SMART-D
Tools for Multi-Agency Purchasing and PDL Options

January 26, 2021

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Introduction

State Medicaid programs must navigate the complicated landscape of drug purchasing and reimbursement. To help states innovate in the area of drug purchasing, 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 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 were 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 US 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 2022 and provide research and technical assistance to states in 2 focus areas:

1. Multi-payer purchaser partnerships involving Medicaid, other public purchasers, and private insurance carriers; and
2. Single and aligned preferred drug lists (PDLs) for Medicaid managed care states.

This document is a compendium of tools and strategies the SMART-D team developed to assist states pursuing policy changes for multi-agency purchasing and for single and aligned PDLs. We encourage state staff to review the policy briefs *SMART-D Multi-agency Purchasing Framework for States* and *Medicaid Preferred Drug List Options for States* published in 2020. These 2 policy briefs and additional SMART-D research, resources, and toolkits are located on the Center's website (centerforevidencebasedpolicy.org).

Preliminary Considerations and Planning Questions

Multi-agency Purchasing

The SMART-D brief, *Multi-agency Purchasing Framework for States*, lays out concepts for states to explore when 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:

- State Goal and Support - Develop an overarching state goal and secure strong support from the executive and/or legislative branches.
- Drug Class Selection - Identify a drug class that: (1) links to the state's goal and, (2) has competition within the drug class.
- Agency Alignment - Ensure alignment exists among participating agencies and there is one lead agency.
- Budget and Analytics - Align the budgets and data analytics between state agencies.
- Purchasing Strategies - Establish the purchasing strategies to solicit the required information from manufacturers for both Medicaid and non-Medicaid pricing.
- Future Considerations - Develop a "future state" scenario that would allow the program to expand with additional participating payers and states.

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. Included below are several questions that states should consider when assessing their readiness for a multi-agency purchasing initiative.

Step 1: State Goal and Support

- 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

- 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

- What is the current relationship between key state agencies (i.e. 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

- 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 process and for 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

- 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's office involved?

Step 6: Future Considerations

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

Preferred Drug List Options

The SMART-D brief, *Medicaid Preferred Drug List Options for States*, 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? How does its Medicaid program and the role of pharmacy fit into the picture?*

   The 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. 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 25 of the SMART-D brief 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 ended 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 non-preferred 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?*

   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.

SMART-D Readiness Assessment Overview

SMART-D readiness assessment aims to provide states the opportunity to better understand their "readiness" in the areas of multi-agency purchasing initiatives or planning for changes to the state Medicaid agency's PDL approach. To provide the most accurate assessment of your state, we

recommend that a team of state staff participate in the assessment. The team should be comprised of the following representatives:

- From your Medicaid agency: pharmacy, data analytics, policy, finance and budget, information technology, government/legislative affairs, managed care contracting (if applicable), and executive leadership. (*Please note that agency executive leadership involvement is important to get an accurate readiness assessment.*)
- Pharmacy or other leadership from other state agencies that might participate in exploration of multi-agency purchasing options, including, but not limited to: corrections, public health, public employees, general services, etc.

Your state readiness assessment should take approximately 90 minutes to complete depending on how much information is shared. The assessment includes the following sections:

1. State Contacts and Readiness Assessment Participants
2. Data Capabilities
    a) System Readiness
    b) Legal and Political Readiness
    c) Overall Readiness

The readiness assessment is designed to help discover the state's strengths and weaknesses related to development and implementation of a multi-agency purchasing initative or PDL policy change and to identify areas where technical assistance might be needed. As the multi-disciplinary team answers the assessment questions, they will gain a sense of whether there is leadership momentum and the building blocks needed to proceed. If not, the multidisciplinary team can use the information gathered through the assessment to identify areas where the state will need to build capacity for a future endeavor.

Readiness Assessment for Multi-agency Purchasing

1. State Contacts and Readiness Assessment Participants

Please list the names and position titles of the individuals who participated in this readiness assessment.

2. Data Capabilities

Access to data and the ability to run analytics may be a key component of a state project on multi-agency purchasing. The questions in this section are intended to provide an initial picture of the state's ability to access its Medicaid data or data within other agencies.

Please indicate your level of agreement with the following statement related to ***your state's Medicaid data capabilities***.

Your state has access to data needed to manage and track health, drug, or cost outcomes related to prescription drugs within Medicaid.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Please indicate your level of agreement with the following statements related to your state's ***Medicaid Management Information System (MMIS)/Medicaid Enterprise System (MES)***.

Your state has recently re-procured its MMIS?

Yes	No	Comments

If yes, does this re-procurement impact the IT functions for pharmacy claims, data repository, and prior authorization, other as applicable?

Does your state anticipate significant changes in its agency infrastructure that would adversely impact access to pharmacy claims, cost and utilization data?

Agency:	Yes	No	Comments:
Medicaid			
Corrections			
State Employees			

Public Health			
State Hospital(s)			
Workers Compensation			

3. Multi-Agency Purchasing

State governments fund health care through a range of programs including Medicaid, public employee health benefits and workers compensation programs, state hospitals, and corrections facilities. Outside of multi-state purchasing pools, state Medicaid agencies and departments of corrections have not historically aligned strategies to manage or reduce their pharmacy spend to leverage state purchasing power. Given the growing concerns around drug spending, many states are now interested in exploring how to leverage their state purchasing portfolio across agencies as a way to better manage pharmaceutical expenditures.

SMART-D's policy brief on multi-agency purchasing provides the following planning framework for states when considering a multi-agency drug purchasing approach.

- Develop an overarching state goal and secure strong support from the executive and/or legislative branches.
- Identify a drug class that: 1) links to the state's goal and, 2) has strong competition within the drug class.
- Ensure alignment exists among participating agencies and that there is one lead agency.
- Align the budgets and data analytics between state agencies.
- Establish purchasing strategies to solicit the required information from manufacturers for both Medicaid and non-Medicaid pricing.
- Ensure adequate resources exist for project management and outcome tracking for implementation.
- Develop a "future state" scenario that would allow the program to expand with additional participating payers.

Please describe any planning that your state has pursued in the past or is currently pursuing related to drug purchasing across two or more state agencies.

None	Past	Current

If applicable, list agencies involved:

If applicable, describe any executive orders or legislative activity related to multi-agency purchasing:

Please describe your current alignment with one or more state agencies. (i.e., monthly meetings, sharing utilization trends, identifying areas of concern).

None	Past	Current

If applicable, list agencies involved:

Please indicate your state's level of interest in multi-agency purchasing:

Very Strong	Strong	Neutral	Weak	Very Weak

Which drugs and/or drug classes or population health initiatives would you be most likely to pursue in multi-agency purchasing?

3a. Multi-Agency Purchasing: System

This next section attempts to capture your state's internal planning and capacity to develop and implement multi-agency purchasing.

Please indicate your level of agreement with the following statement related to your ***state's internal planning supports***.

Your state has identified population health areas and drugs of interest.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Your state has assigned staff with the necessary experience to lead a multi-agency effort.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Please rate the level of technical assistance that you believe will be needed to develop and implement a multi-agency effort.

Low	Medium Low	Medium	Medium-High	High

Please indicate your level of agreement with the following statements related to ***existing relationships between state agencies*** that might participate in multi-agency purchasing.

The following agencies have experience working with Medicaid on pharmacy related issues

Agency:	Yes	No	Comments:
Medicaid			
Corrections			
State Employees			
Public Health			
State Hospital(s)			
Workers Compensation			

Based on your state's existing relationships between agencies, with which agencies do you think there would be the most promising chance of collaboration?

3b. Multi-Agency Purchasing: Legal and Political Readiness

A state will need to marshal legal resources and political/executive support to pursue a multi-agency purchasing initiative. This section assesses the state's readiness to gather those resources for a sustained planning and implementation effort.

The state can draw on **legal expertise** from its attorney general's office or agency counsel to:

1. Address procurement issues across agencies?
2. Confirm approached to compliance with the federal anti-kickback statues?

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					

Please indicate your level of agreement with the following statements related to your **Governor's office**:

1. A multi-agency purchasing initiative would directly support the Governor's position and would be considered a high priority.
2. The governor's office would consider assigning a staff member to participate in planning for a multi-agency purchasing initiative.
3. The governor's office would consider drafting an executive order or other formal communication to set the stage for a multi-agency purchasing initiative.

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					
3					

Please indicate your level of agreement with the following statements related to your **State Legislature:**

1. A multi-agency purchasing initiative is something that your state legislature would most likely support.
2. There are legislative champions who have the necessary influence to support a multi-agency purchasing initiative.

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					

General comments on political readiness:

3c. Overall Readiness: Multi-Agency Purchasing

This last section attempts to capture a realistic assessment of your state's overall readiness.

On a scale from 1-5 (*with 5 being the highest*), please indicate your state's level of ***interest*** to pursue a multi-agency purchasing initiative?

High		Medium		Low
5	4	3	2	1

On a scale from 1-5 (with 5 being the highest), please indicate your state's level of ***readiness*** to pursue to pursue a multi-agency purchasing initiative?

High		Medium		Low
5	4	3	2	1

What are the 3-5 critical areas (i.e. agency capacity, alignment across agencies, political support, data capabilities) that would need to be immediately addressed in order for your state to successfully implement a multi-agency purchasing initiative?

Readiness Assessment for Preferred Drug List Options

SMART-D's draft policy brief on PDL management strategies describes the following continuum of options for state Medicaid agencies to consider when contemplating a change to locus of pharmacy benefit functions and managed care risk. During today's readiness assessment we will discuss where your state is on this continuum and whether your state is considering making any changes to its PDL management approach.

Single PDL Carved Out of MCOs	Single PDL Carved In to MCOs	Aligned PDLs Carved In to MCOs	Multiple PDLs Carved In to MCOs
•MCOs & FFS program use the same single PDL set through state DUR process •Pharmacy is carved out of MCO risk	•MCOs & FFS program use the same single PDL set through state DUR process •Pharmacy is included in MCO risk	•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	•Each MCO and the FFS program set their own PDLs •Pharmacy is included in MCO Risk

1. State Contacts and Readiness Assessment Participants

Please list the names and position titles of the individuals who participated in this readiness assessment.

2. Data Capabilities

Access to data and the ability to run analytics may be a key component of a state project on PDL management strategies. The questions in this section are intended to provide an initial picture of the state's ability to access its Medicaid data or data within other agencies.

Please indicate your level of agreement with the following statement related to ***your state's Medicaid data capabilities***.

Your state has access to data needed to manage and track health, drug, or cost outcomes related to prescription drugs within Medicaid.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Please describe any changes that your state has made to its Medicaid PDL strategy in the past two years.

Please indicate your state's level of interest in pursuing a change in its Medicaid PDL configuration.

Very Strong	Strong	Neutral	Weak	Very Weak

Please rate your level of interest in the types of Medicaid PDL strategy changes or enhancements below *(5 is highest and 1 is lowest)*.

Medicaid PDL Strategy	**5**	**4**	**3**	**2**	**1**	**NA**
Shift from multiple PDL to an aligned PDL or single PDL						
Change level of risk that MCO bears for pharmacy benefit						
Assess strategies to manage clinician administered drugs						
Change locus of pharmacy benefit functions from state to MCO or from MCO to state:	**5**	**4**	**3**	**2**	**1**	**NA**
a. Management of preferred drug list						
b. Negotiation of rebates						
c. Drug utilization reviews						
d. Processing and payment of claims						
e. Data analytics and reporting						
f. Contracting with specialty pharmacy						
Other change in pharmacy benefit function or PDL configuration, *please describe*:	**5**	**4**	**3**	**2**	**1**	**NA**

3a. PDL Options: System and Data Readiness

This next section attempts to capture your state's internal capacity to support PDL strategy changes

Please indicate your level of agreement with the following statement related to your ***state's internal planning supports***.

Your state has identified a specific PDL strategy change that it would like to explore and/or plan to implement.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Your state has staff resources within the Medicaid program with the necessary experience and time to lead a PDL strategy change.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

Please rate the level of technical assistance that you believe will be needed to develop and implement PDL strategy change.

High		Medium		Low
5	4	3	2	1

3b. PDL Options: Political and Stakeholder Readiness

A state may need to marshal political support to pursue a PDL strategy change initiative. This section assesses the state's readiness to gather those resources for a planning and/or implementation effort.

Please indicate your level of agreement with the following statements related to your **agency leadership:**

1. A PDL strategy change would support the agency's goals and be considered a high priority.
2. Agency leadership would consider assigning staff to lead such an effort.

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					

Please indicate your level of agreement with the following statements related to your **Governor:**

1. A PDL strategy change is consistent with the Governor's priorities and would be likely to receive support.

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					

Please indicate your level of agreement with the following statements related to your **State Legislature:**

1. A PDL strategy change is consistent with the Legislature's priorities and would be likely to receive support.
2. There are legislative champions who have the necessary influence to support a PDL strategy change.

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					

Please indicate your level of agreement with the following statements related to your **stakeholders:**

1. A PDL strategy change would likely be supported by prescribers
2. A PDL strategy change would likely be supported by MCOs
3. A PDL strategy change would likely be supported by pharmacies
4. A PDL strategy change would likely be supported by patient advocates

#	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1					
2					
3					
4					

3c. PDL Options: Overall Readiness

This last section attempts to capture a realistic assessment of your state's overall readiness to pursing a change in its Medicaid PDL configuration.

On a scale from 1-5 *(with 5 being the highest),* please indicate your state's level of ***interest*** to pursue a change in its Medicaid PDL configuration.

High		**Medium**		**Low**
5	4	3	2	1

On a scale from 1-5 (with 5 being the highest), please indicate your state's level of ***readiness*** to pursue a change in its Medicaid PDL configuration.

High		**Medium**		**Low**
5	4	3	2	1

What are the 3-5 critical areas (i.e. agency capacity, political support, data capabilities) that would need to be immediately addressed in order for your state to successfully implement a change in its Medicaid PDL configuration?

Templates and Strategies

The following section focuses on templates the SMART-D team developed through our technical assistance work with states. These templates are designed as a guide for state to organizing their thinking, understand, and planning on implanting a state policy change in multi-agency purchasing or PDL.

Sample Multi-agency Purchasing Timeline

Developing a realistic timeline is an important tool in managing any project, especially one that involves multi-state agencies.

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Sample Multi-Agency Workplan (High Level)

Key Actions	April				May				June				July				August				
RFP Development																					
Multi-agency kick-off meeting (Medicaid, Corrections, Public Employees, Public Health)																					
Weekly team meetings																					
Data analysis on drug utilization and cost																					
Payment and distribution white board session(s) with participating agencies																					
Price benchmarking and bid strategy																					
Finalize integration with public health approach																					
Completed draft of RFP																					
Internal review of draft RFP																					
Legal review of RFP																					
Final review and edits to RFP																					
Final sign-off of and Issue RFP																					
Questions from prospective bidders																					
Answers circulated to all prospective bidders																					
Bids due																					
Evaluate bids																					
Conduct oral interviews with finalists, if needed																					
Announce “Apparently Successful Bidder”																					
Begin contract negotiations																					

Individual Agency Interview Questions

Aligning multiple agencies around leveraged drug purchasing requires collaboration and trust. Individual interviews with agency leaders can help highlight opportunities for collaboration and identify barriers to working together. There can be significant challenges in aligning efforts due to myriad operational issues and regulations within each agency. The following questions are a starting point for these initial agency discussions:

1. Please describe your agency/program staff who manage your agency's/program's pharmaceuticals.
2. What are your biggest pain points today regarding pharmaceuticals?
3. How does your agency/program currently purchase and distribute pharmaceuticals?
4. What drugs or drug classes, if any, does your agency exclude or carve out?
5. What do you see as the largest barriers to successfully implementing a multiagency/program purchasing initiative like this one?
6. What are some other innovative strategies or opportunities you are exploring in your agency?
7. Please describe your agency's/program's current alignment with one or more agencies (i.e. monthly meetings, sharing utilization trends, identifying areas of concern).

Hepatitis C Drug Model Template

This template is intended to provide a simple model for estimating the high-level budget expenditures and number of cases treated in a hep C DAA purchasing effort. To customize the estimates for your state, please update the sample figures on this "Assumptions" tab and add any notes or explanations as needed. Please note that this model is intended to be a first cut estimate to support planning efforts and it is anticipated that a state may do more detailed modeling as part of RFP development or scoring.

Assumptions			
Item			**Notes**
2020 DAA Net Cost			
2020 Hep C DAA Net Cost - Medicaid	$23,000		Average cost per patient, across all DAAs, net of rebate or discount. The average cost across all manufacturers and regimen types will disguise the individual prices and rebate amounts while still enabling general modeling of expenditures.
2020 Hep C DAA Net Cost - Agency 1	$37,000		
2020 Hep C DAA Net Cost - Agency 2	$39,000		
2020 Hep C DAA Net Cost - Agency 3	$44,000		
2020 Hep C DAA Net Cost - Agency 4	$38,000		
2020 Hep C Cases Treated by Agency			
2020 # cases treated - Medicaid	2,000		Cases reimbursed by agency in 2020 (inclusive of 340B if applicable)
2020 # cases treated - Agency 1	500		
2020 # cases treated - Agency 2	350		
2020 # cases treated - Agency 3	350		
2020 # cases treated - Agency 4	400		
Hep C Population by Agency:			
Estimated Medicaid Hep C Population	30,000		Estimate for number of Hep C patient to be treated within each agency's population
Estimated Agency 1 Hep C Population	4,000		
Estimated Agency 2 Hep C Population	4,500		
Estimated Agency 3 Hep C Population	50		
Estimated Agency 4 Hep C Population	800		
Projected DAA Cost Post-RFP			
Projected Net Cost to Medicaid Post-RFP	$18,000		Estimate of hoped for price from drug manufacturer
Projected Non-Medicaid Cost Post-RFP	$25,000		
Incidence Rate			
State Rate of Hep C - Overall Population	3.05%		Dept of Public Health can often provide an estimate
New Case Incidence Rate	0.03%		
340B Volume			
2020 cases reimbursed as 340B by Medicaid	400		Number of individuals treated by CEs with 340B drugs where CE was reimbursed by Medicaid or by Corrections (if applicable).
2020 cases reimbursed as 340B by Corrections	100		

Estimated Total Costs for Elimination in Medicaid and Agencies' Populations

A state will need to consider how many people it will treat per year and how many cases will be left in its target population at the end of year 3. This treatment goal per year is dependent on the:

- Capacity of the public health and health system identify, test and refer for treatment on an annual basis; and
- The overall state spending limit for hep C DAAS and individual agency spending limits per year.

Estimated Total Costs for Elimination in Medicaid and Agencies' Populations

Totals			
	Estimated Cost	**Total Hep C Population**	**Total Drug Cost**
Medicaid	$18,000	30,000	$540,000,000
Agency 1	$25,000	4,000	$100,000,000
Agency 2	$25,000	4,500	$112,500,000
Agency 3	$25,000	50	$1,250,000
Agency 4	$25,000	800	$20,000,000
Totals		39,350	773,750,000

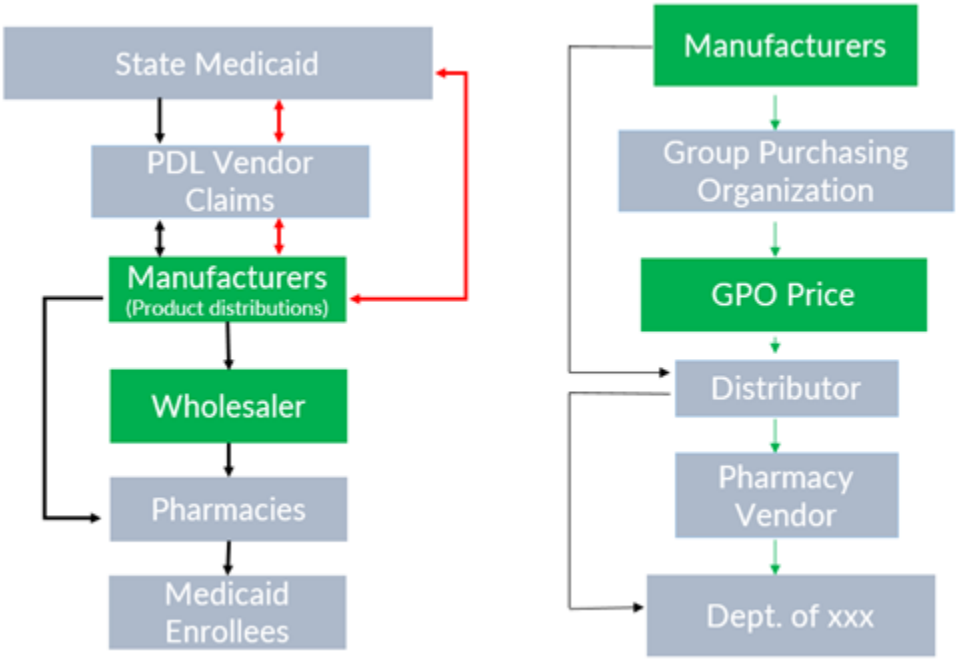
Estimated Patients Treated Per Year				
	Total Hep C Population	**Year 1**	**Year 2**	**Year 3**
Medicaid	30,000	7,000	8,000	8,000
Agency 1	4,000	1,000	1,200	1,500
Agency 2	4,500	1,200	1,200	1,200
Agency 3	50	17	17	17
Agency 4	800	180	250	250
Totals	39,350	13,117	10,967	10,967

Whiteboard Session

There are many perceived challenges to aligning purchasing strategies between Medicaid and other agencies, including mapping distribution approaches across agencies. The distribution of prescription drugs varies greatly between corrections, state hospitals, Medicaid, and public employee health plans. Generally, corrections 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.

When undertaking multi-agency purchasing, a state will benefit from mapping the current drug procurement, payment and distribution processes used by participating state agencies. Once the current processes are known, then the agencies can discuss what an ideal-state multi-agency purchasing and distribution process would look like in the future. This ideal state process can be used to shape how state agencies would work together and be the process that is proposed in any joint-agency solicitation.

Included below are sample distribution processes that might be used by a state Medicaid program and another state agency. A state can use these sample processes as a starting point for their own mapping conversation.



Sample Request for Proposal (RFP) Multi-Agency Hepatitis C Purchasing

Required State RFP Content

A state will need to work with its procurement agency to ensure that its RFP includes the necessary procurement language and required statements. While specific format, language and instructions will vary by state, some sections commonly included are:

- Mandatory minimum requirements
- Definitions
- RFP coordinator and contact information for the state
- Bidder questions
- Delivery of proposals
- Proprietary information and state public disclosure law
- Evaluation
- Reporting

ESTIMATED SCHEDULE *(example schedule below)*

Issue Request for Proposals	January 4, 2021
Questions from Bidders Due	January 18, 2021
Answers Posted	January 29, 2021
Proposal Due	March 1, 2021
Evaluate Proposals	March 2 – March 12, 2021
Conduct Oral Interviews with Finalists, if required	Week of March 29, 2021
Announce "Apparently Successful Bidder"	April 9, 2021
Begin Contract Negotiations	April 19, 2021
Begin Contract Work	July 1, 2021

BACKGROUND (*example language below)*

The State is initiating this RFP to solicit proposals from drug manufacturers interested in participating on a project to treat more patients with hepatitis C virus (HCV) who are Medicaid beneficiaries and inmates within the State's Department of Corrections (DOC).

National HCV Trends

According to the Centers for Disease Control and Prevention (CDC), HCV infection is the most common blood-borne condition in the US HCV is unrelated to other types of viral hepatitis, such as hepatitis A virus and hepatitis B virus infections, and unlike those diseases, has no vaccine available to prevent infection.

HCV is usually spread when blood from an infected person enters the body of someone who is not infected. Today, most people become infected with HCV by sharing needles or other equipment to

prepare or inject drugs. Before 1992, HCV was also commonly spread through blood transfusions and organ transplants. After that, widespread screening of the blood supply in the US virtually eliminated this source of infection.

Persons born between the years 1945 and 1965 ("baby boomers") are at higher risk for HCV. Baby boomers make up roughly one-quarter of the US population but around three-quarters of chronic HCV cases. They account for at least two-thirds of HCV-associated outpatient, emergency department, and hospital visits. As young adults, baby boomers had higher risks of blood-borne exposures due to unscreened blood products, medical or dental exposures without modern infection control measures, and injection drug use when compared to previous or subsequent generations. HCV testing only became available for clotting factor products in 1987 and for blood and organs in 1992. One-time screening for HCV infection is recommended for baby boomers, who have around a 3% prevalence of HCV infection.

The CDC estimates 1% of the US population is infected with chronic HCV, or roughly 3.5 million individuals. Nationally, between 2010 and 2015 there has been a 2.9-fold increase in new HCV cases. Only about half of those with chronic HCV are diagnosed and aware of their infections. After diagnosis of HCV, linkage to ongoing health care is critical so that the infected person can be evaluated by a specialist and referred as appropriate. Nationally, only about one-third of those diagnosed with HCV (32–38%) are referred to care, around one-tenth (7–11%) receive treatment, and about half of those treated (5–6%) are cured. The burden of HCV infection is much higher in the US correctional population compared to the general community. Typical HCV prevalence among inmates nationally has been reported as 17% to 29%.

In the past few years, new medications, direct-acting antivirals (DAAs), have become available that can effectively treat and cure HCV patients with shorter treatment times and fewer side effects. Yet, the high costs for these drugs has stifled aggressive outreach efforts and limited the ability to treat more individuals.

HCV in the State

The State has experienced a xx increase in reported HCV cases in recent years, with just over xxx cases meeting CDC and Council of State and Territorial Epidemiologists (CSTE) case definition criteria reported from 2015 through 2020. This is primarily due to the opioid epidemic and the increase in the number of individuals that inject drugs. The State estimates the number of HCV infections to be around xxx. This does not, of course, account for persons who have HCV but have never been tested, which is likely to be around 50%. Therefore, it is estimated that the true number of individuals living with HCV in the State may be around xxx.

The State's Medicaid program is the primary program with HCV infected individuals that is administered by the State. Collectively, Non-Medicaid Programs estimate about xxx total people they serve to be chronically infected with HCV. Since 2017, these agencies have treated xxx individuals at a total cost of $xxx. Table 1 through Table 3 summarize the total expenditures and number of individuals treated by program.

Table 1. Annual HCV DAA expenditure

Fiscal Year	Medicaid	DOC	Public Employees	State Hospitals	Other
FY2017	$xxx	$xxx	$xxx	$xxx	$xxx
FY2018	$xxx	$xxx	$xxx	$xxx	$xxx
FY2019	$xxx	$xxx	$xxx	$xxx	$xxx
FY2020	$xxx	$xxx	$xxx	$xxx	$xxx

Table 1a. Medicaid Annual HCV DAA expenditure net of rebates

Fiscal Year	Medicaid	DOC	Public Employees	State Hospitals	Other
FY2018	$xxx	$xxx	$xxx	$xxx	$xxx
FY2019	$xxx	$xxx	$xxx	$xxx	$xxx
FY2020	$xxx	$xxx	$xxx	$xxx	$xxx

Table 2. Average Cost (net of rebates) per individual treated

Fiscal Year	Medicaid	DOC	Public Employees	State Hospitals	Other
FY2018	$xxx	$xxx	$xxx	$xxx	$xxx
FY2019	$xxx	$xxx	$xxx	$xxx	$xxx
FY2020	$xxx	$xxx	$xxx	$xxx	$xxx

Table 3. Number of individuals treated

Fiscal Year	Medicaid	DOC	Public Employees	State Hospitals	Other
FY2018	xxx	xxx	xxx	xxx	xxx
FY2019	xxx	xxx	xxx	xxx	xxx
FY2020	xxx	xxx	xxx	xxx	xxx

This RFP is designed for the State to receive discounted pricing for the purchase of DAAs by Medicaid and Non-Medicaid Programs, including a subscription-like model for Medicaid and guaranteed net unit best price for Non-Medicaid Programs.

A key objective of this RFP is to work with a drug manufacturer to bring down the cost of medications to enable the State, and ultimately other purchasers, to reallocate resources to critical societal needs. The pricing, rebate and terms associated with this procurement will create the stability that is required to ensure long-term and predictable expenditure on treating HCV and obtain necessary resources that are critical to a successful treating more individuals with HCV.

It is the intent to select a single Apparent Successful Bidder (ASB). However, the State reserves the right to re-procure for new drugs consistent with those changes. In addition, nothing in this RFP or any resulting contract will prohibit the State's Medicaid Program or Non-Medicaid Programs from purchasing other DAAs that may assist treatment for patients when medically necessary. Separate contracts will be entered with the ASB(s) for the Medicaid population and for the Non-Medicaid populations.

Medicaid Program

Through this procurement, the State seeks a subscription-like model supplemental rebate specific to the Medicaid program in which the State receives a low guaranteed net unit price (GNUP) for DAAs up to a certain number of beneficiaries treated per 12 months, at which point any additional purchase of DAAs will be at a minimal to no additional cost to HCA. This will allow the ASB to sustain its revenue and ensures that the State is able to treat as many Medicaid enrollees with HCV as possible. Bidders are also asked to provide the GNUP for a certain number of beneficiaries treated per 12 months. For illustrative purposes only, the table below shows a GNUP at $1,000 per claim and after 1600 beneficiaries receive treatment in a given fiscal year, the GNUP might fall to $0.01 per day.

Period	**Number of Beneficiaries Treated Benchmark**	**GNUP up to and including 1600 beneficiaries treated per 12 months**	**GNUP above 1600 beneficiaries treated per 12 months**
1/1/2022-12/31/2022	1600	$1,000 per claim	$0.01

The State's Medicaid Program will give preferred status to the selected DAA(s) of the ASB. Consistent with the State's current Medicaid Preferred Drug List (PDL), this preferred status will allow providers to prescribe the selected regimen with minimal prior authorization criteria. Also consistent with the current PDL and other programs and processes, other DAAs will still be considered as non-preferred regimens, but will require prior authorization, and such authorization will only be made when clinically appropriate.

Non-Medicaid Programs

Through this RFP, the State's Non-Medicaid Programs seek a single best GNUP. For Non-Medicaid Programs with their own facilities, the State expects that the selected ASB will also provide for a distribution channel to deliver drugs to facilities that purchase DAAs directly.

As with the Medicaid population, the Non-Medicaid Programs will give preferred status consistent with its existing PDL and current processes to the selected DAAs of the ASB. This preferred status will allow providers to prescribe the regimen with minimal prior authorization criteria. Non-preferred regimens will still be covered but will require prior authorization and such authorization will only be made when clinically appropriate.

The State's Non-Medicaid Programs may pursue options to partner with a 340B Covered Entity for treatment of select inmates. Bidders are asked to provide pricing that is competitive with the 340B sub-ceiling price that it would offer to the State's Non-Medicaid individuals being treated by a 340B covered entity partner.

PRICING *(example below)*

Medicaid

Period	**Number of Beneficiaries Treated Benchmark (X)**	**GNUP per claim up to and including X beneficiaries treated per 12 months**	**GNUP per claim above X beneficiaries treated per 12 months**
1/1/2022-12/31/2022		$	$
1/1/2023-12/31/2023		$	$
1/1/2024-12/31/2024		$	$

Non-Medicaid Programs

Period	**GNUP per claim**
1/1/2022-12/31/2022	$
1/1/2023-12/31/2023	$
1/1/2024-12/31/2024	$