SMART-D

TECHNICAL ASSISTANCE TOOLS FOR STATE MEDICAID DRUG ALTERNATIVE PAYMENT MODELS

Center for Evidence-based Policy
Oregon Health & Science University
3030 SW Moody, Suite 250, Mailstop MDYCEBP
Portland, Oregon 97201
centerforevidencebasedpolicy.org

May 2018

ACKNOWLEDGMENTS

This report was written and prepared by:

Rhonda Anderson, BSc, Pharm, RPh
Mike Bonetto, PhD
Gretchen Morley, MPA
Susan Stuard, MBA

Suggested citation:
Anderson, R., Bonetto, M., Morley, G., & Stuard, S. (2018). *SMART-D Technical Assistance Tools for Alternative Payment Models*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (Center) with funding from the Laura and John Arnold Foundation for the State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D). The document is intended as a reference and is provided with the understanding that the Center is not engaged in rendering any clinical, legal, business, or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document. Consult legal counsel for assistance in addressing any legal, regulatory, or compliance issues involving the matters discussed in this report.

About the Center for Evidence-based Policy

The Center for Evidence-based Policy (Center) is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring diverse and relevant perspectives are considered, and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

TABLE OF CONTENTS

INTRODUCTION TO
MEDICAID DRUG APMs & PLANNING TOOLS

Prescription drug costs are the single fastest growing component of U.S. health care spending. A major factor in this surge has been the introduction of high-cost specialty drugs to treat serious conditions such as cancer, hepatitis C, blood disorders, and HIV. These innovative drugs are being introduced at an accelerating pace and present exciting opportunities to improve the health and lengthen the lifespan of patients. Yet, high prices pose a challenge for all health care payers' budgets, especially state Medicaid programs that must ensure access to a broad range of health services for low-income individuals and families within state budget parameters and federal requirements. Additionally, because of federal restrictions, state Medicaid agencies have limited access to traditional pharmacy benefit management tools commonly used by commercial insurers such as deductibles, premiums, and patient cost-sharing. With very few exceptions, states are required to reimburse for all drugs produced by pharmaceutical manufacturers that participate in federal rebate agreements under the Medicaid Drug Rebate Program (MDRP).

To help state Medicaid programs navigate the complicated landscape of drug purchasing, the Center for Evidence-based Policy at Oregon Health & Science University launched the State Medicaid Alternative Reimbursement and Purchasing Test for High-Cost Drugs (SMART-D) initiative with financial support from the Laura and John Arnold Foundation. The initiative is a collaborative effort to support states in the development of alternative payment models (APMs) for prescription drugs, which can improve patient access to evidence-based therapies while allowing states to predict and manage prescription drug costs.

In its simplest form, a Medicaid drug APM is an arrangement between the state agency and a drug manufacturer that ties payment for a drug or class of drugs to an agreed-upon outcome measure or measures. Currently, in Medicaid drug purchasing, the manufacturer sets the acquisition price that wholesalers, pharmacies, and providers pay to obtain the drug, ultimately submitting claims to Medicaid for reimbursement for drugs dispensed to patients. Medicaid reimbursement is based on the acquisition price submitted on claims, with a subsequent time-delayed reconciliation for rebates that manufacturers pay back to states. An APM is designed to change the price-setting dynamic and create shared risk between the manufacturer and payer for an agreed-upon outcome measure. APMs are generally focused on financial or health outcomes. More complex APM structures utilize policy tools such as 340B covered entities or a center of excellence approach.

Implementing APMs for high-cost drugs is not an effort to be taken lightly—it requires time, planning, data, and sustained oversight. Although this level of effort might seem daunting, as new drugs come to market at a rapid pace, states have the challenge of meeting patients' needs in a fiscally responsible way. In 2016, the SMART-D initiative identified more than 110 new, high-cost drugs waiting for approval by the U.S. Food and Drug Administration (FDA), and pharmaceutical manufacturers continue to produce new innovative therapies. Medicaid programs currently use value-based strategies for medical benefit spending, and have latitude to pursue value and outcome-based arrangements for pharmacy spending under current law. In the absence of federal action, states must manage their Medicaid pharmacy spending with evidence-based strategies and outcomes-driven arrangements.

This toolkit provides an implementation guide for states interested in pursuing APM arrangements with drug manufacturers. Many of the tools and resources included here have been developed and refined through the SMART-D initiative and informed by lessons learned from participating state Medicaid agencies.

OVERVIEW

SMART-D INITIATIVE

The SMART-D initiative is 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. APMs identified through SMART-D are voluntary collaborations between drug manufacturers, Medicaid programs, and Medicaid providers. They build upon the substantial contracting experiences that drug manufacturers have in international and U.S. commercial markets.

The SMART-D initiative seeks to enable states to:

- Provide access to effective drug therapy for Medicaid enrollees
- Develop payment strategies for innovative drugs
- Enhance patient health outcomes
- Improve state fiscal status

To date, the SMART-D initiative has unfolded in 3 phases and involved 6 states at varying levels of technical assistance interaction. In the first quarter of 2018, 4 SMART-D states are actively pursuing APM arrangements for reimbursement of drugs in Medicaid pharmacy programs.

The SMART-D project has achieved the following phases:

PHASE 1

COMPREHENSIVE RESEARCH, DEVELOPMENT, AND RELEASE OF REPORTS

The goals in Phase 1 were to map the landscape of Medicaid drug purchasing and identify APM options for states in the existing regulatory framework. Medicaid drug purchasing is extraordinarily complicated. State program officials must navigate federal statutes and regulations, state budget frameworks, complex market incentives, and nontransparent drug pricing and rebates. SMART-D explored these complexities in a way that helps states more easily develop APMs. Drawing upon international and U.S. commercial market models, the research identified a series of alternative payment options and legal pathways for state Medicaid programs to use when paying for high-cost drugs. The SMART-D reports are briefly summarized on page 3 and can be found on the initiative's website.

PHASE 2

IDENTIFY COLLABORATION OPPORTUNITIES WITH DRUG MANUFACTURERS

SMART-D supported states as they began to develop financial- or health outcome-based APM concepts by:

- Determining the strategic fit, scope, and potential design of APMs within state Medicaid programs and identifying key stakeholders to engage in the planning process
- Assessing technological readiness to identify, manage, and track health, drug, or cost outcomes related to APMs, while ensuring appropriate patient confidentiality
- Establishing or building upon a professional relationship between the state and one or more drug manufacturers to facilitate good-faith discussions about APM opportunities
- Identifying the appropriate legal pathways that pair with targeted APM and state Medicaid program design

PHASE 3

IMPLEMENTATION TECHNICAL ASSISTANCE AND SUPPORT TO STATES

As state officials developed models with drug manufacturers, the SMART-D team provided support by facilitating state team planning, building budget models to explore potential APM options, and supporting conversations and negotiations with drug manufacturers. The SMART-D team worked directly with the Centers for Medicare & Medicaid Services (CMS) staff to develop an outcome-based contract template that states can use for APM agreements with manufacturers.

GETTING STARTED

KICK OFF THE CONVERSATION IN YOUR STATE

Implementing Medicaid drug APM initiatives takes energy, time, and commitment, and can be difficult to juggle and sustain with the many other competing demands on state Medicaid leaders and staff. Taking time to identify expectations and goals and investing in a well-rounded APM development team are critical to success. The tools, suggestions, and resources in this section were developed through the SMART-D initiative to assist states in the start-up phase of APM development.

UNDERSTAND APMs

During Phase 1, the SMART-D project produced a series of 5 reports to orient states to pharmaceutical APM approaches. The research encapsulated complex issues, addressed the current status of drug coverage and purchasing in state Medicaid programs, and outlined the high-cost drug landscape while identifying new opportunities to integrate value into purchasing. These reports can be used by state and federal policymakers, drug manufacturers, and others to understand and initiate state-level APM activity. State teams are encouraged to review the full reports. A high-level summary of findings is provided below. Appendix A includes a presentation that the state team can use to discuss this material.

MEDICAID AND SPECIALTY DRUGS: CURRENT POLICY OPTIONS

JUNE 2016

State Medicaid directors are actively managing prescription drugs, with an added focus on high-cost specialty drugs, to appropriately reach the most patients despite limited budgets. Management tools discussed in this report include Medicaid drug payment and pricing strategies (actual acquisition cost and 340B pricing), utilization management (prior authorization, clinical edits, preferred drug lists, and care management), and managed care coverage of prescription drugs (carving-in the pharmacy benefit and MCO care management).

SMART-D ECONOMIC ANALYSIS

SEPTEMBER 2016

This SMART-D analysis found that 64 high-cost specialty drugs accounted for 32.6% of Medicaid drug reimbursement spending and 3.1% of overall Medicaid spending in 2015. Each of these 64 drugs had reimbursements of more than $600 per prescription and an annual Medicaid expenditure of $72 million or more per year. Moreover, pipeline analyses show accelerating activity in the area of high-cost specialty drugs. These trends reinforce state officials' interest in strategic alignment of drug reimbursement with overall payment reform efforts, and specifically, the possibility of implementing APMs for high-cost specialty drugs.

SMART-D ALTERNATIVE PAYMENT MODEL BRIEF

OCTOBER 2016

This report details APMs that are used by private and public payers to manage drug utilization and costs in the United States and Europe. APMs are widely used in Europe and their use appears to be increasing in the U.S. commercial market. Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and to limit the risk of uncontrolled drug spending. These APMs, focused on lowering costs and expanding patient access, have proven easier to administer. In health outcome-based APMs, drug payments are tied to predetermined health outcomes and/or clinical measurements, or the drug is given conditional coverage while data on its effectiveness are being collected and assessed. Financial-based or health outcome-based APMs require additional planning and data collection, but have the potential to increase the quality, value, and efficacy of treatments.

SMART-D LEGAL BRIEF

SEPTEMBER 2016

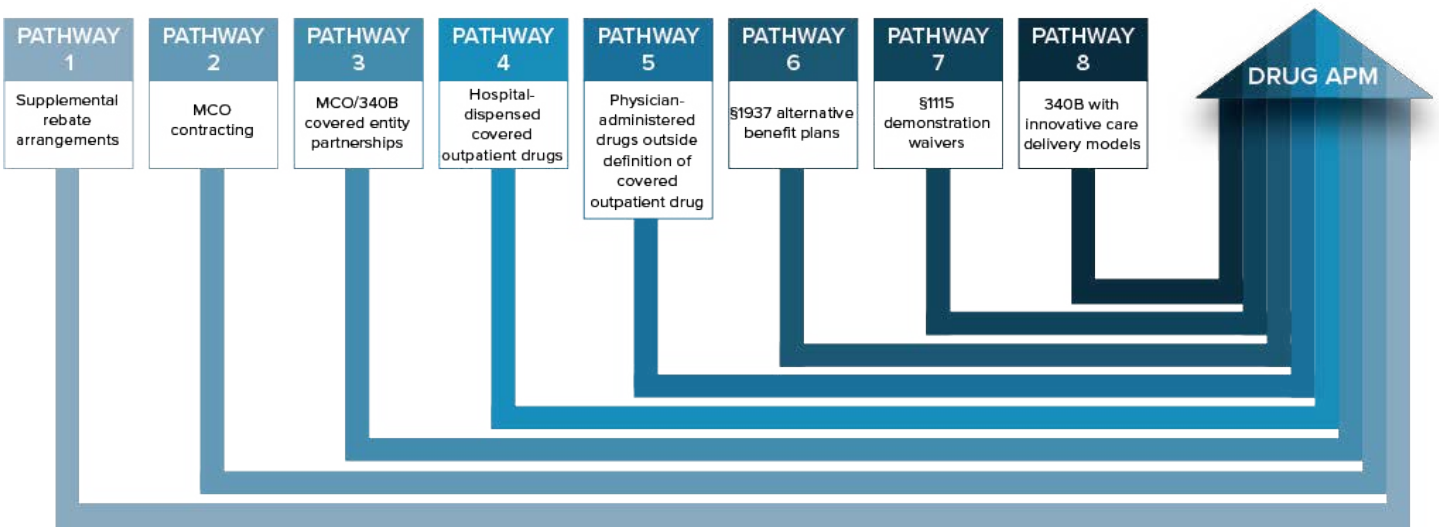
Although the federal MDRP constrains state Medicaid purchasing flexibility in return for guaranteed statutory rebates, states still have latitude to pursue APMs. The SMART-D legal analysis identified 8 potential legal pathways that states can employ to implement financial- and outcome-based payment arrangements with drug manufacturers and other health care providers. These legal pathways, constitutional questions, and case law are explored in the legal analysis.

SMART-D SUMMARY REPORT

SEPTEMBER 2016

This report weaves together the findings from the SMART-D detailed reports, providing an overall view into Medicaid pharmacy challenges and opportunities for states to engage in APMs.

Figure 1. ***Drug APM Legal Pathways***



ASSESS READINESS

After some of these core concepts and potential APM strategies are understood, the next step is to assess the state's readiness to develop and implement APMs to manage high-cost drugs. Key areas to evaluate are:

CURRENT APM EXPERIENCE & PLANS in prescription drug APMs, including whether they are financial- and/or health outcome-based and the level of state interest in developing and implementing an APM in the next year.

SYSTEM READINESS, including assessing staffing capacity, need for external technical assistance, access to necessary data to support APM development, and current relationships with drug manufacturers.

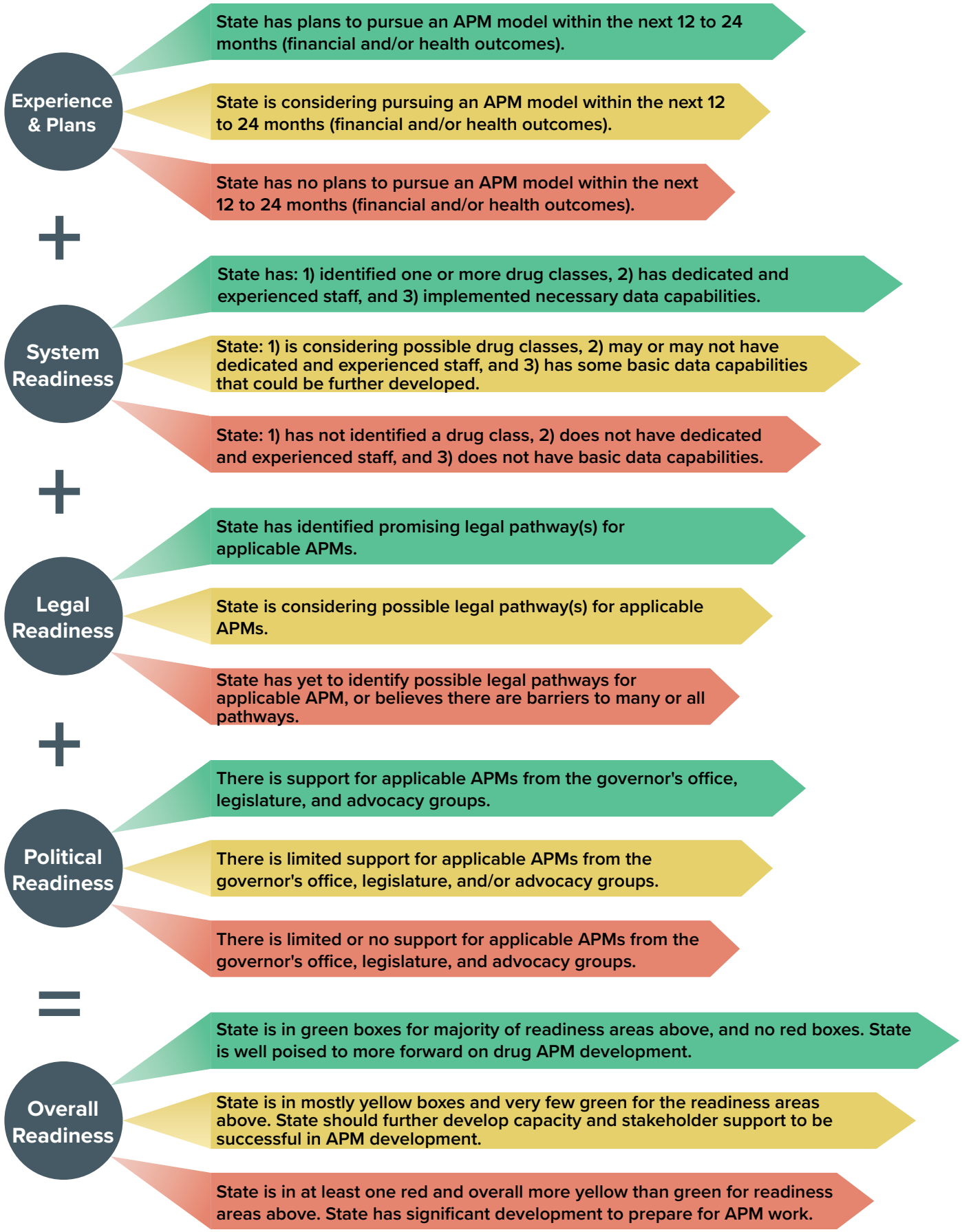
LEGAL READINESS, including interest in the legal pathways highlighted above and detailed in the SMART-D legal brief.

POLITICAL READINESS, including assessing the level of support from the state agency and executive branch, the state legislature, and other significant stakeholders.

OVERALL READINESS, including identifying critical areas that would need to be immediately addressed for the state to successfully implement a drug APM.

Appendix B includes a readiness assessment tool that state agency leadership and staff can use to evaluate readiness for APM strategy development and implementation. To ensure a comprehensive perspective, engage a balanced team of state staff to complete the assessment, including expertise from across the Medicaid agency (e.g., pharmacy, data and analytics, policy, finance and budget, information technology, managed care contracting if applicable, and executive leadership). The readiness assessment is designed to help discover the state's strengths and weaknesses related to APM selection, development, and implementation, and to identify areas where technical assistance might be needed.

Figure 2. *Evaluating Levels of Readiness in Key Areas*



DEFINE AGENCY COMMITMENT & PROJECT LEADERSHIP

A key requirement for a successful APM is the commitment of leadership to support development, negotiations, and implementation. In addition, thoughtful development of the team with attention to the breadth of perspectives and diverse representation are integral to the momentum and follow-through needed to implement an APM. State teams are encouraged to do the following:

Designate a project champion who is a high-level policy official able to provide input and guidance on the development of an APM strategy, marshal the necessary agency resources, and offer input needed to draft an APM implementation plan. State teams that are working on drug APMs have designated a chief policy, medical, and/or pharmacy officer as the lead, depending on the state agency structure. The project champion should have access to the broader policy leadership vision to ensure that APM work aligns with state policies and broader program reform efforts.

Designate a project manager who serves as the day-to-day lead for meetings and deliverables. The project manager role is to ensure that regular meetings are scheduled, pharmacy and policy issues are researched, and an APM implementation plan is drafted. The project manager works with the project champion to ensure the necessary senior leadership input and resources to develop the APM implementation plan.

Designate a state team representing a range of perspectives including:

- Pharmacist
- Data analyst familiar with Medicaid claims data, including fee-for-service (FFS), pharmacy, medical, hospital, and if applicable, managed care organizations' (MCOs) data
- Staff familiar with the Medicaid program's structure, current clinical editing, drug utilization review, preferred drug list coverage, supplemental rebate arrangements, and expenditures by category for the pharmacy program
- Agency representatives from budget/finance, policy, and legal services

Formalize your state team. After your project leadership and state team are selected, take the next step to formalize the project within the context of other state initiatives and priorities. This can be accomplished through an officially approved charter that defines the role and expectations for the project, as well as a formalized work plan that clearly states project goals and milestones.

IDENTIFY & ENGAGE KEY STAKEHOLDERS

Depending on the drug or drug class and selected APM(s), it is essential to identify and engage key stakeholders and partners who would support the initiative, as well as those who may present significant barriers or have concerns. It is important to identify stakeholders who could serve as implementation partners for the APM, such as a research center or school of pharmacy. This strategic partner could assist with utilization data access, evaluation, and validation at appropriate times in the project. The state team should plan to revisit this list of key stakeholders after selecting the APM strategy. It is necessary to identify stakeholder groups relevant to the selected model and continue to retain their engagement throughout the project. Examples of potential stakeholders to consider engaging in APM processes include the following:

- Patient advocacy groups
- Health systems, health centers, and other providers
- Legislators
- Pharmaceutical manufacturers
- Universities and/or research centers
- Pharmacy benefit manufacturers

For partners who are performing a clear role in the development of the state's APMs, such as data support, consider establishing or amending interorganizational agreements to clarify the roles and expectations for the partnership.

TIPS & CONSIDERATIONS

FOR GETTING STARTED

1 KNOW HOW APM WORK FITS INTO THE STATE'S LARGER REFORM EFFORTS

- ✓ Understand the state's reform strategies, payment structures, and reimbursement incentives. How will an APM build on those elements to improve health outcomes and control costs?
- ✓ Have someone on the state team who knows or can contact individuals who understand how state policies, the Medicaid state plan, and any Medicaid waivers affect this APM work.

2 SET REALISTIC EXPECTATIONS WHEN GETTING STARTED

- ✓ Be realistic about the agency's capacity to develop and implement an APM. Set stretch goals but be realistic about the objectives for a first APM. A pilot could be an appropriate place to start and could allow a state to test its ability to implement an APM.
- ✓ Carefully assess the data capacity available to the state team. Does the pharmacy staff have direct access to pharmacy data? Does the agency have a partner, such as a university or vendor, that could help with data support?
- ✓ Be cautious about anticipating net savings with initial Medicaid APM implementation; the immediate state-level outcomes are likely to be better patient access and drug adherence, leading to budget predictability.

3 PULL TOGETHER THE RIGHT TEAM

- ✓ Successful teams have a clear champion in the state agency who possesses clear insight and leverage on state initiatives and politics.
- ✓ Consider state agency composition and stability of structure: what mix of team members will lend the widest perspective and the most stability, competency, and credibility to the project?
- ✓ The team MUST include a pharmacist or clinical lead from the pharmacy program.

4 ESTABLISH CLEAR TEAM PROCESSES TO MAINTAIN MOMENTUM

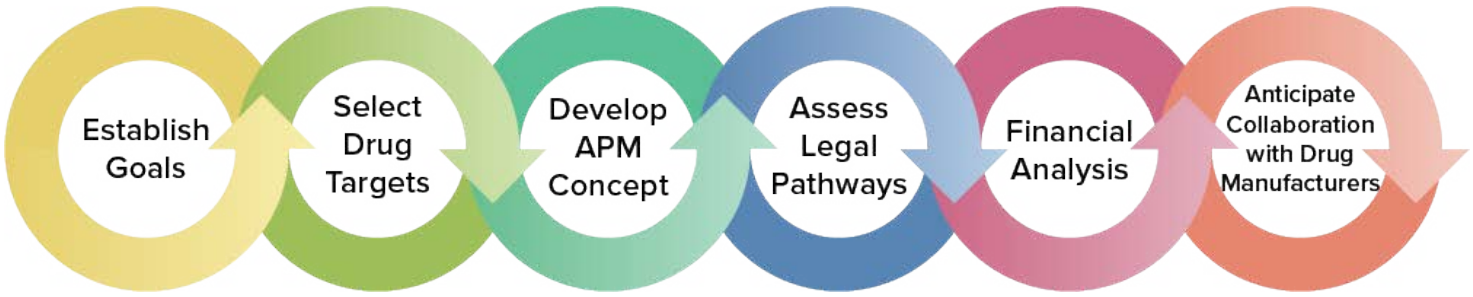
- ✓ Obtain agency leadership buy-in early and keep them apprised of project progress.
- ✓ Have regular team meetings and engage team members to ensure that the project doesn't lose momentum when new priorities emerge.
- ✓ Assess all technical assistance opportunities, particularly access to an external third party to work with the state in developing an APM.
- ✓ As APMs develop, consider the agency's calendar and how to manage APM development and implementation through busy times (e.g., mobilizing state staff to focus on APMs can be difficult if the state legislature is focused on other topics).

DEVELOPING A DRUG APM

Before a state begins negotiating with a manufacturer on drug APMs, the state team should identify goals, consider which drugs to target and why, and match potential drugs with possible legal pathways for initial APM development. Data on drug utilization and cost are critical at each stage of decision making, and the state's ability to access necessary data may be the basis for choosing one APM strategy over another. This section provides an overview of considerations and questions to ask as the state team identifies drugs to target and APM strategy options. The process outlined below will help prepare the state team for negotiation and contracting discussions with manufacturers and stakeholders, and will build the foundation for APM efforts.

The SMART-D Initiative has developed the following 6-step process to develop a drug APM.

Figure 2. ***SMART-D Six Step Process to Develop a Drug APM***



STEP 1: ESTABLISH GOALS

The first step in developing an APM is defining the agency's goals. This must include input from senior leadership and the state team. These goals will serve as guide rails for the entire project and help ensure that the APM aligns with the agency's needs.

Consider using a facilitated discussion with the state team and key agency leaders to collaboratively identify goals. Be sure to accurately capture the discussion by recording the meeting or using a dedicated note taker. Ensure that participants have received a summary analysis of the readiness assessment, and consider having summary information available during the discussion. The SMART-D research reports can be utilized as background information for educating the team on APM options. After the meeting, synthesize the notes into a summary of the team's goals and distribute to the team for reference. Consider using the following prompts to guide the discussion:

1. How would the state define success for development and implementation of a drug APM? What value-based goal would the state like to target (e.g., financial, health outcome, patient access)?
    a. *Cost savings? Financial outcome?*
    b. *Improved health outcomes?*
    c. *Improved patient access?*
    d. *Experience piloting an APM?*
    e. *Other?*
2. What is the agency's payment reform strategy and how can a drug APM fit within that?
    a. *Are pharmacy costs included in provider and/or managed care arrangements?*
    b. *Can an APM align with the state's larger goals for payment reform?*
    c. *Are there quality measure incentives or other metrics used for reimbursement that can support a drug APM?*

3. What constraints and barriers does the state anticipate for APM planning?
    a. *Think of timing and how to navigate staff resources during periods of high pressure/demand (e.g., legislative sessions, major system changes, agency reorganization).*
    b. *What drug classes might be off the table because of political environment, statutory constraints, legal action, or other factors?*

4. What levers are available to the state in support of a drug APM?
    a. *Where can the state exercise control over pharmacy utilization? FFS states and single preferred drug list (PDL) states might have broad control. MCO states might need to look into more collaborative models with their managed care partners.*
    b. *Does the state have drug classes that are carved-out of managed care contracts? Drugs that are carved-out of the MCO benefit might be an easier place to start.*
    c. *Does the state have a robust PDL coordination process with its managed care partners?*
    d. *Does the pharmacy program have a strong pharmacy benefit manager (PBM) partnership? This could be essential for APM negotiations and data collection.*

STEP 2: SELECT DRUG TARGETS

After clear goals have been identified and agreed to, the state team should identify a preliminary list of drugs to target for possible APM development. This step of the process requires some preplanning and more meeting time than the goal-setting discussion. Plan to set aside 1 to 2 hours for Step 2. If combining Steps 2 and 3 (*Develop APM Concepts*) into 1 meeting, then plan for 2 to 3 hours of discussion with the state team.

Before the meeting, work with budget and finance and/or analytic team members to pull data on high-cost and high-utilization drugs for the Medicaid population. Consider pulling reports that:

- Identify the top 25 or 50 highest cost brand drugs, noting per-unit cost and total annual spending.
- Indicate total spending within the drug classes associated with these high-cost drugs.
- Provide access to any financial analysis previously conducted on high-cost drugs and associated health service utilization.

Data, overlaid with the overall project goals, are integral in APM development. The SMART-D team has found the following process to be useful in identifying preliminary drugs or drug classes for an APM:

1. Review the cost and utilization data the state agency has prepared and then have an open-ended discussion about drugs that are of concern to agency staff.

2. Team members write down their top 3 to 5 wish list target drugs or drug classes for assessing potential APM options. Strongly encourage all team members to participate, even those who do not consider themselves pharmacy experts. Instruct team members not to include their name with the list.

3. Tally the drug and/or drug class wish lists on a whiteboard, slide presentation, or easel paper for all team members to see.

4. Using this tallied list, the group selects 3 to 6 drugs or drug classes to discuss under Step 3 below. When selecting the 3 to 6 drugs or drug classes for discussion, it may be useful to revisit the goals that the state team set in Step 1. The project champion and agency leadership should be prepared to take a decisive role in honing the selections.

STEP 3: DEVELOP APM CONCEPTS

With the preliminary list of drugs identified in Step 2, the next step is to assess each option against a range of considerations outlined below. Full team participation is important for this step as the discussion will likely form the basis of the APM concept(s) to be pursued by the state. The synthesized notes from this

conversation will provide the state team with material for fleshing out both the Overview and APM strategy sections of the APM template in Appendix E.

Appendix C provides a discussion worksheet for this exercise. For each of the drugs highly prioritized in Step 2, discuss the following considerations:

1. Why this drug or drug class?
    a. *What is the state's rationale for interest in specific drug or drug class?*
2. What data are available to support APM design and measurement for this drug or drug class?
3. What is the value-based goal for the selected drug of interest?
    a. *Is it financial- or health outcome-based or both?*
4. What features of this drug or drug class could make it a good option for an APM?
5. What are cost-containment tools used to manage this drug?
    a. *What are barriers for the state?*
6. What is the agency's relationship to the drug's manufacturer(s)?
7. Why should the manufacturer consider an APM for this drug?
    a. *What would make the drug manufacturer want to collaborate on a different contracting arrangement?*
    b. *Is there a possibility for a triple win scenario—would the state, manufacturer, and patient and provider community all benefit from such an arrangement?*
8. How could a possible APM for this drug fit within the state's payment reform strategy?

Individual state circumstances might preclude development of some drug APMs, and these roadblocks often emerge when discussing questions 4, 5, 6, and 7 above. If the team runs into such a roadblock, document the issue and move on to discuss another drug target.

STEP 4: ASSESS LEGAL PATHWAYS

Assessing the best legal pathway for an APM is less complicated than it initially appears. The SMART-D initiative has found that the interdisciplinary state team—involving pharmacy and policy staff—can be relied upon to vet the legal pathways and make good recommendations. Of course, the agency's legal counsel should review any recommendation made by the state team, but vetting and selecting a legal pathway is an exercise that draws first on pharmacy operations and policy knowledge.

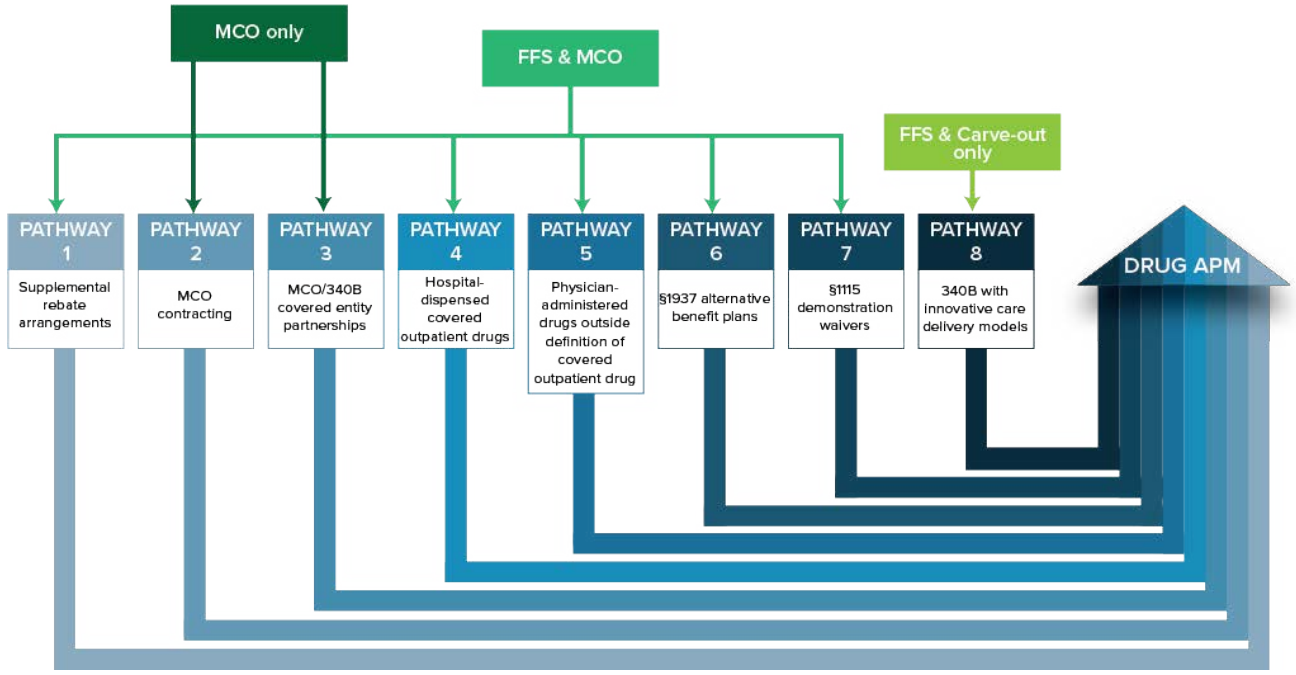
First, the state team should review the legal pathways summary and overview slides in Appendix A. For a more detailed discussion of the legal pathways, team members can also review the SMART-D Legal Brief. Next, the team should use the pathway selection guide described below and included in Appendix D to target the specific pathways that are a good fit for their state policy environment and targeted drug APM.

LEGAL PATHWAY SELECTION GUIDE

Using the selection guide in Appendix D, the state team will eliminate pathways that are not appropriate for the state policy environment and, simultaneously, focus on pathways that may be a better fit for the targeted drug or drug class.

The guide contains questions about the state's program configuration and specific drugs and/or drug classes being considered for an APM. The viability of some of the legal pathways vary based upon whether the state program is FFS, managed care with the pharmacy benefit carved in, or managed care with the pharmacy benefit carved out. Figure 3 provides an overview of the pathways according to state program type.

Figure 3. ***Overview of Pathways by State Program Type***



After the state team has established a shorter list of legal pathways using the questions outlined in Appendix D, the team will need to assess viable pathways for each targeted drug or drug class. Is the team targeting a physician-administered drug or perhaps a drug prescribed primarily in a hospital setting? Is the state considering partnering with a 340b entity to build a center of excellence model? Is the state considering negotiating a supplemental rebate agreement approach that is health-outcome based? The selection guide in Appendix D will guide the team through these questions and identify which legal pathways crosswalk to the state's developing APM approaches.

After completing the state- and drug-level questions, the state team should have identified a viable pathway or pathways for further consideration. If no pathway emerged as viable, then the state team should revisit the questions or consider abandoning the specific drug APM because it might not be feasible to develop and implement.

TIPS FOR LEGAL PATHWAY SELECTION

- States experimenting with drug APMs have found that an outcome-based supplemental rebate agreement—either Pathway 1 or Pathway 2—can be used in most situations. So, the state team could discuss whether one of these options should be considered.
- The SMART-D team worked with the Centers for Medicare & Medicaid Services (CMS) to develop a model outcome-based supplemental agreement to facilitate the contracting process with manufacturers. The template is in Appendix J.
- CMS has asked that states submit a State Plan Amendment (SPA) if they want to use an outcome-based supplemental rebate agreement. The SPA is needed because the APM negotiation process represents a change in how Medicaid pharmacy benefits are managed.
- Some examples of instances in which states might need a §1115 demonstration waiver for a drug APM include but are not limited to:
  - Closing all or part of the state formulary
  - The state or its MCOs negotiate an unlimited license for a drug and need to waive the requirement to file for a rebate for each unit of the drug

STEP 5: FINANCIAL ANALYSIS

The purpose of the financial analysis is twofold: 1) to model the potential impacts of a developed APM concept and 2) to assess the agency's technical data capability to monitor and evaluate an APM.

It is important at this point to gather available drug costs, drug utilization, and target population data for the drug or drug class and to work as a team to model the potential effects of the developed APM concept. The model does not have to be elaborate. At a minimum, lay out the best cost, utilization, manufacturer rebate, and any other relevant data available for the APM target population. Engage the team to develop assumptions of the potential dynamic expected under the APM, drawing from research conducted by state advisory groups (such as a pharmacy & therapeutics committee or drug utilization review board) and any other relevant sources. Appendix H includes a customizable model spreadsheet that can be used to pull all the applicable data components into one place and provide an overall assessment of the potential APM impact.

The state team might want to look at associated health care costs for the APM target population. For example, perhaps the APM strategy focuses on a drug or drug class that promises to reduce hospitalizations with appropriate patient compliance and the state would collect additional manufacturer rebates if certain reductions were not realized. To do this, the state team needs a good understanding of baseline hospital and other service utilization associated with the APM target population. This will all need to be assessed early on in the APM development process and reevaluated throughout implementation. As with all state data concerns, the process of modeling potential APM impact may take creative outside-the-box thinking that is also grounded in the reality of the available data. Consider incorporating a sensitivity analysis into the model to think through the best and worst case scenarios based on the research available.

The process of modeling the potential impact of the APM will also highlight the strengths and shortcomings in the available data capacity as the state begins to negotiate an APM. Some questions to map out include:

- How will the proposed APM's value-based goal be tracked, measured, and evaluated?
- What are the agency's data capabilities to track health outcomes and/or financial metrics related to the drug?
- Are there partners the state could team up with to analyze data and support discussions with manufacturers, such as local research centers, universities, or other state agencies?

The financial analysis will provide context for conversations with manufacturers on what the state would like to see from an APM. This analysis will also help the state team identify and understand the data required for APM tracking during implementation and outcome evaluation.

STEP 6: ANTICIPATE COLLABORATION WITH DRUG MANUFACTURERS

Before the state prepares to contact drug manufactures to discuss drug APM concepts, take the time to review the 8 traits of collaboration in Figure 4 on page 13. The state team should be prepared to discuss these items with a drug manufacturer as part of the negotiation, and it may be useful for the state team to identify and articulate the agency's recommendation for these items prior to negotiation.

Figure 4. ***Traits for APM Collaboration***

NEGOTIATING & CONTRACTING

States vary in the level of contact between drug manufacturer representatives and state staff. Many state Medicaid agencies use vendors to negotiate drug rebates and have limited experience directly negotiating with drug manufacturers. In these circumstances, states should involve their vendor, as appropriate, in the APM planning and negotiation. The SMART-D Initiative has developed 2 tools to help states work through an APM agreement with drug manufacturers: 1) a term sheet template that describes important elements of an APM agreement, and 2) a model outcome-based contract for executing an APM using the supplemental rebate contracting process.

INITIAL TERM SHEET DISCUSSIONS

The SMART-D Initiative developed a term sheet (Appendix I) to provide states with important APM agreement concepts. This worksheet will help the state and the manufacturer(s) work through the APM concept and begin to identify common expectations. The term sheet elements include:

- Covered Product and Therapeutic Area
- Purpose of the APM
- Utilization Period
- Outcome-Based Benchmarks
- Intervention Population
- Evaluation Methodology
- Data Aggregator
- Preferred Status
- Other Supports (as Bona Fides)
- Base Administrative Rebate
- Payment for Outcome-Based Measures
- Outcome-Based Supplemental Unit Rebate Amount
- Rebate Calculation Methodology
- Joint Committee for APM Research and Concept Development

MODEL APM CONTRACT

The SMART-D initiative developed a model outcome-based supplemental rebate contract for review and approval by CMS, with the goal of establishing a template that would be suitable for CMS and provide a clear tool for states to use to execute final APM agreements with manufacturers. CMS has reviewed the template and supports its use by states and manufacturers to implement drug APM agreements. CMS has indicated that states will need to submit Medicaid SPAs for APM implementation because the APM negotiation process represents a shift in how pharmacy benefits are managed.

TIPS FOR CONTRACTING

- If pursuing an outcome-based supplemental rebate contract, think ahead about the state's SPA process, particularly public notice and CMS review timeframes, to anticipate implementation dates. SPAs can be made effective going back to the first day of the quarter in which the amendment was submitted to CMS.
- Start early to engage manufacturers when narrowing down a list of drugs to gauge mutual interest in an APM arrangement.
- Make use of relationships, whether pharmacy benefit management vendors, 340b providers, state Medicaid provider networks and associations, or other states, to encourage discussions of similar ideas.
- Is the state a member of a multistate pharmaceutical purchasing pool? If so, think through what this may mean for APM development. In some cases, permission might be necessary to negotiate additional rebates with manufacturers outside the pool.

LEGAL PATHWAY HIGHLIGHT

§1115 DEMONSTRATION AUTHORITY

OVERVIEW OF THE CONCEPT & STATE INTEREST

The §1115 demonstration authority permits the Secretary of the Department of Health and Human Services (HHS) to waive certain provisions of the Medicaid statute and permit alternative uses of federal funds to implement an "experimental, pilot, or demonstration project" that "is likely to assist in promoting the objectives of the program." Demonstrations are to be budget neutral; that is, cost the federal government no more than would occur under the current Medicaid program.

The process for applying for a demonstration can be extensive, requiring public comment periods, detailed descriptions of the intent, budget neutrality calculations, and negotiated final terms and operational protocols. It is, however, the avenue for approval to implement a new project that surpasses the current Medicaid program architecture and the other identified legal pathways.

Federal approvals of the §1115 authority to waive aspects of the MDRP in §1927 of the Social Security Act are extremely limited and controversial.

In October 2017, Massachusetts submitted a §1115 application to gain authority to manage a closed formulary under MassHealth. Another possibility for states to consider is to use the §1115 waiver authority to permit a state to only cover a new high-cost drug, perhaps one with limited evidence, if the manufacturer is willing to enter into an APM with the state.

Although all demonstration waiver decisions are at the discretion of the HHS Secretary, and there is no guarantee that a demonstration will be approved, waivers provide a current legal option for states to think creatively about APMs and other new levers to better manage their drug benefit.

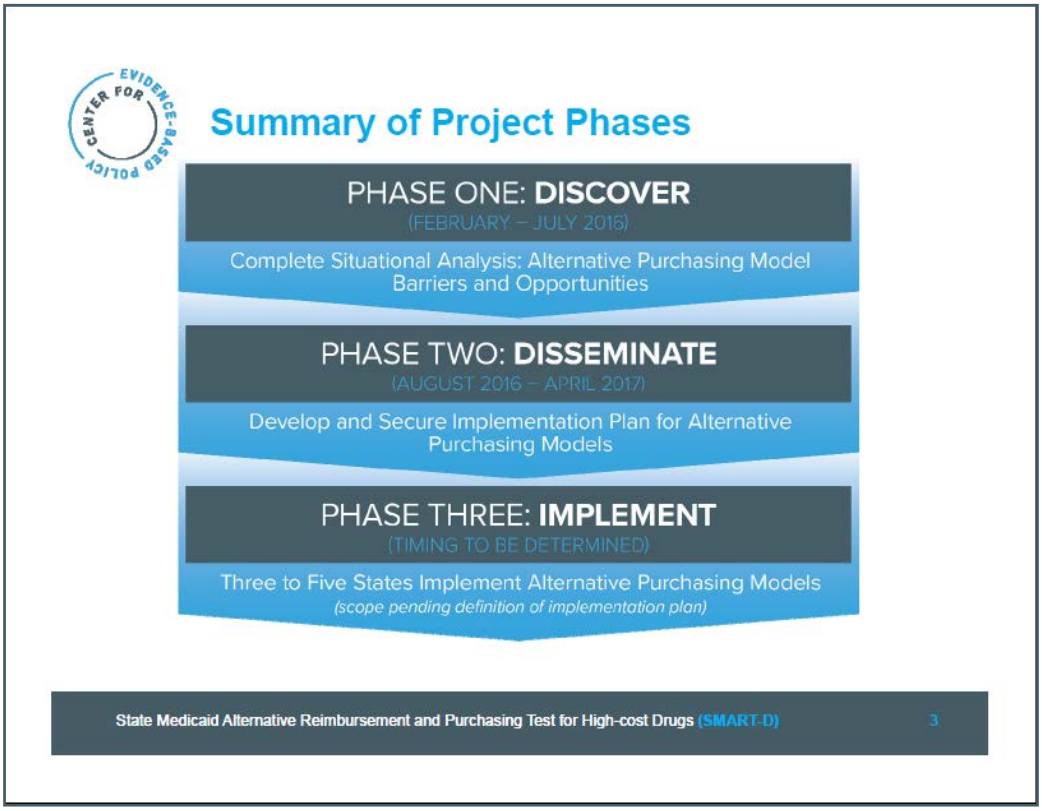
CONSIDERATIONS WHEN DEVELOPING A DRUG APM WAIVER CONCEPT

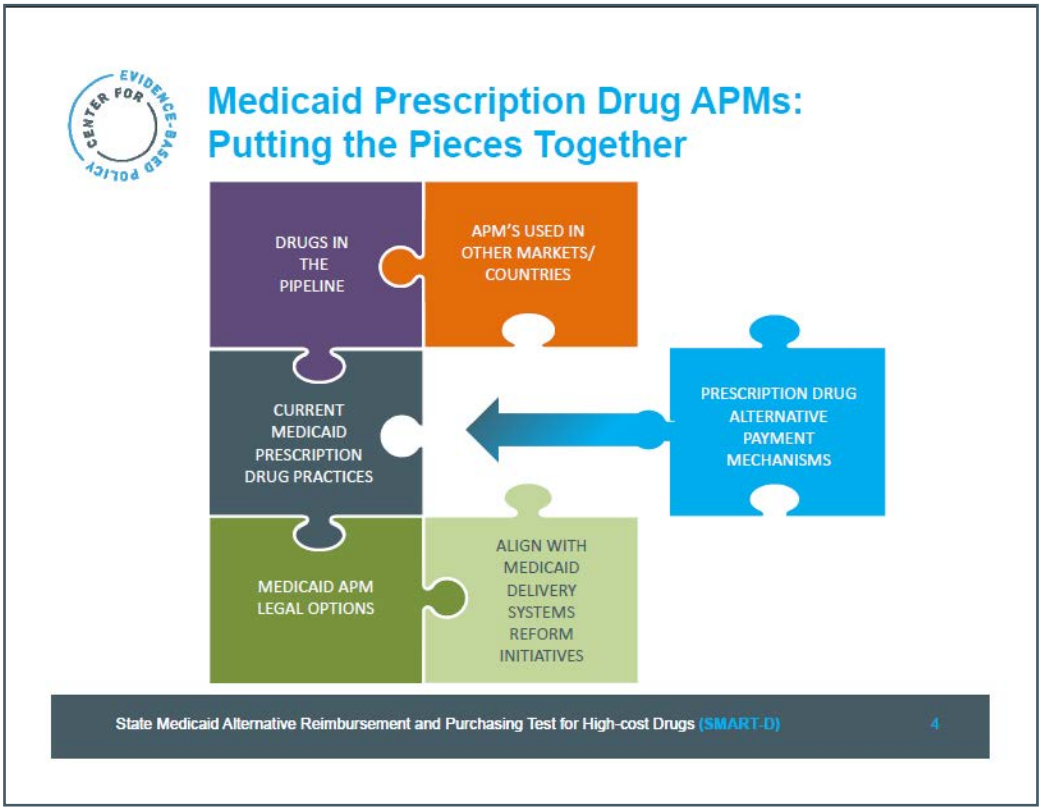
If the state team is interested in a §1115 waiver, members should discuss the following questions to develop a briefing document for agency leadership.

1. What is the goal of the demonstration? What will the state be testing?
2. What does the state want to achieve through the demonstration? How does the demonstration further Medicaid coverage goals?
3. What eligibility groups and services would the demonstration affect? Who is the target population?
4. How would enrollee access to benefits or services be affected?
5. Explain how the proposed changes would be administered (FFS, managed care, ACOs, etc.) and how this is different from the current state program.
6. Provide a summary of financing and budget impact of proposed demonstration. Specifically:
    - Current and historical trends (CMS likes to see 5 years of history) for spending for program expenditures affected by the demonstration
    - Projections of costs both with and without the demonstration, showing how the proposed concept would be budget neutral to the federal government
7. What statutory provisions and expenditure authorities does the state believe are needed to implement the proposed demonstration?
8. How does the state believe affected stakeholders (consumers, providers, health plans, tribes) will respond to the proposed demonstration approach?

APPENDIX A

SMART-D PHASE 1 RESEARCH SUMMARY


Summary of Project Phases
PHASE ONE: DISCOVER
(FEBRUARY – JULY 2016)
Complete Situational Analysis: Alternative Purchasing Model Barriers and Opportunities
PHASE TWO: DISSEMINATE
(AUGUST 2016 – APRIL 2017)
Develop and Secure Implementation Plan for Alternative Purchasing Models
PHASE THREE: IMPLEMENT
(TIMING TO BE DETERMINED)
Three to Five States Implement Alternative Purchasing Models
(scope pending definition of implementation plan)
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)
3


Medicaid Prescription Drug APMs: Putting the Pieces Together
DRUGS IN THE PIPELINE
APM'S USED IN OTHER MARKETS/ COUNTRIES
CURRENT MEDICAID PRESCRIPTION DRUG PRACTICES
PRESCRIPTION DRUG ALTERNATIVE PAYMENT MECHANISMS
MEDICAID APM LEGAL OPTIONS
ALIGN WITH MEDICAID DELIVERY SYSTEMS REFORM INITIATIVES
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)
4

Alternative Payment Models

- An APM is a contract between a payer and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure
- Our research has highlighted two pathways of APMs in Europe and the U.S.:
  - Financial-based
  - Health outcome-based

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 5

APMs

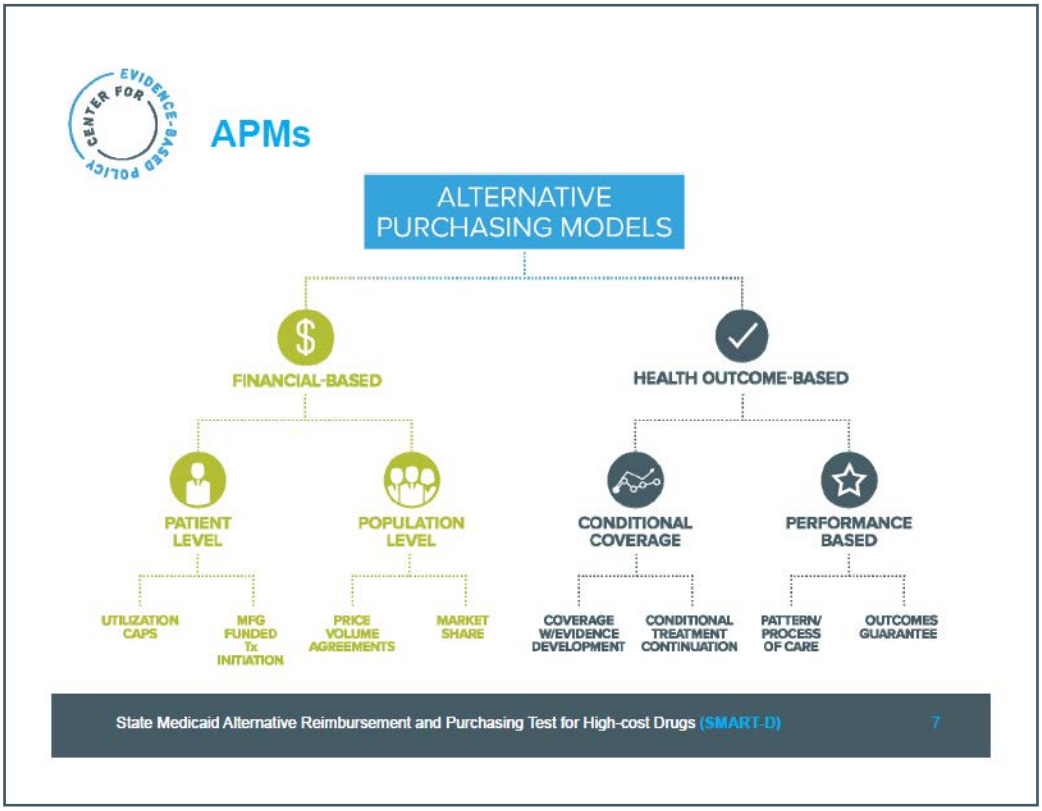
Financial-based APMs

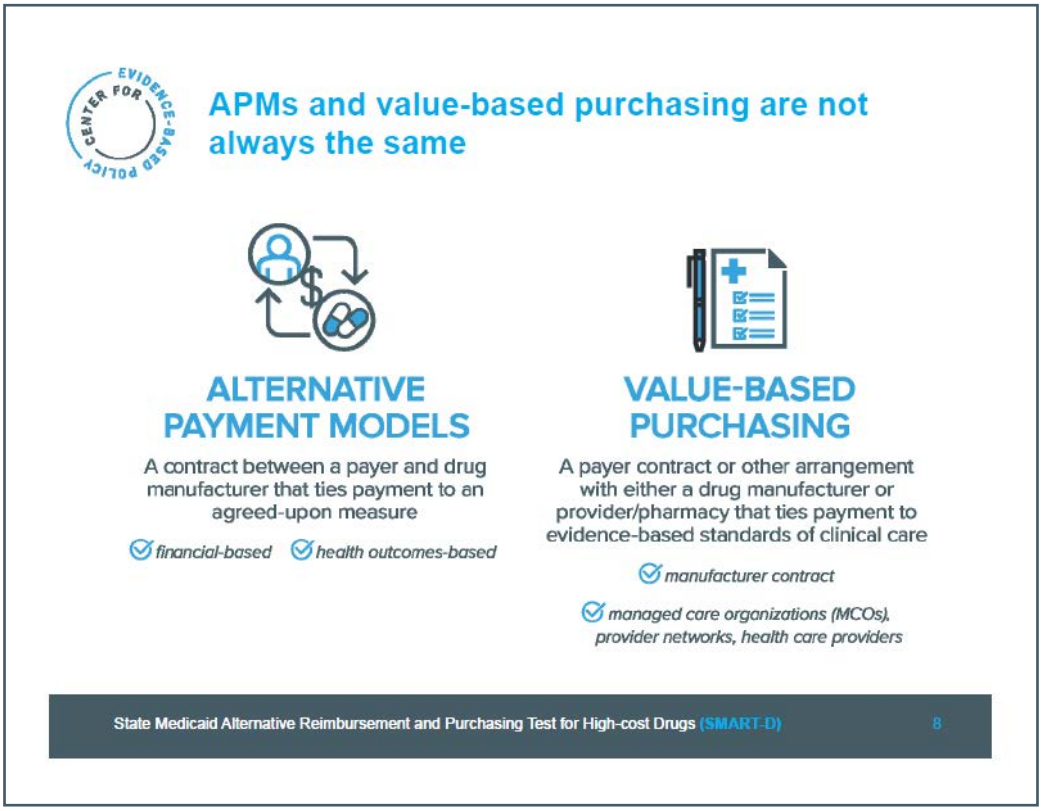
- Designed at either patient or population level
- Rely on financial caps or discounts to provide predictability and limit financial risk
- Financial targets tend to be easier to administer

Health outcome-based APMs

- Payments tied to predetermined clinical outcomes or measurements
- Sometimes conditional coverage while data is collected regarding clinical effectiveness
- Can require significant data collection, but have potential to increase quality, value and efficiency of treatment

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 6


APMs
ALTERNATIVE PURCHASING MODELS
FINANCIAL-BASED
HEALTH OUTCOME-BASED
PATIENT LEVEL
POPULATION LEVEL
CONDITIONAL COVERAGE
PERFORMANCE BASED
UTILIZATION CAPS
MFG FUNDED Tx INITIATION
PRICE VOLUME AGREEMENTS
MARKET SHARE
COVERAGE W/EVIDENCE DEVELOPMENT
CONDITIONAL TREATMENT CONTINUATION
PATTERN/ PROCESS OF CARE
OUTCOMES GUARANTEE
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 7


APMs and value-based purchasing are not always the same
ALTERNATIVE PAYMENT MODELS
A contract between a payer and drug manufacturer that ties payment to an agreed-upon measure
financial-based
health outcomes-based
VALUE-BASED PURCHASING
A payer contract or other arrangement with either a drug manufacturer or provider/pharmacy that ties payment to evidence-based standards of clinical care
manufacturer contract
managed care organizations (MCOs), provider networks, health care providers
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 8

Legal and Compliance Analysis Framework

Bill von Oehsen and his team at Powers Pyles Sutter & Verville PC developed a detailed legal analysis for:

- Understanding the current federal and state legal framework for Medicaid prescription drug coverage and payment through the Medicaid Drug Rebate Program (MDRP)
- Exploring potential options within and outside MDRP to use APMs to drive the use of clinically valuable drugs and manage prescription drug costs

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 9

Legal and Compliance Analysis Framework

- Accommodate different state Medicaid delivery system models (fee-for-service or managed care contracting)
- Support value-based payment approaches with pharmacies and other health care providers, in addition to agreements negotiated directly with prescription drug manufacturers
- Align with state Medicaid value-based payment and delivery system transformation efforts

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 10

Federal and State Requirements

- Medicaid Drug Rebate Program (MDRP)
  - Rebate calculation is statutorily fixed
  - Rebates are NDC-specific, not indication-specific
  - States cannot use closed formularies, although preferred drug lists are allowed
  - Prescription limits are regulated
- Medicaid Non-MDRP
  - Fee-for-service reimbursement for retail drugs is set at actual acquisition cost
  - Patient cost-sharing is subject to limits

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 11

Federal and State Requirements (cont'd)

- Other federal issues
  - Prohibition against off-label promotion by manufacturers
  - Anti-kickback statute
  - Overlapping discounts with 340B prices, payer rebates, etc.
- Relevant state law
  - Preferred drug list and prior authorization exclusions
  - "Any willing provider" laws
  - Regulation of MCOs and pharmacy benefit managers (PBMs) requiring transparency, etc.

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 12

State Opportunities
Pathways

- Pathway One: **Supplemental Rebate Arrangements**
- Pathway Two: **MCO Contracting**
- Pathway Three: **MCO/340B Covered Entity Partnerships**
- Pathway Four: **Hospital-Dispensed Covered Outpatient Drugs**
- Pathway Five: **PADs That Fall Outside "Covered Outpatient Drug" Definition**
- Pathway Six: **Alternative Benefit Plan**
- Pathway Seven: **Section 1115 Waiver**
- Pathway Eight: **340B with Innovative Care Delivery Models**

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 13

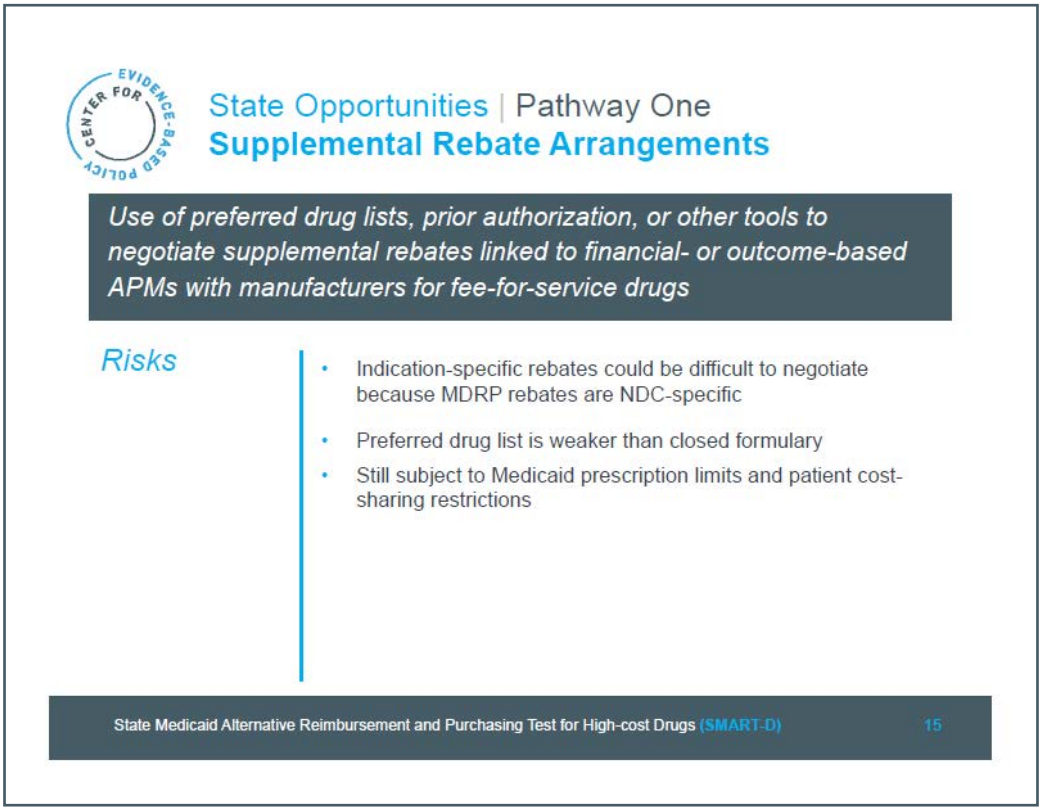
State Opportunities | Pathway One
Supplemental Rebate Arrangements

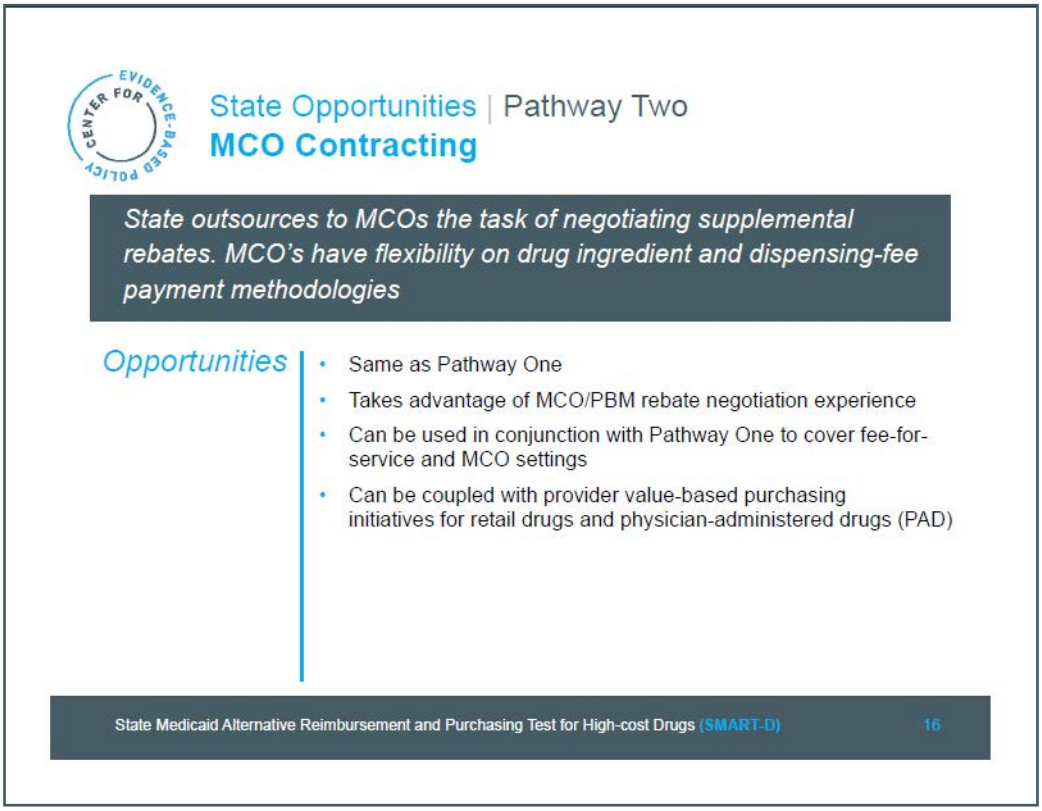
Use of preferred drug lists, prior authorization, or other tools to negotiate supplemental rebates linked to financial- or outcome-based APMs with manufacturers for fee-for-service drugs

Opportunities

- Rebates can be adjustable/indication specific
- Supplemental rebates are exempt from "best price" determinations
- Infrastructure already in place
- Multistate rebates permitted
- Accepted and supported by Centers for Medicare & Medicaid Services (CMS) https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 14


State Opportunities | Pathway One
Supplemental Rebate Arrangements
Use of preferred drug lists, prior authorization, or other tools to negotiate supplemental rebates linked to financial- or outcome-based APMs with manufacturers for fee-for-service drugs
Risks
Indication-specific rebates could be difficult to negotiate because MDRP rebates are NDC-specific
Preferred drug list is weaker than closed formulary
Still subject to Medicaid prescription limits and patient cost-sharing restrictions
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)
15


State Opportunities | Pathway Two
MCO Contracting
State outsources to MCOs the task of negotiating supplemental rebates. MCO's have flexibility on drug ingredient and dispensing-fee payment methodologies
Opportunities
Same as Pathway One
Takes advantage of MCO/PBM rebate negotiation experience
Can be used in conjunction with Pathway One to cover fee-for-service and MCO settings
Can be coupled with provider value-based purchasing initiatives for retail drugs and physician-administered drugs (PAD)
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)
16

State Opportunities | Pathway Two
MCO Contracting

State outsources to MCOs the task of negotiating supplemental rebates. MCO's have flexibility on drug ingredient and dispensing-fee payment methodologies

Risks

- Could conflict with existing MCO/PBM rebate arrangements. Would need to address through MCO contracting.
- Uncertain as to whether MCOs can negotiate supplemental rebates "on behalf of" the state and thus retain "best price" determination exemption.
- Still subject to Medicaid prescription limits and patient cost-sharing restrictions
- Potential role of state regulation of MCOs/PBMs or preferred drug lists
- More significant off-label promotion and anti-kickback statute risks

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 17

State Opportunities | Pathway Three
MCO/340B Covered Entity Partnerships

Value-based purchasing arrangements with 340B providers/pharmacies for 340B drugs reimbursed by state's MCOs, with or without accompanying APM arrangement with manufacturer

Opportunities

- Rebates can be adjustable/indication specific
- 340b drug prices are exempt from "best price" determination
- 340B price is below Medicaid net price, so less pressure to negotiate large rebates if covered entities share savings with MCOs
- Can establish closed formulary
- Exempt from MDRP prescription limits
- Can establish "centers of excellence" and "whole person" care models with covered entities

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 18

State Opportunities | Pathway Three
MCO/340B Covered Entity Partnerships

Value-based purchasing arrangements with 340B providers/pharmacies for 340B drugs reimbursed by state's MCOs, with or without accompanying APM arrangement with manufacturer

Risks

- Need cooperation of 340B covered entities
- Need utilization, patient outcome and other data from covered entities
- Need to establish this arrangement through MCO contracting
- More significant off-label promotion and anti-kickback statute risks
- Potential role of state "any willing provider" and PBM/MCO laws

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 19

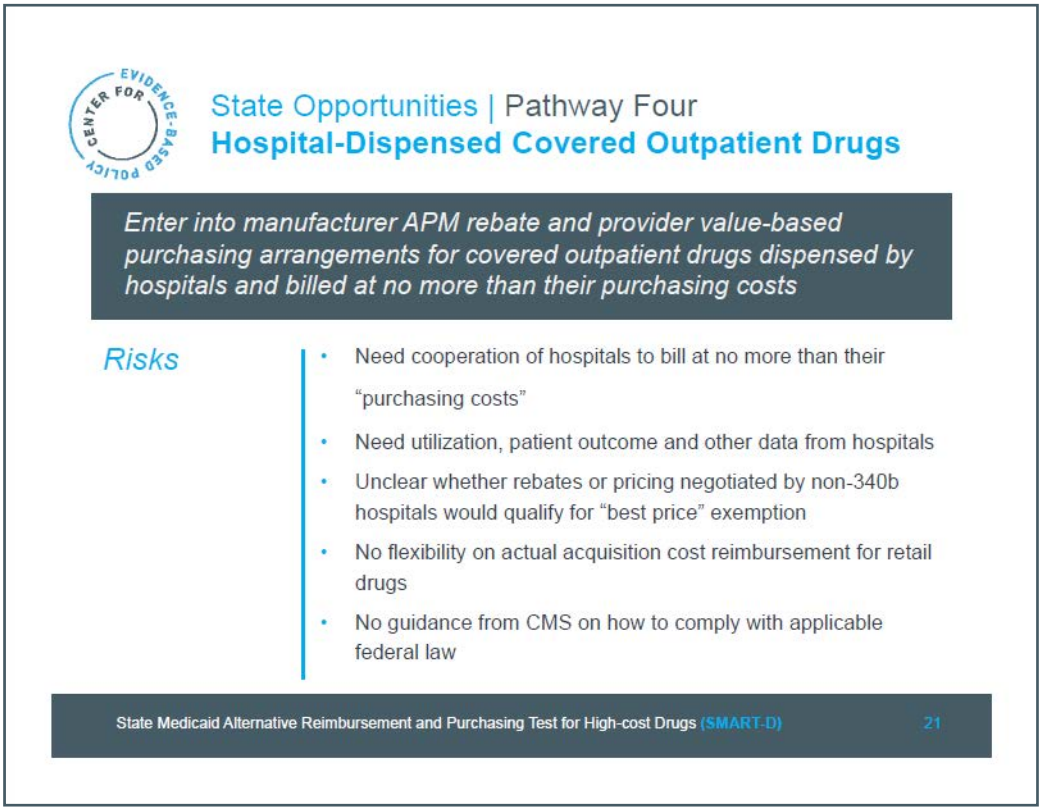
State Opportunities | Pathway Four
Hospital-Dispensed Covered Outpatient Drugs

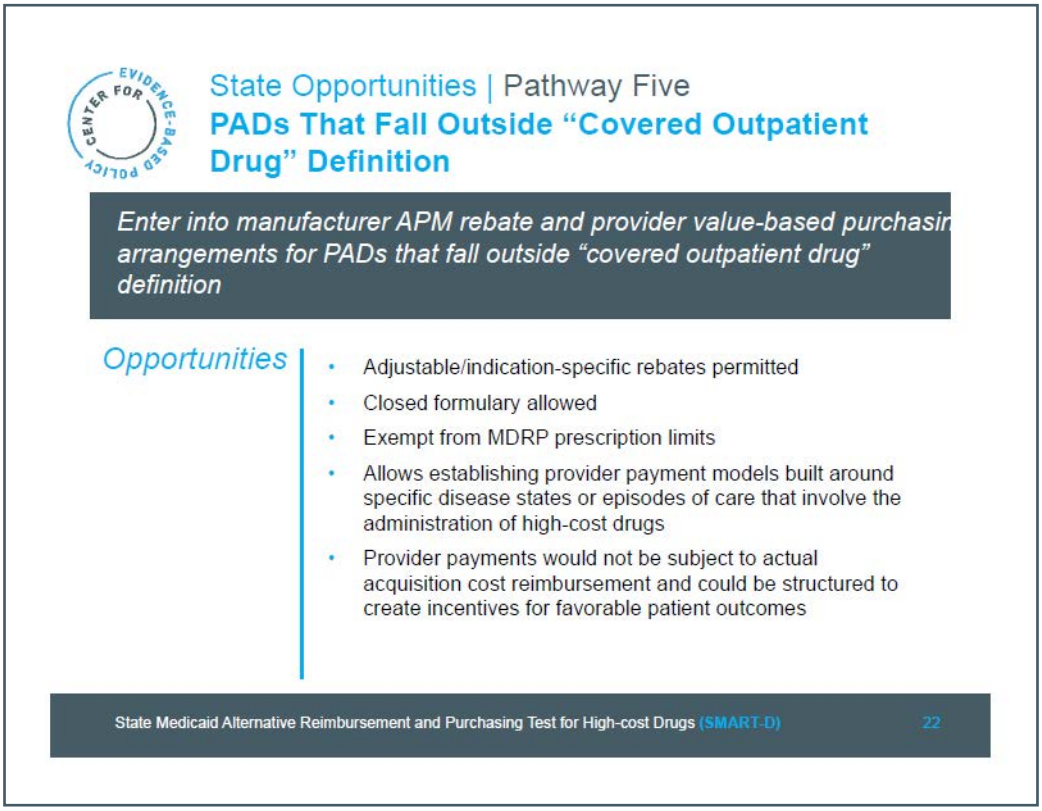
Enter into manufacturer APM rebate and provider value-based purchasing arrangements for covered outpatient drugs dispensed by hospitals and billed at no more than their purchasing costs

Opportunities

- Adjustable/indication-specific rebates permitted
- Closed formulary allowed
- Exempt from MDRP prescription limits
- Allows establishing "centers of excellence" and "whole person" care models with hospitals
- Less pressure to negotiate large rebates because 340B and non-340B hospitals bill at no more than their "purchasing costs"
- States can define "purchasing costs" in their state plan
- Can be used in conjunction with Pathway Three with 340b hospitals

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 20


State Opportunities | Pathway Four
Hospital-Dispensed Covered Outpatient Drugs
Enter into manufacturer APM rebate and provider value-based purchasing arrangements for covered outpatient drugs dispensed by hospitals and billed at no more than their purchasing costs
Risks
Need cooperation of hospitals to bill at no more than their "purchasing costs"
Need utilization, patient outcome and other data from hospitals
Unclear whether rebates or pricing negotiated by non-340b hospitals would qualify for "best price" exemption
No flexibility on actual acquisition cost reimbursement for retail drugs
No guidance from CMS on how to comply with applicable federal law
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 21


State Opportunities | Pathway Five
PADs That Fall Outside "Covered Outpatient Drug" Definition
Enter into manufacturer APM rebate and provider value-based purchasi arrangements for PADs that fall outside "covered outpatient drug" definition
Opportunities
Adjustable/indication-specific rebates permitted
Closed formulary allowed
Exempt from MDRP prescription limits
Allows establishing provider payment models built around specific disease states or episodes of care that involve the administration of high-cost drugs
Provider payments would not be subject to actual acquisition cost reimbursement and could be structured to create incentives for favorable patient outcomes
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 22

State Opportunities | Pathway Five
PADs That Fall Outside "Covered Outpatient Drug" Definition

Enter into manufacturer APM rebate and provider value-based purchasi arrangements for PADs that fall outside "covered outpatient drug" definition

Risks

- State would have to be willing to surrender MDRP rebates, which may be difficult to make up
- No clear exemption from "best price" determination
- Unclear how model would work in managed care environment
- Need utilization, patient outcome and other data from providers
- Model is untested

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 23

State Opportunities | Pathway Six
Alternative Benefit Plan

Pathway Six: Section 1937 Alternative Benefit Plans
Establish closed formulary for drugs provided to Medicaid expansion populations that receive essential health benefits under Affordable Care Act

Opportunities

- Closed formulary to focus on most clinically effective and cost-effective drugs

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 24

State Opportunities | Pathway Six
Alternative Benefit Plan

Pathway Six: Section 1937 Alternative Benefit Plans
Establish closed formulary for drugs provided to Medicaid expansion populations that receive essential health benefits under Affordable Care Act

Risks

- For states that have not implemented an alternative benefit plan, complexity of administering a separate benefit package
- Complexity of administering option for medically frail enrollees to receive benefits through the traditional Medicaid benefit package

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 25

State Opportunities | Pathway Seven
Section 1115 Waiver

Seek to relax formulary restrictions and other MDRP requirements in order to test new value-based purchasing models for prescription drugs and related services

Opportunities

- Align prescription drugs with states' broader value-based purchasing initiatives, via waiver of MDRP limitations
- Build prescription drugs into ACO-like payment models or directives to MCOs to increase use of alternative payment models, allowing flexibility for drug utilization and cost management by ACOs and MCOs

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 26

State Opportunities | Pathway Seven
Section 1115 Waiver

Seek to relax formulary restrictions and other MDRP requirements in order to test new value-based purchasing models for prescription drugs and related services

Risks

- 1115 waiver or waiver amendment must be approved by CMS through an extensive process
- Federal budget neutrality requirement must be met

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 27

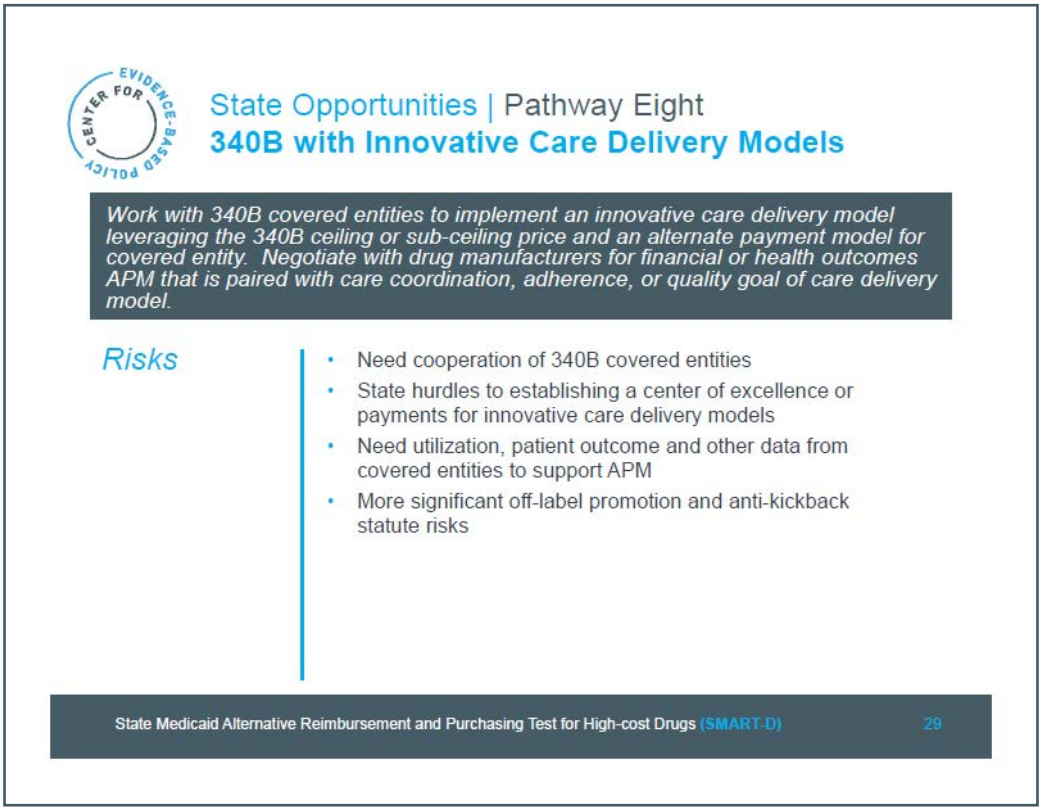
State Opportunities | Pathway Eight
340B with Innovative Care Delivery Models

Work with 340B covered entities to implement an innovative care delivery model leveraging the 340B ceiling or sub-ceiling price and an alternate payment model for covered entity. Negotiate with drug manufacturers for financial or health outcomes APM that is paired with care coordination, adherence, or quality goal of care delivery model.

Opportunities

- Can be applied in both a fee-for-service and managed care environment
- Through collaborative effort with covered entity for "centers of excellence" and "whole person" care models, may be able to get reimbursement for sub-ceiling price
- If drug adherence or compliance is important to condition being targeted, there may be an opportunity to negotiate with the manufacturer
- Rebates can be adjustable/indication specific
- 340b drug prices are exempt from "best price" determination

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 28

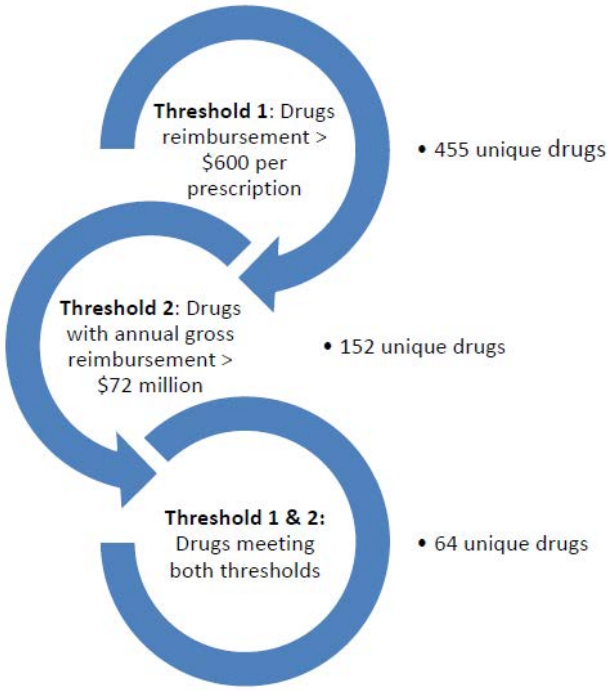

State Opportunities | Pathway Eight
340B with Innovative Care Delivery Models
Work with 340B covered entities to implement an innovative care delivery model leveraging the 340B ceiling or sub-ceiling price and an alternate payment model for covered entity. Negotiate with drug manufacturers for financial or health outcomes APM that is paired with care coordination, adherence, or quality goal of care delivery model.
Risks
Need cooperation of 340B covered entities
State hurdles to establishing a center of excellence or payments for innovative care delivery models
Need utilization, patient outcome and other data from covered entities to support APM
More significant off-label promotion and anti-kickback statute risks
State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)
29


Economic Analysis of High Cost Drugs

SMART-D Definition of "High-Cost"

- No common definition across federal and state agencies
- SMART-D definition informed by Medicare, MACPAC, and GAO definitions
- Adopted a two-part definition that could be aligned with the available Medicaid data:
  - Reimbursements of more than $600 per prescription
  - Total Medicaid reimbursements of $72 million per year

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



64 High-Cost Drugs

- Accounted for:
  - $9.3 million prescriptions or 1.5% of prescriptions reimbursed by Medicaid
  - $16.9 billion in Medicaid reimbursements, before rebates, or 32.6% of Medicaid drug reimbursement dollars
- ***The estimated $16.9 billion spent on these 64 high-cost drugs account for 3.1% of the total national Medicaid spending for all services***.
  - In FY 2015, the Medicaid program spent an estimated $538.4 billion (Kaiser, 2015b).

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

New high-cost drugs reimbursed by Medicaid (FY 2015)

Brand Name	Breakthrough Therapy?	FY 2015 Total Reimbursement per Prescription	FY 2015 Gross Cost to Medicaid
Harvoni	Yes	28,300	1,540,228,000
Sovaldi	Yes	24,400	643,446,000
Novoseven	No	81,500	219,484,000
Tecfidera	No	5,300	199,262,000
Tivicay	No	1,400	166,653,000
H.P. Acthar	No	43,700	138,727,000
Triumeq	No	2,400	127,545,000
Viekira Pak	Yes	25,400	111,334,000
Olysio	No	19,900	73,568,000

Source: Medicaid State Drug Utilization Data records, FY 2014-2015

SMART-D Website and Phase 1 Reports

- See www.smart-d.org
- Research and reports tab:
  1. Summary Report
  2. Legal Brief
  3. Economic Analysis
  4. APM Brief
  5. MED Policy Report

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) 35

APPENDIX B
STATE APM READINESS ASSESSMENT TOOL

This document is a state self-assessment tool focused on helping state teams think through and gauge their state's readiness to develop and implement APMs to manage high-cost drugs. The structure is designed to help identify strengths and potential areas for improvement to successfully develop and implement drug APMs.

To provide the most accurate assessment, we recommend having a small, diverse team complete the assessment together. The team should consist of the following representatives from the Medicaid agency: pharmacy, data analytics, policy, finance and budget, information technology, managed care contracting (if applicable), and executive leadership.

We recommend that state team members complete the assessment individually, and then meet to **discuss the results**, produce a consensus version, and develop an action plan for priority areas. We discourage teams from completing the assessment individually and then averaging the scores to get a consensus score without having first discussed as a group. The discussion is a great opportunity to identify opportunities and priorities for APM work.

FINANCIAL-BASED APMs

Financial-based APMs, designed at either the population or patient level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. These APMs focus on lowering costs and expanding patient access and tend to be easier to administer than health outcome-based APMs (described below). For example, AstraZeneca and UK health authorities established an APM for Lynparza (olaparib), a novel ovarian cancer therapy, in which the manufacturer is responsible for the cost of the drug for patients who remain on treatment after 15 months.

- A population-level financial-based APM is a price-volume agreement n which financial expenditures for a medication are controlled by setting an agreed-upon budget ceiling. If the total amount spent for a drug exceeds this threshold, the manufacturer is responsible for the additional cost, often through a rebate paid back to the payer.
- A patient-level APM ties financial benchmarks to individual patient drug utilization. This type of agreement can be in the form of a price cap or a dose cap. Under a price cap arrangement, drugs are provided free once patients reach a fixed financial utilization limit. Under a dose cap arrangement, the manufacturer and payer agree on a predetermined level of consumption, and anything beyond this agreed limit is paid for by the manufacturer.

HEALTH OUTCOME-BASED APMs

Health outcome-based APMs are tied to predetermined clinical outcomes or measurements or else coverage is conditional while data is being collected. These APMs require additional planning and data collection, but have the potential to increase the quality, value, and efficiency of treatments. Examples of health outcome-based APMs:

- In 1988, Merck agreed to compensate patients and payers for the prescription costs of Zocor (simvastatin) if the drug failed to lower LDL cholesterol to target concentrations.
- In 2007, Millennium, a subsidiary of Takeda, agreed to provide a rebate for UK patients who did not respond (based on tumor shrinkage) to the multiple myeloma treatment Velcade (bortezomib).

FOCUS AREA #1: CURRENT APM EXPERIENCE & PLANS

This initial section explores the state's current activities to engage in drug APM agreements. A summary of financial- and health outcome-based APMs is provided on page 34 for reference.

	FINANCIAL-BASED	HEALTH OUTCOME-BASED	NONE
1. Indicate which, if any, prescription drug APMs the state currently has in place or is currently pursuing			
2. Describe any health outcome-based and/or financial-based APMs the state currently has in place or is pursuing and the corresponding drug(s) and drug manufacturer(s)			

	VERY STRONG	STRONG	NEUTRAL	WEAK	VERY WEAK
3. Indicate the state's level of interest in pursuing a financial- and/or health outcome-based APM within the next 12 to 24 months					
4. In the next 12 to 24 months, for which drugs and/or drug classes would you be most likely to pursue a financial and/or health outcome-based APM?					

Based on the responses above, gauge the state's ***current plans*** to engage in drug APMs

- ☐ **State has plans to pursue an APM model within the next 12 to 24 months (financial and/or health outcomes)**
- ☐ **State is considering pursuing an APM model within the next 12 to 24 months (financial and/or health outcomes)**
- ☐ **State has no plans to pursue an APM model within the next 12 to 24 months (financial and/or health outcomes)**

FOCUS AREA #2: SYSTEM READINESS

This section attempts to capture the state's internal planning and capacity to develop and implement prescription drug APMs.

	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
STATE'S INTERNAL PLANNING					
State has identified disease areas and drugs of interest for an APM					
STATE'S INTERNAL CAPACITY					
State has assigned staff with the necessary experience to develop and implement a prescription drug APM.					
State requires significant technical assistance to develop and implement a prescription drug APM.					
STATE'S DATA CAPABILITIES					
State has access to data needed to manage and track health, drug, or cost outcomes related to prescription drug APMs.					
State recently reprocured its MMIS within the past 24 months.					
Consider what the next 24 months looks like with he MMIS (i.e., upgrade, planning, RFP, implementation).					
RELATIONSHIP WITH DRUG MANUFACTURERS					
State is interested in revising and/ or enhancing its contracts with drug manufacturers to demonstrate better value and outcomes and/or budget predictability.					
State Medicaid agency has strong relationships with a few drug manufacturers to possibly move forward with an APM arrangement.					
Based on the state's relationships with drug manufacturers, which drug classes and/or drug manufacturers, if any, do you believe would have the best chance of success with an APM?					

Based on the responses above, gauge the state's current ***system readiness***

- ☐ **State has: 1) identified one or more drug classes, 2) has dedicated and experienced staff, and 3) implemented necessary data capabilities**
- ☐ **State: 1) is considering possible drug classes, 2) may or may not have dedicated and experienced staff, and 3) has some basic data capabilities that could be further developed**
- ☐ **State: 1) has not identified a drug class, 2) does not have dedicated and experienced staff, and 3) does not have basic data capabilities**

POSSIBLE DRUG APM LEGAL PATHWAYS

To enable states to move forward with prescription drug APMs, SMART-D has identified the following 8 legal pathways for developing APMs.

Pathway 1 Supplemental Rebate Arrangements

Use of PDLs, prior authorization, or other tools to negotiate supplemental rebates linked to financial- or health outcomes-based APMs with manufacturers for drugs.

Pathway 2 MCO Contracting

State outsources to MCOs the task of negotiating supplemental rebates, or MCOs use flexibility on drug ingredient or dispensing fee payment methodologies.

Pathway 3 MCO/340B Covered Entity Partnerships

Value-based arrangements with 340B providers or pharmacies for 340B drugs reimbursed by states' MCOs, with or without accompanying manufacturer APM arrangement.

Pathway 4 Hospital-dispensed Covered Outpatient Drugs

Provider value-based arrangements for covered outpatient drugs dispensed by hospitals and billed at no more than their purchasing costs, with or without accompanying manufacturer APM rebate arrangement.

Pathway 5 Physician-administered Drugs Outside Definition of Covered Outpatient Drug

Enter into manufacturer APM rebate and provider arrangements for PADs that fall outside "covered outpatient drug" definition.

Pathway 6 §1937 Alternative Benefit Plans

Establish closed formulary for dugs provided to Medicaid expansion populations that receive essential health benefits under the Affordable Care Act.

Pathway 7 §1115 Demonstration Waivers

Seek to relax formulary restrictions and other MDRP requirements in order to test new value-based models for prescription drugs and related services.

Pathway 8 340B with Innovative Care Delivery Models

Innovative care delivery model that leverages the 340B ceiling or subceiling price and an APM for covered entity. Allows for the negotiation with drug manufacturers for financial- or health outcome-based APM paired with care coordination, adherence, or quality goal of care delivery model.

FOCUS AREA #3: LEGAL READINESS

This section assesses state interest in each legal pathway. A brief description of each pathway is included on page 37. A full description of the pathways is in the SMART-D summary report at www.smart-d.org.

	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
OUTCOME-BASED CONTRACTS					
State currently has interest in establishing an APM using supplemental rebate agreements with manufacturers negotiated directly by the state or through a multistate purchasing pool.					
MANAGED CARE CONTRACTING					
State currently has interest in having MCOs and their PBMs negotiate supplemental rebates on behalf of the state that are passed directly and wholly to the state.					
MCO/340B COVERED ENTITY PARTNERSHIPS					
State currently has interest in establishing an APM through the 340B program in which the drug is paid for by a Medicaid MCO.					
HOSPITAL-DISPENSED COVERED OUTPATIENT DRUGS					
State currently has interest in identifying specific drugs that are hospital-dispensed, covered outpatient drugs and/or specific hospitals (such as 340B hospitals) that could be a part of an APM arrangement.					
PHYSICIAN-ADMINISTERED DRUGS					
State currently has interest in identifying specific drugs that are physician-administered and could be a part of an APM arrangement outside the limitations of the Medicaid Drug Rebate Program.					
STATE ALTERNATIVE BENEFIT PLAN					
State has an Alternative Benefit Plan? If yes, state has interest in identifying specific populations and drugs within the state's Alternative Benefit Plan for APM arrangements.					
SECTION 1115 WAIVERS					
State currently has interest in pursuing Section 1115 authority to implement innovative programs that promote value-based arrangements.					
340B INNOVATIVE CARE DELIVERY MODELS					
State currently has interest in pursuing a 340B innovative care delivery model that promotes a value-based arrangement.					

FOCUS AREA #3: LEGAL READINESS CONTINUED

Rank the 8 pathways below in terms of the state's interest in pursuing an APM arrangement under each legal pathway within the next 12 to 24 months (8 being the strongest level of interest).

RANKING	LEGAL PATHWAYS
	Supplemental rebate arrangements
	MCO contracting
	MCO/340B covered entity partnerships
	Hospital-dispensed covered outpatient drugs
	Physician administered drugs
	Alternative Benefit Plan
	Section 1115 Waiver
	340B innovative care delivery models

Based on the responses above, gauge the state's ***legal readiness***

- ☐ State has identified promising legal pathway(s) for applicable APM
- ☐ State is considering possible legal pathway(s) for applicable APMs
- ☐ State has yet to identify possible legal pathways for applicable APM, or believes there are barriers to many/all pathways

FOCUS AREA #4: POLITICAL READINESS

As with any delivery system or payment reform initiative, there are numerous stakeholders involved and political waters to navigate. To implement a prescription drug APM, state Medicaid agencies need to work with a broad range of stakeholders, including but not limited to, the governor, legislators, drug manufacturers, patient advocates, providers, pharmacies, MCOs, and PBMs. Each group may have its own political influence within a given state. This next section assesses state readiness related to the political and stakeholder environment.

	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
GOVERNOR					
A prescription drug APM identified by the state Medicaid agency would be supported by the governor and is considered a high priority for the administration.					
STATE LEGISLATURE					
The state Medicaid agency has key legislative champions who have the necessary influence to help support a prescription drug APM.					
A prescription drug APM identified by the Medicaid agency would be something the state legislature would most likely support.					
PATIENT ADVOCACY ORGANIZATIONS					
In general, patient advocate organizations in the state support initiatives to increase value and patient outcomes.					
Are there drug classes for which APMs could be difficult to implement because of patient advocate organizations? Which ones?					
Based on the political influence of the state's patient advocate organizations, which drugs and/or drug classes do you believe would have the **best AND least** chance of success with an APM?					
HEALTH CARE PROVIDER COMMUNITY					
A prescription drug APM identified by the Medicaid agency would be something the health care provider community would support.					
Are there drug classes for which APMs could be difficult to implement because of opposition from specific groups within the health care provider community? Which ones?					
Based on the engagement and political influence of the state's health care provider community, which drugs and/or drug classes, if any, do you believe would have the **best AND least** chance of success with an APM?					
PHARMACY & PHARMACIST COMMUNITIES					
A prescription drug APM identified by the Medicaid agency would be supported by the pharmacy and pharmacist communities.					

FOCUS AREA #4: POLITICAL READINESS CONTINUED

	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
Are there drug classes for which APMs could be difficult to implement because of opposition from the pharmacy and pharmacist communities? Which ones?					
Based on the engagement and political influence of the state's pharmacy and pharmacist communities, which drugs and/or drug classes, if any, do you believe would have the **best AND least** chance of success with an APM?					
MEDICAID MANAGED CARE ORGANIZATIONS					
A prescription drug APM identified by the Medicaid agency would be something the MCO community would support.					
Are there drug classes for which APMs could be difficult to implement because of opposition from the MCO community?					
Based on the engagement and political influence of the state's MCO community, which drugs and/or drug classes, if any, do you believe would have the **best AND least** chance of success with an APM?					

Rank the interest groups below in terms of their support of a possible prescription drug APM (5 being the strongest level of support).

RANKING	LEGAL PATHWAYS
	Drug manufacturers
	Patient advocate organizations
	Health care providers
	Pharmacies/pharmacists
	MCOs

Based on the responses above, gauge the state's *political readiness*

- ☐ There is support for applicable APMs from governor's office, legislature, and advocacy groups.
- ☐ There is limited support for applicable APMs from the governor's office, legislature, and/or advocacy groups.
- ☐ There is limited or no support for applicable APMs from the governor's office, legislature, and advocacy groups.

OVERALL READINESS

This last section attempts to capture a realistic assessment of the state's overall readiness based on state team discussions on the above topics. Looking across the issue areas, is the state mostly green and well positioned to take on APM activities? Is the state mostly yellow, indicating key areas where the team can focus to develop the state's potential? Or did team members mark one or more reds, indicating concerns that there is less certain support and technical readiness for APM implementation?

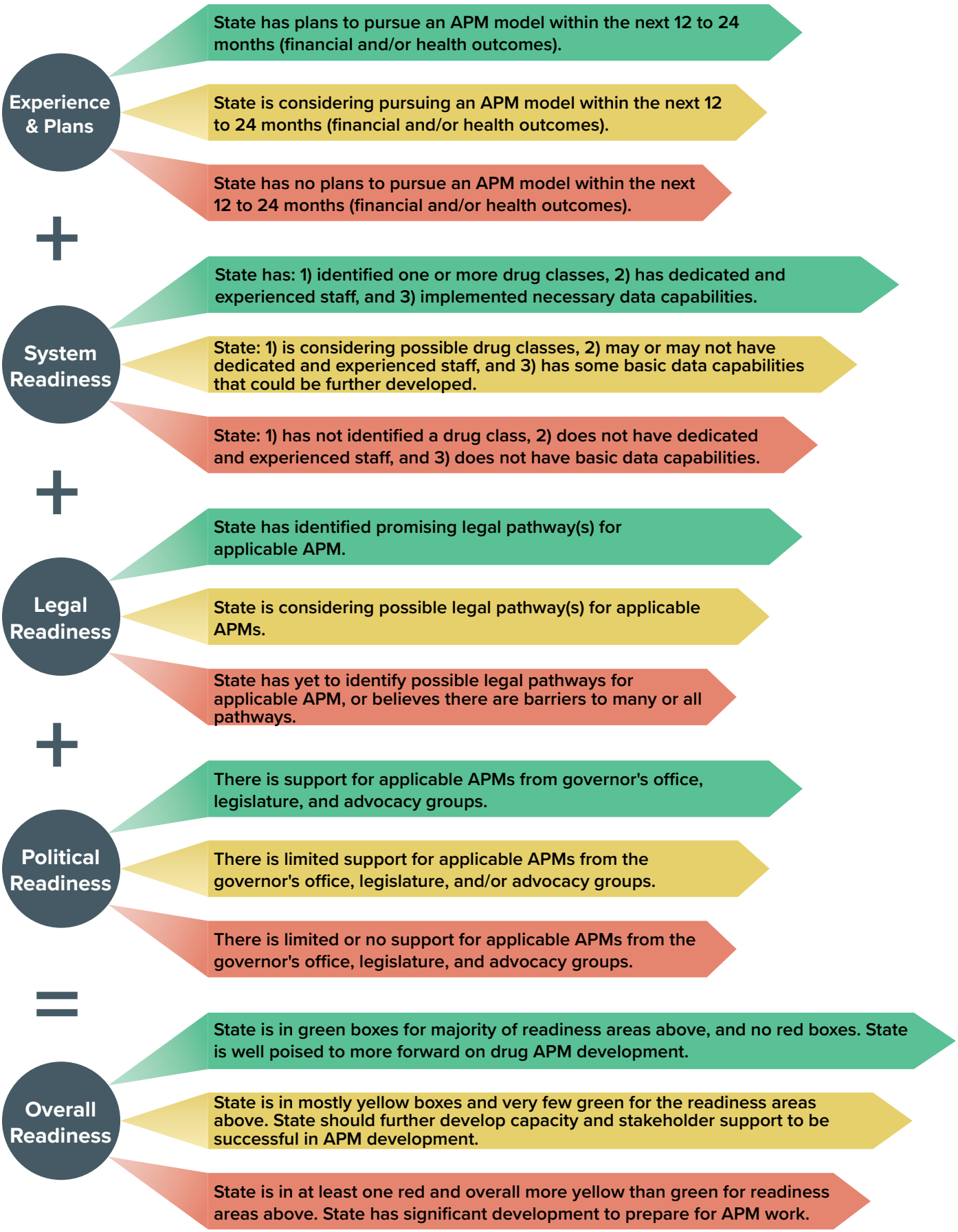
Also, based on the responses above, what are the 3 to 5 critical areas (e.g., agency capacity, waiver negotiations, political stakeholders) that would need to be immediately addressed in order for the state to successfully implement a prescription drug APM within the next 12 to 24 months?

Based on the responses above, gauge the state's ***overall readiness***

- ☐ **State is in green boxes for majority of readiness areas above, and no red boxes. State is well poised to more forward on drug APM development.**
- ☐ **State is in mostly yellow boxes and very few green for the readiness areas above. State should further develop capacity and stakeholder support to be successful in APM development.**
- ☐ **State is in at least one red and overall more yellow than green for readiness areas above. State has significant development to prepare for APM work.**

APPENDIX B: State APM Readiness Assessment Tool

Evaluating Levels of Readiness in Key Areas



APPENDIX C
APM DEVELOPMENT DISCUSSION WORKSHEET

For each of the preliminary drug targets identified, the team should discuss and document notes for the 8 questions listed below. These notes are important and will serve as the basis of the APM Concept Overview and APM Strategy sections of the APM template found in Appendix E.

1. Why this drug?
   - What is the state's rationale for interest in the specific drug or drug class?
   - Recent or projected cost growth is concerning?
   - Concerns that drug is overused?
   - Would the state like the drug to be placed in larger whole person care or other delivery model?
   - Improve price transparency with partners?
   - Contact from a manufacturer?
   - Other?

2. What data are available to support the state team's APM design for this drug/drug class?
   - What are the current volume and costs for this drug?
   - What are the current supplemental rebate agreements?
   - What do you know about the health care costs of clients using this drug?

3. What is the value-based goal for the selected drug of interest? For the goal selected, brainstorm a hypothetical outcome measure.
   - Financial goal
   - Health outcome goal
   - Both

4. What features of this drug or drug class could make it a good option for an APM?
   - Is there competition within the drug class?
   - Where is drug in its branded lifecycle? Is the CPI penalty large, making the drug manufacturer less likely to negotiate?
   - Will there be new, potentially lower cost entrants in the class soon?

5. What are the existing cost-containment tools used to manage this drug? And where are there roadblocks for the state?
   - Consider implications as a managed care or FFS state. Does the state have a single PDL or does it carve-out this drug class? What is willingness of MCO partners to collaborate?
   - What is the existing prior authorization for this drug and drug class? What are the options to modify or add prior authorization for the drug?
   - Does the drug fall within restricted classes set by state law or is it politically protected?
   - Is the drug/drug class politically hot with wide support (e.g., opioids)?

6. What is the agency's relationship to the drug's manufacturer?
   - Can the state capitalize on relationships with manufacturers, either directly or via partners, such as 340B entities?
   - If there is no relationship or an acrimonious relationship with the drug manufacturer, how would the state conduct outreach and encourage collaboration?

7. Why should the manufacturer consider an APM for this drug? What would make the drug manufacturer want to collaborate on a different contracting arrangement?
   - Increased market share?
   - Improved evidence of efficacy versus others in drug class?
   - Other?

8. How could a possible APM for this drug fit within the state's payment reform strategy?
   - Are there policy levers that would support an APM, such as quality measure incentives, reporting streams, total cost of care models?

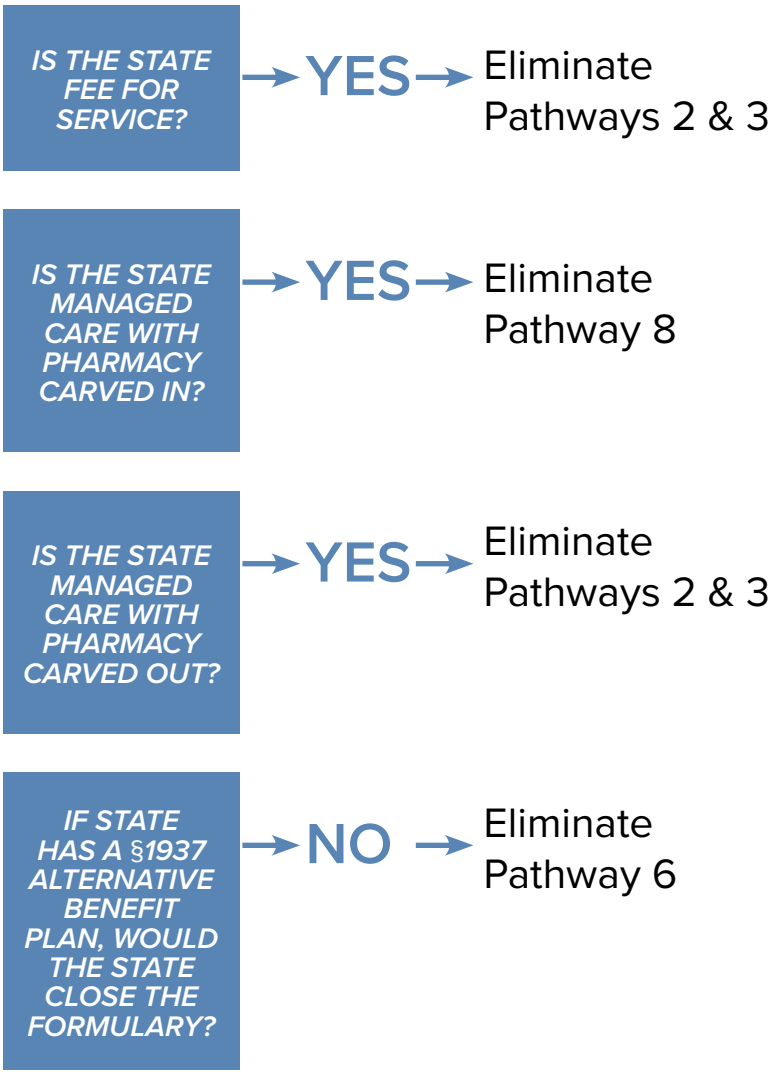
APPENDIX D
STATE TEAM WORKSHEET: ASSESSING THE BEST LEGAL PATHWAY(S)

This worksheet is designed to provide a step-by-step approach to identifying viable legal pathways for the APMs under consideration. As the state team walks through this selection guide, the team will eliminate pathways that are not appropriate for the state policy environment and, simultaneously, focus on pathways that may be a fit for the specific drug class targeted.

After completing the state- and drug-level questions, the state team should have identified a viable pathway or pathways for further consideration. The state team should consult with agency legal counsel about their preliminary legal pathway selection. If no pathway emerges as viable, then the state team should revisit the questions or consider abandoning the specific drug APM because it may not be feasible for the state to implement.

PART 1: STATE PROGRAM CONFIGURATION

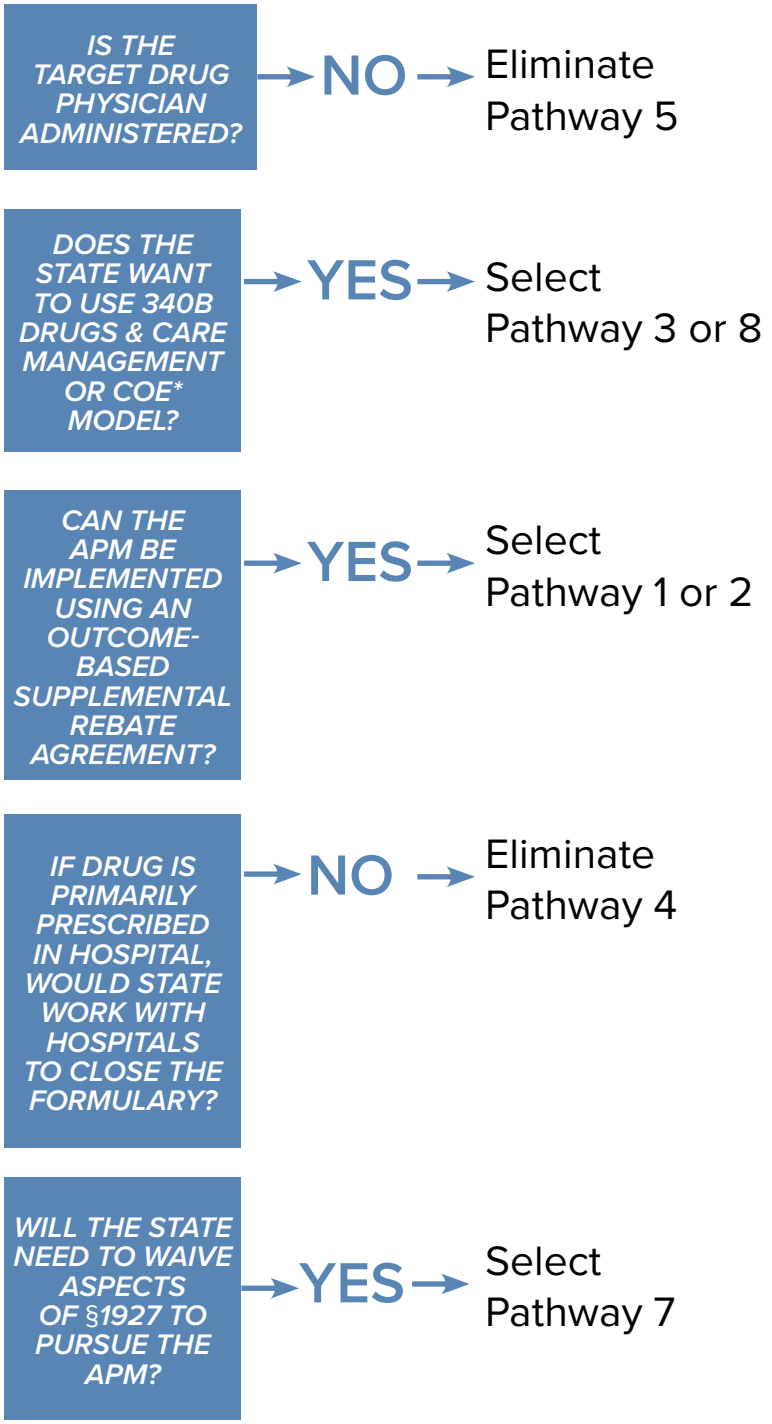
Viable pathways vary based upon whether the state program is FFS, managed care with the pharmacy benefit carved in, or managed care with the pharmacy benefit carved out. Have the state team review the questions below and eliminate some pathways that are not appropriate for the state policy environment.



LEGAL PATHWAYS	
PATHWAY 1	Supplemental Rebate Arrangements
PATHWAY 2	MCO Contracting
PATHWAY 3	MCO/340B Covered Entity Partnerships
PATHWAY 4	Hospital-Dispensed Covered Outpatient Drugs
PATHWAY 5	Physician-Administered Drugs Outside Definition of Covered Outpatient Drug
PATHWAY 6	§1937 Alternative Benefit Plans
PATHWAY 7	§1115 Waivers
PATHWAY 8	340B with Innovative Care Delivery Models

PART 2: DRUG-SPECIFIC QUESTIONS

After the state team has established a shorter list of pathways using the state-level questions above, then the team will need to assess viable pathways for each targeted drug or drug class. The questions below will help the state team eliminate some pathways from consideration and focus on others that may be viable.



LEGAL PATHWAYS	
PATHWAY 1	Supplemental Rebate Arrangements
PATHWAY 2	MCO Contracting
PATHWAY 3	MCO/340B Covered Entity Partnerships
PATHWAY 4	Hospital-Dispensed Covered Outpatient Drugs
PATHWAY 5	Physician-Administered Drugs Outside Definition of Covered Outpatient Drug
PATHWAY 6	§1937 Alternative Benefit Plans
PATHWAY 7	§1115 Waivers
PATHWAY 8	340B with Innovative Care Delivery Models

**Center of Excellence*

APPENDIX E

SAMPLE STRUCTURE FOR APM PLAN

APM Section	Summary
1. APM Executive Summary	
2. Drug Overview	
3. APM Strategy	
4. APM Legal Pathway	
5. State Policy Analysis	
6. Cost and Utilization	
7. State Data Analysis Plan	
8. Challenge Level & Risk Mitigation	
9. Communication Plan	

APPENDIX F

EXAMPLE APM CONCEPT: ATYPICAL ANTIPSYCHOTIC LONG-ACTING INJECTABLES (LAIS)

DRAFT

APM Section	Summary
1. APM Executive Summary	Long-acting injectable (LAI) antipsychotics, a leading area of treatment for schizophrenia has become a growing share of the state's Medicaid fee-for-service (FFS) drug costs. In 20XX, four leading LAIs represented x% of FFS drug costs. The integration of mental and physical health care is a central to the goals for the state Medicaid program. An APM focused on increasing the use of LAIs could support better health outcomes and reduction of ER/inpatient services required by individuals with schizophrenia.
2. Drug Overview	LAIs are indicated for the treatment of schizophrenia. Schizophrenia is a chronic and severe mental disorder that is often disabling, with symptoms that can include hallucinations, delusions, difficulty sustaining activities, and inability to understand information or feelings. Schizophrenia is a devastating and costly disorder for most people diagnosed with the disease. The overall U.S. cost is estimated to be $62 billion annually, including direct health care and indirect societal costs. Although there is no cure, there has been significant treatment success using atypical antipsychotics. There are more than 15 new medications for the treatment of schizophrenia currently in various stages of development by both biotech and pharmaceutical companies. Additionally, there are many new and improving psycho-social treatments and cognitive therapies being rolled out with some success. Together these new treatments hold significant promise for positive outcomes for patients. One of the leading areas of treatment are LAIs. The LAI pharmacologic strategy is designed for treating patients who relapse, leading to increased medical costs, often including hospitalizations, due to nonadherence. These drugs are designed to overcome the disease side effect of patients' disbelief of having the illness, as successful treatment stabilizes patient symptoms. LAI therapy is designed to be continuous, using an injected drug, thus improving adherence. A study found 28% greater percentage of days covered (PDC) > 80% and persistence was 45% greater compared to orals. (Reference: PMID: 28919292. DOI: 10.1016/j.clinthera.2017.08.008) Continuous dosing happens in the form of IM injections at intervals of 30, 60, or 90 days as applicable to the specific drug.

APM Section	Summary
3. APM Strategy	***Health outcome based supplemental rebate*** The goal of this health outcome APM is to achieve an additional health-outcome based rebate of xx% paid by the manufacturer if targeted schizophrenia patients' hospitalizations do not decrease by xx%, in aggregate, from the baseline year to the intervention year. Maintenance treatment with LAI therapy has been shown effective in reducing the rate of relapse in schizophrenia and thus reduced hospitalizations. To measure health outcomes for hospital admissions, the state Medicaid agency and drug manufacturer will agree on a definition of patients to include in this APM. Hospitalization days will be measured in a baseline year that pre-dates the patients' LAI therapy. The state will seek to stabilize intervention patients on LAI therapy over a 6-9-month period and receive an additional to-be-determined supplemental rebate (not related to health outcomes) during this initial stabilization period. After the agreed upon 6-9-month stabilization period, the health outcome measurement year will commence. Using claims data, the state will measure the intervention patients' hospitalization days in the measurement period as compared to their hospitalization days in the baseline period. If a reduction in hospitalization days of xx% is not achieved, then the drug manufacturer will pay an additional health outcome rebate of xx% in addition to any other rebate.
4. APM Legal Pathway	Pathway One: Supplemental rebates based upon health outcome. This pathway is well established and CMS has encouraged states to use supplemental rebates in its July 14, 2016, Medicaid Drug Rebate Program Notice, Release No. 176 (see https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf) The SMART-D team at the Center for Evidence-based policy has drafted a template outcomes-base supplemental rebate contract which is currently under review by CMS. The state's Medicaid program will use this model APM contract and customize the appendices to the agreement for the LAI health-outcome terms. The state Medicaid program must file a SPA with CMS for use of this outcomes-base supplemental rebate template contract.
5. State Policy Analysis	Integration of mental and physical health is a central goal in the state's Medicaid program. This APM would support the health and cost goals for the state's integration initiatives.

<table>
<tr><th>APM Section</th><th>Summary</th></tr>
<tr><td>6. Cost and Utilization</td><td>
State Medicaid programs are entitled to a minimum 23.1% rebate on average manufacturer price as required by the Medicaid Drug Rebate Program.

During calendar year 20XX, the state spent a total of $x on LAI products for x claims accounting for x members. If the APM health-outcome threshold of a xx% reduction in hospital days is not met, then Medicaid would receive an additional health outcome rebate of an estimated $x million (after accounting for statutory federal rebate of 23.1%). If the APM health-outcome threshold is met, the state would expect to see a significant savings in its spending for inpatient hospital days. [Additional analysis can be conducted to estimate expected savings from reduced hospital inpatient days.]

<table>
<tr><th colspan="6">Medicaid, all patients with major disease category of mental diseases and disorders, 20XX</th></tr>
<tr><td>Discharges</td><td>Total Length of Stay (days)</td><td>Average Length of Stay (days)</td><td>Total Charges</td><td>Average Charges</td><td>Average Cost per Day</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2">APM Savings Estimate for Inpatient Days</th></tr>
<tr><td>20XX Medicaid mental disease inpatient days</td><td></td></tr>
<tr><td>x% days due to Schizophrenia and other psychotic disorders</td><td></td></tr>
<tr><td>APM target population captures only x%</td><td></td></tr>
<tr><td>xx% reduction in inpatient days for APM target population</td><td></td></tr>
<tr><td>Possible inpatient saving at cost of $x per day</td><td></td></tr>
</table>
</td></tr>
<tr><td>7. State Data Analysis Plan for APM</td><td>
The health outcome will be documented by measuring the reduction in number of hospital days for the intervention patient group when comparing the pre-LAI therapy period (baseline period) and the stabilized LAI therapy period(measurement period). To finalize the negotiated APM terms, Medicaid and the drug manufacturer will agree upon:

The targeted population will be defined as: insert agreed upon definition
A hospitalization day will be defined as: insert agreed upon definition of a hospitalization day
The baseline hospitalization rate will be calculated as the period: insert time definition for the baseline period (e.g., one calendar year prior to commencing LAI therapy)
The intervention period will be calculated as: insert the time period for measuring the intervention result (e.g., after 6 months of continuous therapy is achieved for a given patient based upon paid claims submitted for the clinician administered LAI therapy).

Agency staff shall maintain a registry of patients that meet the agreed upon criteria for inclusion in this APM and will update it monthly with new eligible patients. On a quarterly basis, agency staff shall use the registry information to calculate hospitalization rates for these patients. The state and the drug manufacturer shall meet quarterly to review the registry and its outcomes.
</td></tr>
</table>

APM Section	Summary
8. Challenge Level & Risk Mitigation	This APM is considered a medium to high challenge level. Some key risks include: ▪ Successfully engaging drug manufacturer(s) in an executed agreement. ▪ Preliminary terms for this APM look for Medicaid to increase appropriate patient utilization of the drug and stabilize patients on treatment. Successful measurement of health-outcome will require a sufficient sample size of patient stabilized on this drug therapy. ▪ LAIs are a clinician-administered drug requiring cooperation, engagement, and aligned incentives for the provider community to support patient adherence and appropriate storage, handling, administration and billing for this drug. ▪ Manual data tracking for the registry. State will need to ensure that a staff member is actively maintaining the registry and can reliably calculate hospitalization rates.

APPENDIX G

EXAMPLE APM CONCEPT: HEPATITIS C (HCV) DRUGS

DRAFT

APM Section	Summary
1. APM Executive Summary	The state Medicaid program has experienced significant growth in prescription drug spending in comparison to overall health care spending. This growth has been due to a myriad of factors including: price increases in existing drugs; increases in the number of newly available costly drugs (specialty drugs and biologics); higher than average numbers of novel drug approvals; a relatively low number of patent expirations; increasing insurance coverage; increasing utilization; and population growth and aging. In addition, prescription drug expenditures are projected to continue rising during the coming decade, adding more pressure to the state's health care budget. The Medicaid agency has pursued several strategies to help identify and implement alternative payment models (APMs) where the cost of a prescription drug is linked to either financial-based or health outcome-based metrics. The state Medicaid program has paid an estimated $xx million (state general fund) for Hepatitis C drug costs during the last budget cycle, making this a high priority area for a possible APM. The state has identified an APM for Hepatitis C that utilizes the 340B Drug Discount Program linked with Centers of Excellence. This APM strategy shows promise to both improve patient care outcomes and create financial predictability and/or discounts for Hepatitis C drug costs. Potential savings achievable through this model in 20XX would have been over $xx million.
2. Drug Overview	Hepatitis C is a viral infection that causes liver inflammation, sometimes leading to serious liver damage. The Hepatitis C virus (HCV) spreads through contaminated blood. People who inject drugs are at particularly high risk for transmitting HCV, creating a public health crisis in some communities. It is estimated that 3-5 million people in the U.S. have chronic HCV. Until recently, Hepatitis C treatment required weekly injections and oral medications that many HCV-infected people couldn't take because of other health problems or unacceptable side effects. Significant advances in treatment for Hepatitis C include use of new, "direct-acting" anti-viral medications, sometimes in combination with older therapies. As a result, people experience better outcomes, fewer side effects and shorter treatment times. The goal of treatment is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response(SVR). Despite the many studies documenting high rates of sustained viral response 12 weeks after treatment (SVR12), no studies have documented improvement in clinical outcomes such as decompensated cirrhosis, liver transplant rates, and mortality. A few studies have reported conflicting results for quality of life, and safety information has begun to plague some of these newer treatments, noting the FDA Black Box warning for risk of reactivation of Hepatitis B.

APM Section	Summary
3. APM Strategy	***Leveraging a state-wide 340B closed formulary model to pursue supplemental rebate and health outcome:*** The goal of this APM is to focus on a whole-person care approach through Centers of Excellence (COE) linked with 340B covered entities that would entail care coordination, expert consultation and adherence support, specifically for treating clinics where specialists are not available. Based on the legal pathway outlined below in Section 4, any drugs purchased through the 340B model are already purchased at discounted prices that approximate, and in many cases are less than, the prices Medicaid pays after receiving the Medicaid Drug Rebate Program (MDRP) rebate. In addition, 340B purchased drugs are exempt from the requirements of the MDRP and, therefore, can be deployed as part of a closed formulary, not just a preferred drug list and the state does not have to share rebate dollars with CMS. The possibility of a closed formulary creates a significant point of negotiation with drug manufacturers that wish to have their drug agent included on the closed formulary of the 340B covered entity. Similar COEs in other states have been comprised of a disproportionate share hospital (DSH), a group of federally qualified health centers (FQHCs) and other ambulatory providers to coordinate care for the Hepatitis C enrollee population. To implement this model, the state would certify FQHCs to serve as “Centers of Excellence” for the Hepatitis C population based on their ability to deliver an integrated model of infectious disease and primary care services needed by the Hepatitis C patients. A DSH would be designated to serve as the specialty consultant, either in person or via telehealth, to support the specialty needs of this Hepatitis C population. COEs would receive an enhanced payment rate negotiated through Medicaid to cover the expansion of their Hepatitis C patient care services. In exchange, the COEs would return the bulk of their 340B savings on the Hepatitis C drugs to the state and accept a reimbursement rate of actual acquisition cost (AAC) plus a 340B revenue margin (through an agreed upon percentage). This option would also provide the state the opportunity to negotiate, on behalf of the 340B covered entities,with one or more Hepatitis C drug manufacturers in return for exclusive status on the closed formularies of the COE 340Bentities. This means that Medicaid could focus its negotiations with the manufacturers on 1) patient outcome and quality of care measures and 2) deeper rebates within a 340B closed formulary for the COE 340B entities. A health outcome arrangement could seek an additional discount if the patient does not achieve an agreed upon SVR score at the end of a completed 12-week course of treatment. The COEs would be required to maintain a registry of their Hepatitis C patients, support patient adherence, test for SVR, and enter this information in a registry to be shared with the state Medicaid agency.

APM Section	Summary
4. APM Legal Pathway	***Pathway Eight: 340B Innovative Care Delivery Model -Center of Excellence:*** The 340B program allows certain types of safety net providers, called "covered entities," to purchase covered outpatient drugs at substantially discounted prices. Often these providers pay less than the amount Medicaid pays, even after the MDRP rebate is factored in. 340B covered entities include FQHCs, disproportionate share hospitals (which serve a high proportion of Medicaid and uninsured patients), children's hospitals, clinics funded by the Ryan White HIV/AIDS Program,and hemophilia treatment centers, among other safety net providers. Some of these providers treat large and diverse Medicaid populations, some focus on specific conditions, and some do both. By leveraging 340B pricing, the state is less dependent on replacing the MDRP rebate revenue and can focus its negotiations with the manufacturers on patient outcome and quality of care measures and worry less about the size of its rebates. This approach may also lighten the state's administrative burden to seek MDRP rebates and manage manufacturer rebate disputes. With Pathway Eight, the state can work with 340B covered entities through COEs to implement an innovative care delivery model leveraging the 340B ceiling or sub-ceiling price and an alternative payment model for the covered entity. Additionally, a COE approach may create enough leverage with a manufacturer to offer a supplemental discount through a coverage with evidence development model or health outcomes approach.
5. State Policy Analysis	The state would use a Center of Excellence (COE) approach through 340B covered entities to organize care for Hepatitis C patients. The COEs would ensure that these patients receive high quality services to support their complex needs and also adhere to the dosing regimen.

<table>
<tr><th>APM Section</th><th>Summary</th></tr>
<tr><td>6. Cost and Utilization</td><td>
The state's Medicaid program reviews approximately xx new requests per month for Hepatitis C treatment.

It is anticipated that during 20XX the number of new requests per month for treatment will increase to approximately xx. The state general fund costs are estimated to be $xx million.

While 340B pricing is confidential, a reasonable estimate of savings through 340B purchasing alone is a xx% reduction on pharmacy claims paid. Negotiating for a health outcomes arrangement in addition to 340B pricing, is expected to save another xx% off the 340B price.

In addition, there is an expected reduction in medical claims cost due to the COE's comprehensive whole-person approach that could be quantified upon further analysis.

20XX Final Hepatitis C Budget (State General Fund)
<table>
<tr><th></th><th>20XX Actuals</th><th>Estimated Drug Spending Using 340B with COE Model</th><th>Estimated Drug Spending Using 340B and Health Outcome Contract with COE Model</th></tr>
<tr><td>Total Pharmacy Claims Paid</td><td></td><td></td><td></td></tr>
</table>
20XX Hepatitis C Budget Projections (State General Fund)
<table>
<tr><th></th><th>20XX Budget Projections</th><th>Estimated Drug Spending Using 340B with COE Model</th><th>Estimated Drug Spending Using 340B and Health Outcome Contract with COE Model</th></tr>
<tr><td>Total Pharmacy Claims Paid</td><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>7. State Data Analysis Plan</td><td>The health outcome arrangement would seek an additional discount if the patient does not achieve an agreed upon SVR score at the end of a completed 12-week course of treatment. The COEs would be required to maintain a registry of their Hepatitis C patients, support patient adherence, test for SVR, and enter this information in a registry to be shared with the state. On a quarterly basis, state Medicaid agency staff shall use the registry information to calculate achievement of overall SVR scores. The state(on behalf of the 340B covered entities)and the drug manufacturer shall meet quarterly to review the registry and its outcomes.</td></tr>
</table>

APM Section	Summary
8. Challenge Level and Risk Mitigation	This APM is considered a medium challenge level. Key risks include: ▪ Agreement upon health outcome metrics between the state/COE/ manufacturers ▪ Negotiated COE rate ▪ Data collection and analytics ▪ State Medicaid decision to take on additional supplemental rebate negotiations (beyond 340B) with the manufacturers on behalf of the 340B covered entities
9. Communication Plan	Engagement is needed with both internal and external stakeholders to implement a Hepatitis C Center of Excellence model including: ▪ COE candidate organizations ▪ Hepatitis C constituent organizations ▪ Manufacturers

WORKING STATE DRUG APM DATA TEMPLATE

Atypical Antipsychotic Long-Acting Injectables (LAIs)
Last Updated: xx/xx/xxxx

Condition	Pharmaceutical(s): Manufacturer(s): Base Year Data	APM Start Date	APM Approach and Outcome Summary
Identify condition	List all focus medications and manufacturers		Example: Supplemental rebates based on "winner takes all" strategy based on reduced hospitalizations and ED utilization by APM target clients.

Drug Spending Profile of Clients Included in the APM

	Total Spending	# of Clients	Total Spending Per Client	Client Member Months	Total Spending PMPM	Prescription Fill Count	Total Spending Per Perscription Fill	Unit Count	Average Cost Per Unit
Pharmaceutical Name Base year 1 Base year 2 REPEAT FOR ALL DRUGS IN CLASS	RUN TWO YEARS OF HISTORICAL DATA IF POSSIBLE								

Associated Health Care Expenditure Profile of Clients Included in APM

Service	Total Spending	# of Clients (Included in APM)	Total Spending Per Client	Client Member Months	Total Spending PMPM	# of Visits	Total Spending per Visit
Hospitalizations Base year 1 Base year 2							
Emergency Room Visits Base year 1 Base year 2							
Total Pharmaceutical Costs Base year 1 Base year 2							
Total Medicaid Cost of Care Base year 1 Base year 2							

APPENDIX I

TERM SHEET FOR OUTCOME-BASED AGREEMENT
FOR DISCUSSION PURPOSES ONLY

[state Medicaid agency] and [drug manufacturer] (hereinafter collectively referred to as the "Parties") are in discussions to establish an outcome-based contract to positively impact the care of patients and access to appropriate drug therapies.

Note: The sections identified below correspond to items in the outcome-based supplemental rebate agreement included in Appendix J. Please see this appendix for definitions.

Appendix A and B Items	
Covered Product and Therapeutic Area	
Purpose	*[summarize APM]*
Utilization Period	
Outcome-based Benchmarks	
Intervention Population	
Evaluation Methodology	
Data Aggregator	
Preferred Status	*[if applicable]*
Other Supports (in-kind)	*[if applicable]*
Administrative Rebate	*[if applicable]*
Payment for Outcome-based Measures	
Outcome-based Supplemental Unit Rebate Amount	
Calculation Type	
Rebate Calculation Methodology	

This term sheet represents a discussion proposal only, which is subject to agreement on and execution of a definitive written contract. Any Party shall have the right to terminate discussions at any time without obligation. All information, including, but not limited to, the information contained in this term sheet and any discussions pertaining to a collaboration agreement between the Parties, shall be held in confidence and shall not be used for any purpose outside of this agreement or disclosed to any other party.

APPENDIX J
OUTCOME-BASED SUPPLEMENTAL REBATE AGREEMENT

This Outcome-Based Supplemental Rebate Agreement ("Agreement") by and between the [STATE] Department of _____ ("State") and _____ ("Manufacturer") sets forth the terms and conditions of this Agreement.

RECITALS

WHEREAS, State and Manufacturer both participate in the Medicaid Drug Rebate Program ("MDRP"), which requires Manufacturer to pay a rebate to State on covered outpatient drugs pursuant to a statutory formula;

WHEREAS, MDRP allows for supplemental rebates and there may be an existing supplemental rebate arrangement between State and Manufacturer;

WHEREAS, State and Manufacturer desire to enter into an outcome-based supplemental rebate arrangement for the payment of rebates in excess of the MDRP statutory rebate and any existing supplemental rebate;

WHEREAS, State and Manufacturer would like the flexibility of including bona fide, itemized services to support the outcome-based arrangement in accordance with Section 1927(k)(1)(B)(i)(II) of the Social Security Act, 42 U.S.C. Section 1396r-8(k)(1)(B)(i)(II), and 42 C.F.R. Section 447.502;

WHEREAS, State and Manufacturer desire that the outcome-based supplemental rebate arrangement include the payment of a base administrative fee by the Manufacturer to the State to cover the administrative costs related to this Agreement; and

WHEREAS, State and Manufacturer would like the outcome-based supplemental rebate arrangement to encompass drugs purchased in a fee-for-service ("FFS") structure, drugs purchased in a managed care organization ("MCO") structure or both

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the Parties, intending to be legally bound, agree as follows:

1. Definitions. As used herein, the following terms shall have the meanings set forth below:

1.1. "Average Manufacturer Price or AMP" shall mean the Average Manufacturer Price as defined in Section 1927(k)(1) of the Social Security Act, 42 U.S.C. Section 1396r-8(k)(1), and final regulations promulgated by the Centers for Medicare and Medicaid Services ("CMS"), as such statute or regulations may be amended from time to time. The AMP shall exclude rebates paid under this Agreement.

1.2. "Base Administrative Fee" shall mean the amount paid by the Manufacturer to the State to cover the administrative costs related to performance of this Agreement. The fee may be in the form of a one-time fee, a per claim fee, a percentage-based fee, or some other arrangement as determined by the Parties and described in Appendix A.

1.3. "Best Price" shall mean the Best Price as defined in Section 1927(c)(1)(C) of the Social Security Act, 42 U.S.C. Section 1396r-8(c)(1)(C), and final regulations promulgated by CMS, as such statute or regulations may be amended from time to time. The Best Price shall exclude rebates paid under this Agreement.

1.4. "Bona Fide Service Fee" shall mean a fee paid by Manufacturer to a third-party purchaser of covered outpatient drugs that represents fair market value for a bona fide, itemized service and that otherwise meets the definition of "bona fide service fee" codified at 42 C.F.R. Section 447.502. Examples include fees associated with administrative service agreements and patient care programs, such as medication compliance and patient education programs.

1.5. "Bona Fide Service Plan" shall mean a plan agreed upon by the Parties for Manufacturer to pay Bona Fide Service Fees to third-party purchasers. The value of the Bona Fide Service Fees paid under the Bona Fide Service Plan is described in Appendix A.

1.6. "Confidential Information" means any nonpublic confidential or proprietary information of a party, including but not limited to trade secrets, rebate pricing data, and terms of Manufacturer agreements.

1.7. "Covered Product" shall mean the pharmaceutical product or products identified in Appendix A and subject to evaluation and a supplemental rebate under this Agreement.

1.8. "Covered Product Status" shall mean the status of Covered Product granted by the State. At a minimum, State will ensure access to Covered Product and will not disadvantage Covered Product to competitive drugs in Product Class.

1.9. "Data Aggregator" shall mean a State entity or contractor (such as a consulting company, research institution, State designee or other organization under contract with the State) that tracks Covered Product's utilization, evaluates its performance and calculates the Outcome-Based Supplemental Rebates owed by Manufacturer, if any. The Data Aggregator is identified or otherwise described in Appendix A.

1.10. "Evaluation Methodology" shall mean the methodology described in Appendix A for evaluating the performance of the Covered Product based on the Outcome-Based Benchmarks agreed upon by the Parties.

1.11. "Intervention Population" shall mean the group of patients whose use of Covered Product during the Utilization Period generates the Utilization Data that is evaluated by the Data Aggregator for purposes of assessing the performance of Covered Product and calculating the Outcome-Based Supplemental Rebates. The Intervention Population is described in Appendix A and may be a subset of the total Medicaid population using Covered Product during the Utilization Period.

1.12. "National Drug Code" or "NDC" shall mean a unique eleven-digit, three-segment number for identifying a pharmaceutical based on the drug's labeler, its product strength and dosage form and its packaging. The Covered Product will be identified at the NDC-9 digit level to ensure that all package sizes are captured under this Agreement, unless the terms of Appendix A specify that the Covered Product will be identified at the NDC-11 digit level.

1.13. "Outcome-Based Benchmarks" shall mean the measurable benchmarks, thresholds and/or outcomes described in Appendix A used to evaluate the Covered Product's performance for purposes of calculating a supplemental rebate.

1.14. "Outcome-Based Supplemental Rebate" shall mean the amount paid by Manufacturer in excess of the MDRP-mandated rebate and any other state supplemental rebate based on the process described in Section 2 and Appendix A.

1.15. "Outcome-Based Supplemental Unit Rebate Amount" shall mean the amount Manufacturer agrees to pay State under this Agreement at the unit level.

1.16. "Party" or "Parties" small mean State and/or Manufacturer.

1.17. "Performance Data" shall mean the data generated by the Data Aggregator by applying the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data.

1.18. "Preferred Status" shall mean advantages the State may grant to Covered Product using a preferred drug list ("PDL"), prior authorization procedures, step-edit therapy or other means as described in Appendix A

to manage Product Class. The Covered Product in this Agreement may or may not be part of the PDL and subject to PDL edits.

1.19. "Product Class" shall mean a group of pharmaceutical products that are used to treat the same condition or disease state as Covered Product.

1.20. "Rebate Calculation Methodology" shall mean the methodology for calculating the Outcome-Based Supplemental Rebate described in Appendix A.

1.21. "Settle-Up Period" shall mean the period in which the Parties and Data Aggregator evaluate the Performance Data, calculate the Outcome-Based Supplemental Rebates owed by Manufacturer and, if applicable, determine whether the Bona Fide Service Plan was fulfilled. The length of the Settle-Up Period is specified in Appendix A.

1.22. "Unit" shall mean the drug unit is the lowest identifiable amount on which the Outcome-Based Supplemental Rebate is calculated (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) and shall be the same unit as specified by the Manufacturer as part of its submission of data under the MDRP.

1.23. "Utilization" shall mean the total number of units of the Covered Product reimbursed by State during the Utilization Period and included in the assessment of Covered Product's performance according to the Evaluation Methodology.

1.24. "Utilization Data" shall mean the data collected by the Data Aggregator necessary to evaluate the Covered Product's performance and to calculate the Outcome-Based Supplemental Rebates owed by Manufacturer for the applicable Utilization Period.

1.25. "Utilization Period" shall mean the period in which Utilization Data is collected. The length of the Utilization Period is specified in Appendix A.

2. Evaluation and Settle-Up Process

2.1. Utilization. Utilization Data will be collected during the Utilization Period by the State and forwarded to the Data Aggregator.

2.2. Evaluation. The Data Aggregator shall generate Performance Data by using the Outcome-Based Benchmarks and Evaluation Methodology to evaluate the Utilization Data. The Performance Data will be compiled and summarized prior to the beginning of the Settle-Up Period.

2.3. Data-Sharing. State and Data Aggregator will share with Manufacturer periodic reports during the Utilization Period. Any patient health information ("PHI") contained in the reports provided to Manufacturer shall be de-identified in accordance with the Health Insurance Portability and Accountability Act ("HIPAA"). The Parties may use a unique alpha-numeric code as a case identifier to track the care rendered to any individual patient during the Utilization Period. The alpha-numeric code shall not be derived from "Individually Identifiable Health Information," as specified and defined in HIPAA. The reports provided to Manufacturer shall provide data on:

2.3.1. Application of the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data;

2.3.2. The quality and integrity of the Performance Data; and

2.3.3. Preliminary calculation of the Outcome-Based Supplemental Rebates owed by Manufacturer, if

any, based on application of the Rebate Calculation Methodology to the Performance Data.

2.4. Settle-Up. During the Settle-Up Period, the State and Data Aggregator shall calculate all Outcome-Based Supplemental Rebates owed using the Rebate Calculation Methodology in Appendix B. A report of these calculations and the Outcome-Based Supplemental Rebates shall be shared with the Manufacturer within [specify time period] of the Settle-Up period commencing. In no case may the Outcome-Based Supplemental Rebate amount be a negative amount such that State would be obligated to pay Manufacturer any amount under the Agreement, except with respect to overpayments by Manufacturer described in Section 6.5 below. If the Parties cannot agree on the amount owed or any other aspect of the utilization, evaluation and settle-up procedures described above, they will use the dispute resolution process described in Section 6 to address their disagreement.

2.5. CMS Approval and Best Price Contingency. The effectiveness of this Agreement shall be contingent on receipt of approval by CMS. It shall also be contingent on Manufacturer's Best Price and AMP not being affected by the Medicaid Outcome-Based Supplemental Rebate nor the Bona Fide Service Fees payable under this Agreement.

2.6. Effect of Subsequent Changes to MDRP or State Supplemental Rebates. Any changes to any rebates required under the MDRP or any other state supplemental rebates (other than the Outcome-Based Supplemental Rebate) shall not invalidate or otherwise affect the calculation of Outcome-Based Supplemental Rebate or the Base Administrative Fee unless intended otherwise by the Parties as reflected in writing in Appendix B.

3. State Obligations

3.1. Covered Product Status. At a minimum, State shall ensure access to Covered Product and not disadvantage Covered Product to competitive drugs in Product Class.

3.1.1. Details about Covered Product Status in the FFS setting are described in Appendix A.

3.1.2. With respect to covered outpatient drugs reimbursed by MCOs, State will work with MCOs to ensure that Covered Product has Covered Product Status. If relevant, details about Covered Product Status in the MCO setting are described in Appendix A.

3.2. Preferred Status. State may also arrange for Preferred Status for Covered Product.

3.2.1. With respect to covered outpatient drugs reimbursed on an FFS basis, Covered Product may have Preferred Status. If relevant, details about Covered Product's Preferred Status in the FFS setting are described in Appendix A.

3.2.2. With respect to covered outpatient drugs reimbursed by MCOs, State will work with MCOs to ensure that Covered Product has Preferred Status. If relevant, details about Covered Product's Preferred Status in the MCO setting are described in Appendix A.

3.2.3. State may subject Covered Product to prior authorization, step-edit therapy and other management tools that it applies to other drugs within the Product Class.

3.3. Data Aggregator. State shall contract with or otherwise arrange for a Data Aggregator to track Covered Product's utilization, evaluate its performance and calculate the Outcome-Based Supplemental Rebates owed by manufacturer, if any. The contract between State and a third-party Data Aggregator shall comply with the requirements of state and federal anti-kickback laws, including the federal Anti-Kickback Statute at Section 1128B of the Social Security Act, 42 U.S.C. Section 1320a-7b, to the extent those laws are applicable. Nothing in this provision shall prevent the State from serving as the Data Aggregator. Data

Aggregator shall perform the following tasks:

3.3.1. Gather and tabulate Utilization Data relating to the use of the Covered Product during the Utilization Period;

3.3.2. Generate Performance Data by applying the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data;

3.3.3. Meet with and provide interim reports to the Parties regarding the collection and evaluation of the Utilization Data;

3.3.4. Make any adjustments to the collection of Utilization Data and/or Performance Data requested by the State;

3.3.5. Calculate the Outcome-Based Supplemental Rebates owed by Manufacturer, if any, by applying the Rebate Calculation Methodology to the Performance Data.

3.4. Patient Privacy. If the Data Aggregator is a third-party entity, State shall, in accordance with HIPAA, enter into a Business Associate Agreement ("BAA") with Data Aggregator and abide by all patient privacy requirements under HIPAA.

3.5. Cooperation. State will provide necessary information or otherwise cooperate with Data Aggregator so that Data Aggregator can perform its duties under Section 3.3.

3.6. Implementation of Bona Fide Service Plan. If applicable, State will assist Manufacturer with implementation of Bona Fide Service Plan as described in Appendix A. The Parties shall ensure that the Bona Fide Service Plan complies with state or federal anti-kickback laws, such as those appearing in Section 1128B of the Social Security Act, 42 U.S.C. Section 1320a-7b and any applicable safe harbor, including but not limited to the safe harbor for personal services and management contracts codified at 42 U.S.C. Section 1001.952(d).

3.7. Invoicing. If applicable, State or its designee will invoice Manufacturer for the Outcome-Based Supplemental Rebates within ninety (90) days after the end of the Settle-Up Period. State or its designee shall invoice Manufacturer for Outcome-Based Supplemental Rebates separately from the MDRP statutory rebate or any other state supplemental rebate, using the format set forth by CMS. State or its designee shall submit the Outcome-Based Supplemental Rebates invoice to the Manufacturer invoice contact, as identified by the Manufacturer to CMS.

4. Manufacturer Obligations

4.1. Cooperation. Manufacturer will provide necessary information or otherwise cooperate with State and Data Aggregator so they can perform their respective duties described in Section 3.

4.2. Remittance. If applicable, Manufacturer will remit payment of the Outcome-Based Supplemental Rebates within thirty-eight (38) days of postmark on the invoice from State. Interest will accrue until the postmark date of Manufacturer's payment consistent with Manufacturer's rebate agreement with CMS under the MDRP. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay any other rebates, including any rebates under the MDRP or a separate supplemental rebate agreement.

4.3. Implementation of Bona Fide Service Plan. Manufacturer will pay Bona Fide Service Fees to third-party entities in accordance with the Bona Fide Service Plan. Manufacturer will provide the information needed by State to evaluate the financial value of the Bona Fide Service Fees as described in Appendix A.

5. Federal Financial Participation. State will remit the appropriate share of the Outcome-Based Supplemental Rebates received from Manufacturer to CMS as required under its approved State Plan or a federal waiver.

6. Dispute Resolution

6.1. In the event that in any quarter a discrepancy in the Utilization Data is questioned by Manufacturer, the Parties, in good faith, shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the Parties will resolve their dispute in accordance with State hearing procedures as followed by the State or CMS in disputes concerning State Medicaid rebates.

6.2. If Manufacturer, in good faith, believes the Utilization Data is erroneous, the Manufacturer shall pay State that portion of the Outcome-Based Supplemental Rebates claimed, that is not in dispute by the required date. The balance in dispute, including applicable interest, if any, will be paid by Manufacturer to State by the due date of the next quarterly payment after resolution of the dispute.

6.3. State and Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of written notification. Should additional information be required to resolve disputes, State will cooperate with Manufacturer in obtaining the additional information.

6.4. In the event that State and the Manufacturer are not able to resolve a discrepancy regarding Utilization Data, Manufacturer may request a reconsideration of State's determination within thirty (30) days after the end of the 60-day period identified in Section 6.3. Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to State. State shall review the written argument and materials and issue a decision in the matter.

6.5. Any overpayment or underpayment will be refunded to the other party within thirty (30) calendar days of either the Parties' agreement of the over/underpayment amount or the State's decision of Manufacturer's written request for reconsideration.

7. Discretion to Market. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that Manufacturer is liable for the payment of Outcome-Based Supplemental Rebates only for Covered Products dispensed or administered to Medicaid recipients. If Manufacturer elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer shall make every reasonable effort to notify State prior to such actions.

8. Confidentiality Provisions

8.1. Confidentiality. Confidential Information will not be disclosed to any third person or entity not a party to this Agreement or used except in order to implement this Agreement or as may be required by law or judicial order. The term "Confidential Information" does not include information that (a) is or becomes generally available to the public other than as a result of a wrongful disclosure by the receiving party or its employees, officers, directors, agents, advisors, volunteers, contractors, or representatives (collectively, "Agents"), (b) was actually known by the receiving party prior to disclosure hereunder as evidenced by the receiving party's tangible records; (c) is developed or discovered by the receiving party independently and solely without the use of any Confidential Information disclosed hereunder; or (d) is required to be disclosed by law or other legal requirement, provided that the disclosing party is given prompt prior written notice of any such proposed disclosure so it has an opportunity to file appropriate legal objections. Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of not less than three (3) years following termination.

8.2. Patient Information. State, its agents, employees and contractors shall not provide to Manufacturer any patient identifiable information or protected health information or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

8.3. Ongoing Manufacturer Duty. Subject to Section 8.4 hereof, the Manufacturer will hold Utilization Data confidential. If the Manufacturer audits this information or receives further information on such data from State, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

8.4. Third Parties. Pursuant to 42 U.S.C. Section 1396r-8(b)(3)(D), and other applicable state or federal laws, the Parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the Parties will not duplicate or use the information, except in connection with this Agreement or as may be required by law or judicial order. The Parties further agree that any information provided by Manufacturer to State or Data Aggregator pursuant to this Agreement and this Agreement itself constitute trade secrets and/or confidential or proprietary commercial and financial information not subject to public disclosure. If the services of a third party are used to administer any portion of this Agreement, Sections 8.1 through 8.5 of this Agreement shall apply to the third party. In the event that either party is required by law to disclose any provision of this Agreement or pricing information to any person, such party shall provide advance written notice to the other party sufficiently in advance of the proposed disclosure to allow the other party to seek a protective order or other relief.

8.5. Survival. Notwithstanding the non-renewal or termination of this Agreement for any reason by any party, these confidentiality provisions will remain in full force and effect as to all Parties.

9. Term and Termination

9.1. Term. The term of this Agreement shall begin on the ___ day of _____, 2018 (the "Effective Date") and shall end on December 31, 2018 with options to renew for five(5) additional one-year periods. Renewal shall be at the option of the State. If the State elects not to renew, then the Manufacturer will be notified with a minim um of 30-day notice. The option to renew shall be contingent upon the needs of the OHCA, and is at the sole discretion of the OHCA. Options to renew shall be executed by mutual agreement.

9.2. Breach. If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following the delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.

9.3. Accrued Obligations/Remedies. The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

10. General Provisions

10.1. Record Keeping and Audit. Unless a longer period is required by law, during the term of this Agreement and for a period of _____ years thereafter, both parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At Manufacturer's written request, State or its agent shall make such information relevant to this agreement available for inspection by Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once

each year, all such relevant books, and records of the other party to verify compliance with the terms of this Agreement.

10.2. Indemnification. Manufacturer shall indemnify, defend and hold harmless State and its officer, employees and agents from any claims, actions, suits, demands, costs, damages or liabilities (including reasonable attorney's fees and court costs) arising out of or connected with (1) any negligent act or omission of Manufacturer or its employees, agents or contractors, (2) any defect in the Manufacturer's Covered Product, or (3) any breach of this Agreement of any violation of any law or regulation by Manufacturer or its employees, agents or contractors.

10.3. Notices. All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; (iii) sent by certified mail, obtaining a signature indicating successful delivery; or (iv) sent by electronic mail, requesting confirmation of receipt and addressed as follows:

If to Manufacturer:
[NAME]
[ADDRESS]
[EMAIL]

If to State:
[NAME]
[ADDRESS]
[EMAIL]

10.4. Force Majeure. Noncompliance with any obligations hereunder due to a force majeure event, including but not limited to acts of God, laws or regulations of any government, war, terrorism, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract, and a party's performance shall be excused during such force majeure event.

10.5. Assignment. Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.

10.6. No Waiver of Rights. The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.

10.7. Entire Agreement. This Agreement contains the entire agreement and understanding of the parties. This Agreement may not be amended except upon the written agreement of both parties.

10.8. Governing Law and Venue. This Agreement shall be interpreted under and governed by the laws of the State of [STATE], without regard to its conflict of laws principles. In the event of a lawsuit involving this Agreement, venue shall be in any court of competent jurisdiction in [STATE].

10.9. Survival. The provisions of this Agreement that by their nature are intended to continue in their effect following expiration or termination of this Agreement shall survive any such expiration or termination, including, but not limited to, Sections 2, 6, 8, 10.1., 10.2, and 10.8.

10.10. Effect of Future Laws. In the event of the occurrence of a Future Law, each Party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of the Agreement. Agreement on any such terms shall be at the sole discretion of each Party. If the Parties do not agree within sixty (60) days of a Party's written request for negotiations, either Party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect. For purposes of this section "Future Laws" means any statutory enactment or rule promulgation, and any final legal or administrative determinations made by a court or tribunal of competent jurisdiction that materially impairs any Party's ability or obligation to carry out its obligations or receive consideration due under this Agreement. "Future laws" shall not invalidate or otherwise affect the calculation of the Outcome-Based Supplemental Rebate or the Base Administrative Fee except in accordance with Section 2.6.

10.11. Compliance with Law. In connection with its respective obligations under this Agreement, each Party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

10.12. Authority. State and Manufacturer each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

Manufacturer	[STATE] Department [DEPARTMENT NAME]
Name _____	Name _____
Title: _____	Title: _____
Date: _____	Date: _____

Appendix A

Covered Product – The Covered Product subject to this Agreement is specified below. The Covered Product is identified by its NDC-9 number to ensure that all package sizes are captured under this Agreement, unless otherwise specified in the chart below. In the event the Agreement covers multiple products with different NDCs and/or labeler names, the information pertaining to each product is also specified below:

Manufacturer/Labeler Name	NDC	Drug Name

Utilization Period – The Utilization Period shall encompass [_____] calendar quarters. It shall commence on [DATE], the first day of the first calendar quarter, and conclude on the last day of the last quarter.

Outcome-Based Benchmarks – The Parties agree to the following Outcome-Based Benchmarks for evaluating the Utilization Data:

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

Intervention Population – The Parties agree to define the Intervention Population on which the Outcome-Based Benchmarks shall be measured as follows:

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

Evaluation Methodology – The Parties agree to the following Evaluation Methodology for evaluating the performance of the Covered Product during the Utilization Period:

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

Data Aggregator – The Data Aggregator is authorized by State to track Covered Product's utilization, to evaluate its performance and to calculate the Outcome-Based Supplemental Rebates. The Data Aggregator selected by the State for purposes of this Agreement is identified and described below:

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

In the event State desires to change or replace the Data Aggregator, it shall give Manufacturer [30 days] written notice prior to implementation. Nothing in this Agreement prevents the State from serving as the Data Aggregator and performing the tasks described in Section 3.3.

Covered Product Status – The Parties agree that Covered Product will not be disadvantaged to competing products within its Product Class. The Covered Product Status in the FFS and/or MCO setting is described below:

- Covered Product Status in FFS Setting – *[To be filled in or marked as not applicable.]*_____

  _____

  _____

- Covered Product Status in MCO Setting – *[To be filled in or marked as not applicable.]*_____

  _____

  _____

Preferred Status – State may arrange for Preferred Status for Covered Product using a PDL, prior authorization procedures, step-edit therapy or other means to manage Product Class. The Preferred Status for Covered Product in the FFS and/or MCO setting is described below, if applicable:

- Preferred Status in FFS Setting – *[To be filled in or marked as not applicable.]*_____

  _____

  _____

- Preferred Status in MCO Setting – *[To be filled in or marked as not applicable.]*_____

  _____

  _____

Bona Fide Service Plan – The Parties agree to the following Bona Fide Service Plan, including the specific services Manufacturer shall provide under the Bona Fide Service Plan, the financial value of those services:

APPENDIX J: Outcome-based Supplemental Rebate Agreement

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

Appendix B

Base Administrative Fee – The amount paid by the Manufacturer to cover the administrative costs related to this Agreement.

*[To be filled in or marked as not applicable.]*_____

_____

_____

_____

Payment for Outcome-Based Benchmarks – The amount paid by the Manufacturer based on the Outcome-Based Benchmarks calculated as per Appendix A:

*[To be filled in or marked as not applicable.]*_____

_____

Outcome-Based Supplemental Unit Rebate Amount – For each Unit of the Covered Product identified and evaluated by Data Aggregator for the Intervention Population during Utilization Period in question, Manufacturer agrees to pay an Outcome-Based Supplemental Rebate beyond the rebate owed under the MDRP or any other state supplemental rebate. The Outcome-Based Supplemental Unit Rebate Amount will vary as a result of the Outcome-Based Benchmarks and/or Evaluation Methodology described in Appendix A. The different amounts will be determined as follows:

Label Name	NDC	Calculation Type	Discount Per Unit	Outcome Measure
Product A	99999-9999	{Specify WAC, GNUP, AMP, other}	%, $, other	Note 1 below
Product B	99999-9999	{Specify WAC, GNUP, AMP, other}	%, $, other	Note 2 below
Product C	99999-9999	{Specify WAC, GNUP, AMP, other}	%, $, other	Note 3 below

Calculation Type is *[customize one of the options below and/or insert new description]*

- [a percentage discount of WAC, based on the WAC as shown in pricing compendia for the last day of the Utilization Period.]
- [is WAC based GNUP where Supplemental Rebate amount per Unit = [WAC minus Federal RPU minus Discount Per Unit].
- [insert other description as applicable]

Outcome measure note 1: [above target]

Outcome measure note 2: [target]

Outcome measure note 3: [below target]

APPENDIX J: Value-based Supplemental Rebate Agreement

Rebate Calculation Methodology – The Outcome-Based Supplemental Rebates shall be calculated by multiplying the Outcome-Based Supplemental Unit Rebate Amount by the Covered Product's Utilization during the Utilization Period.

Settle-Up Period – The Settle-Up Period shall commence after the close of the Utilization Period and shall terminate [SPECIFY NUMBER] days thereafter. The Settle-Up Period can be extended by written agreement of the Parties.