State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs [SMART-D] Project
Prescription Drug Alternative Payment Models and Medicaid

Washington Prescription Drug Price and Purchasing Summit Series – Part 2

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Today's Objective

- Understand:
  - The federal Medicaid Drug Rebate Program*
  - Alternative payment model (APM) opportunities and risks for state Medicaid programs under current federal law

* Section 1927 of the Social Security Act

SMART-D Project Goals

The Center for Evidence-based Policy (CEbP) at Oregon Health & Science University has undertaken a three-year, three-phase pilot program funded by the Laura and John Arnold Foundation. The program has the following purposes:

- to strengthen the ability of Medicaid programs to manage prescription drugs through alternative payment methodologies, and
- to provide Medicaid leaders with opportunities to shape the national conversation on prescription drug innovation, access, and affordability

Summary of Project Phases

Phase One: Discover
(February – July 2016)

Complete Situational Analysis: Alternative Purchasing Model Barriers and Opportunities

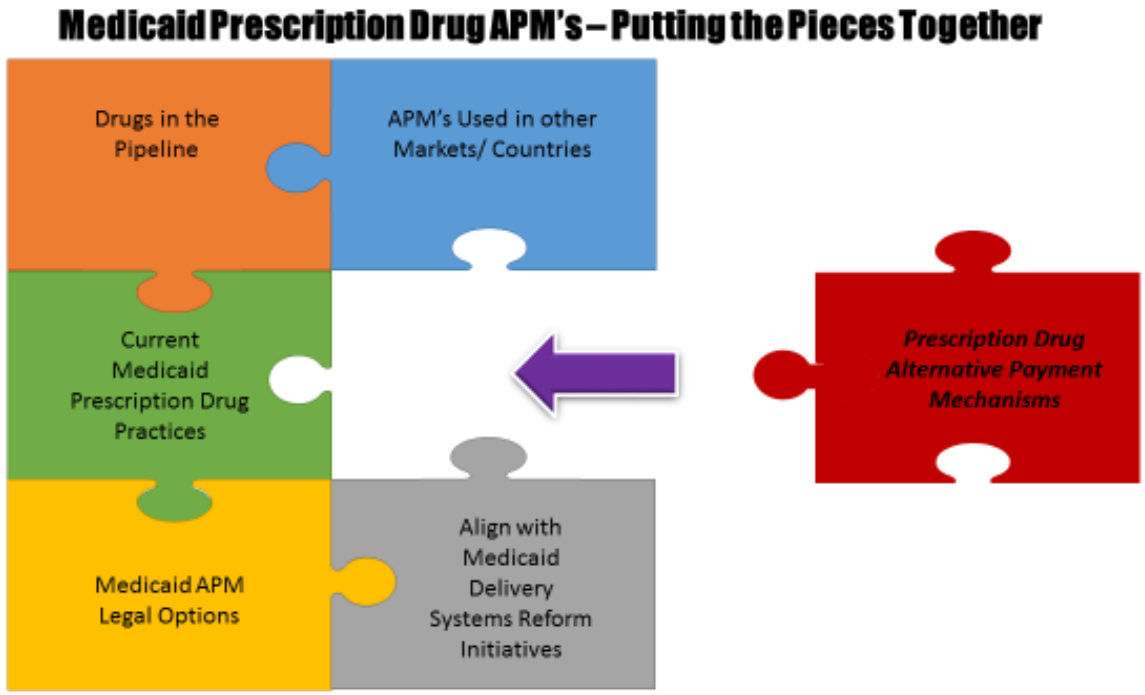
Phase Two: Disseminate
(August 2016-April 2017)

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*)

Prescription drug APM's are designed in a broader context



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.

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.

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

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

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 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 Opportunities
Pathway One: Supplemental Rebate Arrangements

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 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 Opportunities
Pathway Two: MCO Contracting

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 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 Opportunities
Pathway Three: MCO/340B Covered Entity Partnerships

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 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 Opportunities
Pathway Four: Hospital-Dispensed Covered Outpatient Drugs

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

Enter into manufacturer APM rebate and provider value-based purchasing 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 Opportunities
Pathway Five: 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 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 Opportunities
Pathway Six: Alternative Benefit Plan

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 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 Opportunities
Pathway Seven: Section 1115 Waiver

Risks:

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

Anti-Kickback Statute

- The Anti-Kickback Statute is a criminal statute that prohibits intentional exchange of, or offer to exchange, anything of value to induce or reward the referral of federal health care program business.
- 10 types of arrangements excluded from criminal liability in statute, plus HHS/OIG defined “safe harbors.” Currently, there are 25 safe harbors.
- Most relevant are discounts or reductions in price, which include rebates and risk sharing between MCOs and their first-tier contractors.

Anti-Kickback Statute

- If exclusion or safe harbor does not apply, then HHS evaluates on case-by-case basis.
  - OIG instruction to manufacturers: In assessing whether an arrangement might create undue risk, consider the potential to:
    - affect clinical decision making,
    - increase costs to federal health care programs,
    - increase risk of overutilization or inappropriate utilization,
    - create safety or quality of care concerns
- To date, HHS has not issued any regulatory guidance or advisory opinions on APM arrangements. Thus, there's no certainty as to how the OIG would view a particular APM established within a state Medicaid program.

Anti-Kickback Statute

- Two factors likely reduce the risk that the OIG would consider any Medicaid APM as violating the Anti-Kickback Statute:
  1. Manufacturer negotiates directly with a state rather than a commercial entity
  2. Arrangement is reviewed and approved by CMS

Off-Label Promotion

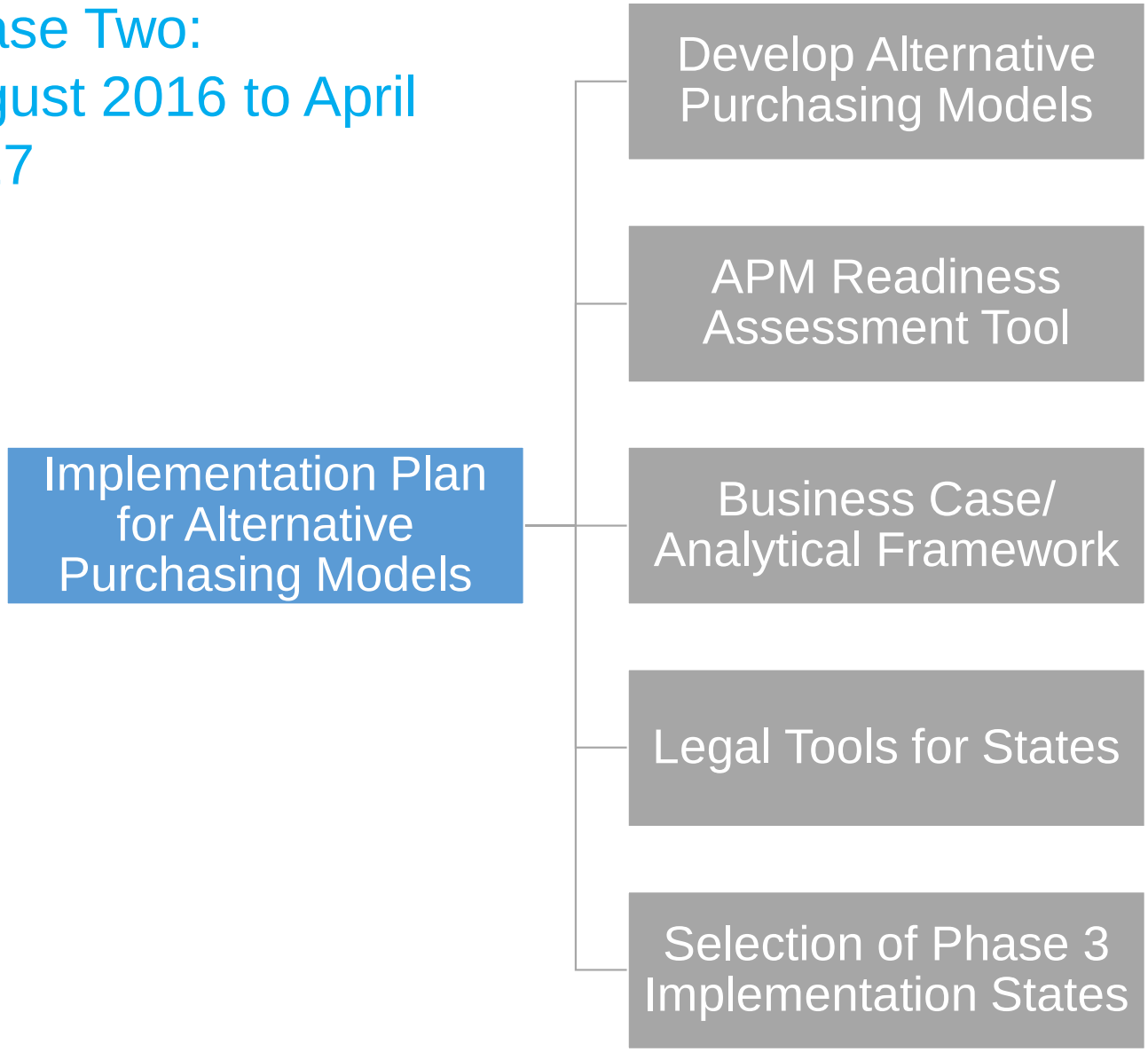
- Off-label promotion is a form of “misbranding,” treated as a criminal violation under the Food, Drug, and Cosmetic Act. When off-label drugs are billed to Medicaid, the manufacturer can face False Claims Act prosecution.
- Questions:
  - Does a health outcome-based APM involve potential off-label use of a drug?
  - If so, could it violate federal law?

Off-Label Promotion

- Measures to limit risk if off-label use is involved:
  - Manufacturer truthfulness, so there is no question of influencing a state's decision about payment associated with the APM.
  - Reliance upon independent clinical data, rather then manufacturer's assertion.
  - Obtaining CMS review and approval.

- Truthful discussions of off-label uses between a drug manufacturer and a state Medicaid agency might be constitutionally protected, based upon recent litigation.

Phase Two: August 2016 to April 2017



Resources & Contact Information

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Appendix: Laura and John Arnold Foundation Prescription Drug Portfolio Strategy

Other grantees in the portfolio strategy:

- Initiative for Medicines, Access, and Knowledge
- Harvard Medical School
- Memorial Sloan Kettering Cancer Institute
- Johns Hopkins/Bloomberg School of Public Health
- Institute of Medicine
- Institute for Clinical and Economic Review
- Kaiser Health News