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 (PBM) 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) [link]

[link]
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 than 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

Implementation Plan for Alternative Purchasing Models

- Develop Alternative Purchasing Models
- APM Readiness Assessment Tool
- Business Case/Analytical Framework
- Legal Tools for States
- Selection of Phase 3 Implementation States
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