partner with commercial health plans in securing prescription drug rebates for non-Medicaid populations is on a voluntary basis.[32] If a state wishes to involve commercial health plans in an arrangement that it has negotiated for Medicaid, the state must seek preapproval from CMS.[32]

Conclusions, Recommendations & Key Questions

States are generally required by statute or state constitution to balance their budget, creating tension across various funding programs, particularly as the costs of one program rises significantly and exponentially, as currently with prescription drugs.

Lawmakers must balance competing spending priorities (public education, health and human services, public safety, transportation, etc.) as well as make decisions about the amount of revenue to collect through taxation and other sources. The rising cost of prescription drugs has continued to stress the budgeting process and place states at risk of inadequately funding certain programs and services.

State leaders are interested in lowering prescription drug costs and improving value by aligning state agencies and leveraging state purchasing power. The following framework lays out a path for state leaders in planning for a multi-agency purchasing initiative.

A state will need to ensure alignment with its strategic direction and marshal resources and political support to successfully pursue a multi-agency purchasing initiative. For each domain of the framework, we include below several questions that states should consider when assessing their readiness for a multi-agency purchasing initiative.

Multi-agency purchasing could be a valuable tool to support state efforts to improve the value of prescription drug purchasing. These SMART-D Phase IV efforts will result in identification of several states that are ready to implement a multi-agency pilot. The Center will work with state officials to help them assess readiness, facilitate multi-agency planning, and develop a pathway for implementation.

Framework for Multi-Agency Purchasing

Step 1: State Goal and Support
Develop an overarching state goal and secure strong support from the executive and/or legislative branches.

- What is the state's health care goal(s) and how does a multi-agency purchasing initiative fit into its strategic plan?
- What does the state hope to achieve with multi-agency purchasing? How does the state intend to measure its goal(s)?
- What is the political support, either through the legislative or executive branches, to pursue a multi-agency purchasing initiative?
- Who will serve as champion(s) for achieving this goal?
- What process will be used to align or coalesce agencies, stakeholders and champions?

Step 2: Drug Class Selection
Identify drug classes that: (1) link to the state's goal, and (2) have competition within the drug class.

- Which drugs or drug classes align with the state's goal?
- Based on the structure of the state's drug benefit, what process will be used to obtain authority to pursue multi-agency purchasing?

Step 3: Agency Alignment

Ensure alignment exists among participating agencies and designate one lead agency.

- What are the current relationships among key state agencies (e.g., Medicaid, corrections, public employees, public health) and what is the likelihood of those agencies working collaboratively toward a common goal of aligned pharmaceutical purchasing?
- What forum or setting will be used for multi-agency collaboration and discussion?
- Under what authority will agencies collaborate?
- How will agency discussions be convened and led? Who is responsible and accountable, and to whom?

Step 4: Budget and Analytics

Align budgets and data analytics among state agencies

- What is the state's ability to access data across agencies to manage and track health, drug, and cost outcomes related to prescription drugs?
- What processes will agencies use to analyze data and budgets across organizations? Who will be responsible for processes and analytics?
- What will the state do to ensure price confidentiality is maintained?
- What are the values and principles the state wishes to uphold in establishing a target price?

Step 5: Purchasing Strategies

Establish purchasing strategies to solicit required information from manufacturers for both Medicaid and non-Medicaid pricing.

- How will the state navigate purchasing for Medicaid and non-Medicaid agencies (given differing regulations, etc.)?
- What services do manufacturers perform that would further the state's goal? Will the state consider including these in its purchasing strategy as bona fides?
- How is the state's attorney general office involved?

Step 6: Future Considerations

Develop a "future state" scenario to allow programs to expand with additional participating payers and states.

- What is the state's goal 3-5 years from now?
- What stakeholders will need to be involved in achieving this?

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Appendix A: List of Interviewees

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.

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

Pistoresi, Ryan, PharmD, M.S. 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, M.S. Chief Pharmacy Officer, Washington State Health Care Authority. September 16 & 26, 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.

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.