STATE MEDICAID ALTERNATIVE REIMBURSEMENT AND PURCHASING TEST FOR HIGH-COST DRUGS (SMART-D)

Presentation to ACAP 2017 Conference

June 30, 2017

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The SMART-D Project

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

The SMART-D initative seeks to strengthen the ability of Medicaid programs to manage prescription drugs through alternative payment methodologies.

Objectives of SMART-D Project

1. Map the landscape of Medicaid drug purchasing
2. Identify payment options for Medicaid programs
3. Increase patient access and outcomes
4. Identify specific opportunities to collaborate with drug manufacturers
5. Provide implementation technical assistance and support to Medicaid programs

SMART-D Phases

Phase I

- February to Aug 2016
- Identify alternative payment options and legal pathways
- Document the landscape

Phase II

- Sept 2016 to July 2017
- State readiness assessment
- Identify APMs and legal pathways
- Technical assistance: Group 1

Phase III

- Starts August 2017
- Technical assistance: Group 2
- Initial pilots commence
- Diffusion of best practices
- Contingent on funding

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

Key Take-Aways

1. Even within the constraints of MDRP, there are legal pathways that Medicaid programs and MCOs can use to enter into alternative payment arrangements with drug manufacturers

2. Medicaid programs are interested but need technical assistance and supportive partners to create capacity and navigate complex planning and implementation issues

3. A subset of drug manufacturers are interested in engaging with Medicaid

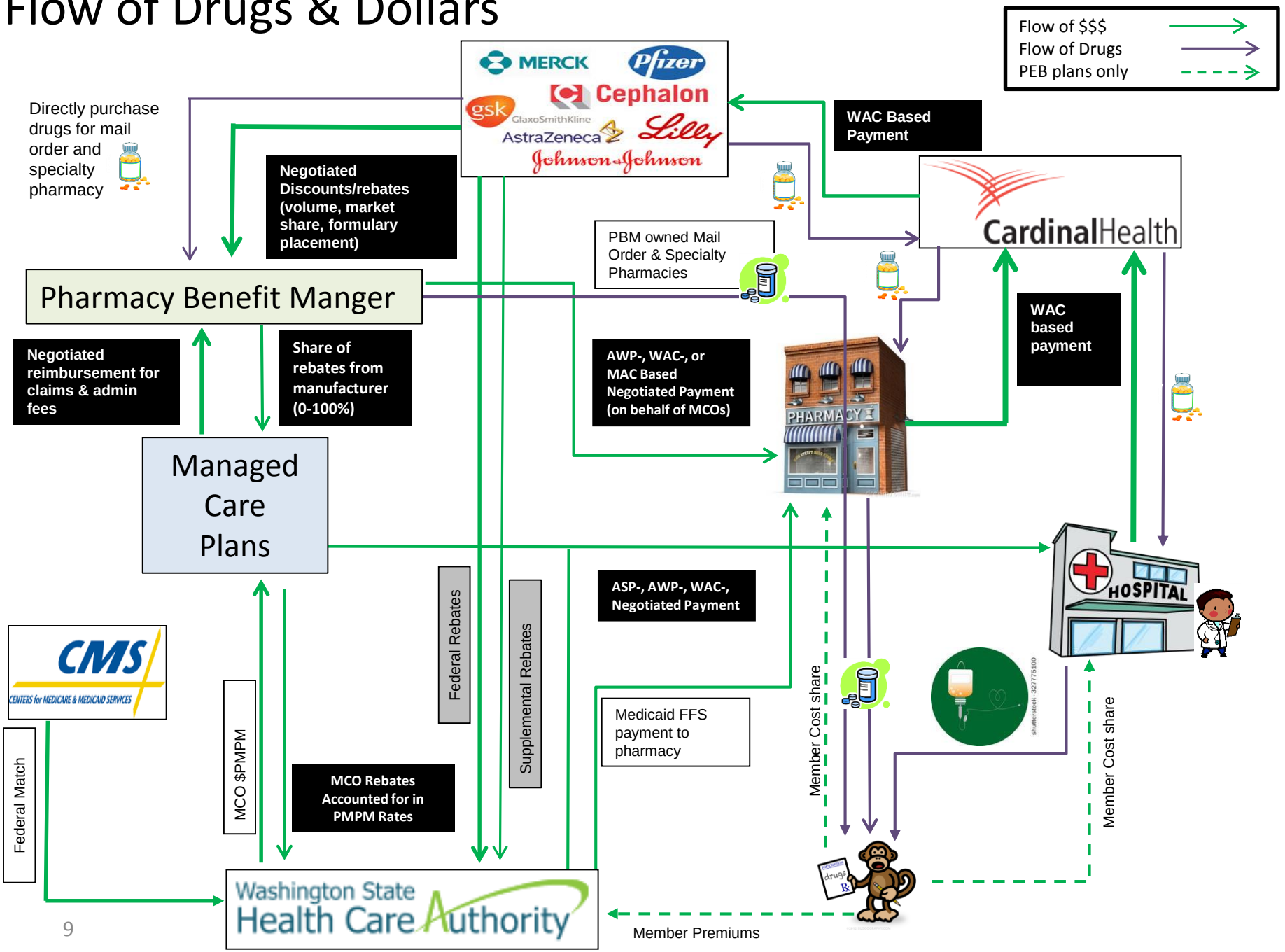
4. MCOs can be a lynch-pin for drug APMs

Items to Cover

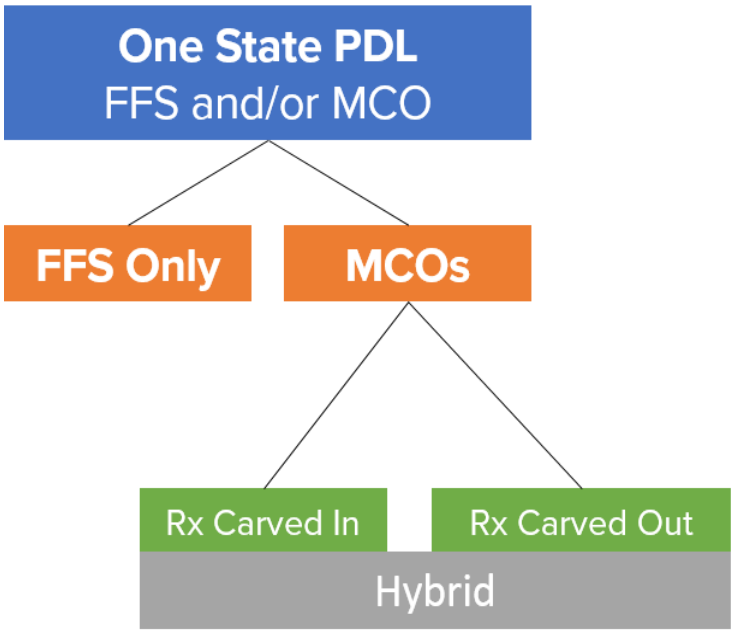
1. Complexity and Dynamics of Medicaid Drug Rebate Program (MDRP)
2. Alternative Payment Models (APMs) and Technical Assistance
3. Legal Pathways and Opportunities

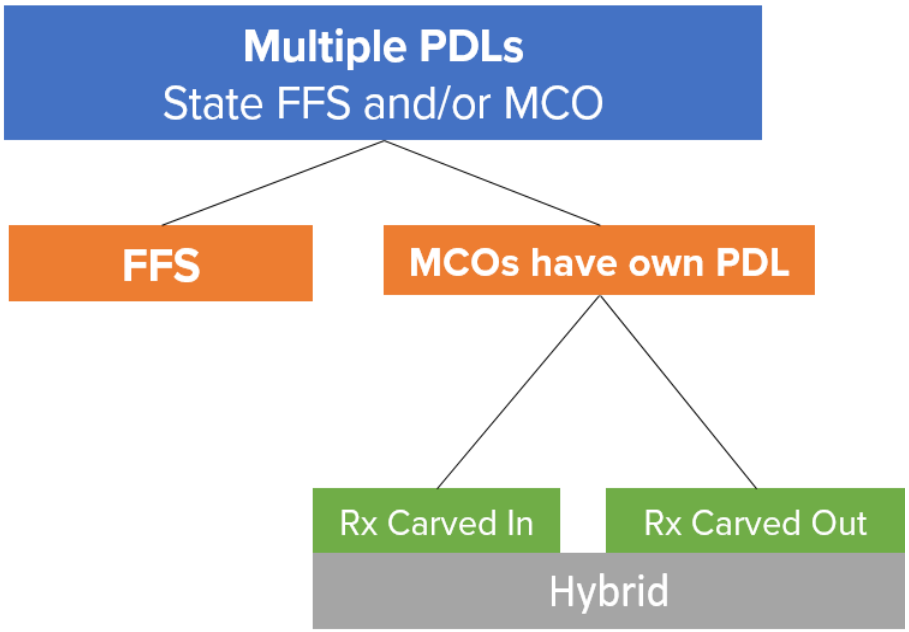
It’s Complicated

Flow of Drugs & Dollars



Variable Configuration of State Medicaid Programs





PDL = preferred drug list; FFS = fee for service; MCO = managed care organization;
RX = drug coverage; Hybrid = combination of carve-in and carve out

MDRP Dynamics

- Medicaid “Best Price” provisions do not necessarily apply to Medicaid
  - Supplemental rebates negotiated by state Medicaid agencies or their designees will not trigger “Best Price”
- “Best Price” is a lever in commercial negotiations
- Consumer Price Index (CPI) penalty impact
  - Incentive for manufacturers to set a high price upon entering MDRP because increases are limited to CPI
  - CPI penalty can reduce price of brand name drug to Medicaid program so it is less expensive than a new generic equivalent

Alternative Payment Models

Alternative Payment Models (APMs)

An APM is a contract between a payer and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure

Financial-based APMs:

- Designed at either patient or population level
- 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
- Can require significant data collection, but have potential to increase quality, value and efficiency of treatment

APM Planning and Technical Assistance

- In late 2016, the SMART-D team conducted state readiness assessments
- Initiated technical assistance with four states in spring 2017
- Another tranche of states kicking off this summer and fall

Planning Questions

1. Why is Medicaid program interested in specific drug APM? What is value-based goal for drug (financial, health outcome, patient access)?
2. What is the current volume of drug and estimated cost?
3. What are the data capabilities to track health outcomes and/or financial metrics related to the drug?
4. What is the competition within the drug class? Where is drug in its branded life-cycle?
5. What are existing cost-containment tools used to manage this drug?
6. What is the agency's or payer's relationship to the drug's manufacturer?
7. Why would the manufacturer consider an APM for this drug?
8. How could a possible APM for this drug fit within the state's or payer's payment reform strategy?

APM Characteristics

Characteristics of alternative models that have generated viable discussions:

a) Good competition in drug class, with some branded drugs newer to market, and a contract outcome measure that can be easily tracked in claims data

b) Rare or orphan diseases where Medicaid can use a center of excellence model for wrap-around patient care services to improve clinical outcomes, access, drug adherence, and data gathering

c) Multi-state opportunities where a drug manufacturer needs scale and a certain number of lives to make an alternative model worthwhile for outcome measurement

Traits for APM Collaboration

Champions

Name champions for clear decision-making process and alignment within senior leadership

Multi-year

A multi-year relationship would allow more run-way to achieve gains

Achievable goals

Arrangement does not need be a home run, but rather a fair chance of purchasing in different way

Simple outcomes

Choose simple, clear goals where data already exist and ensure resources are available to support measurement

Transparency provisions

Design model with transparency for key parties

Adherence supports

Design model with adequate supports for drug adherence and education for patients and providers

Sufficient scale

Arrangement needs to be impactful working across enough lives

Communication plan

Communication plan for state legislature anticipating concerns of drug co., PBMs, patient advocates

Legal Analysis

Legal and Compliance Analysis Framework

The Center worked with Powers Pyles Sutter & Verville PC to develop a detailed legal analysis for:

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

State Opportunities: Pathways

- Pathway One: **Supplemental Rebate Arrangements**
- Pathway Two: **Managed Care Organization (MCO) Contracting**
- Pathway Three: **MCO/340B Covered Entity Partnerships**
- Pathway Four: **Hospital-Dispensed Covered Outpatient Drugs**
- Pathway Five: **Physician-Administered Drugs That Fall Outside "Covered Outpatient Drug Definition**
- Pathway Six: **Alternative Benefit Plan**
- Pathway Seven: **Section 1115 Waiver**

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

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 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)
- Supplemental rebates are excluded from best price when MCO is clearly identified as designee of the state for this activity

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.
- Still subject to Medicaid prescription limits and patient cost-sharing restrictions
- Potential role of state regulation of MCOs/PBMs or preferred drug lists
- Designee language and funds flow back to state Medicaid program needs to be clear to ameliorate 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

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

Pathway Three

- Establish Centers of Excellence (COEs) with 340B covered entities to focus on patient outcomes and whole person care
- Arrangement between COE and MCO:
  - 340B purchased drugs are used in a closed formulary, creating negotiating leverage with manufacturers
  - MCO enhances payment rate to enable COE's expanded services
  - In exchange, COE would return 340B savings and accept a reimbursement rate of actual acquisition cost plus a 340B revenue margin
- If MCO passes these savings onto state, then state performs an annual reconciliation of pharmacy claims to factor in these lower rates

Resources & Contact Information

SMART-D website: www.smart-d.org

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