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

OHSU Center for Evidence-based Policy
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National Conference of State Legislators
San Diego, CA December 10, 2017
Today’s Presentation

• Center for Evidence-based Policy (CEbP): Overview of the Center

• CEbP Work with States

• State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D):
  – Project Overview
  – Initial Experience Working with States
Center for Evidence-based Policy:
Overview of the Center and
Our Work with States
Who We Are

Center for Evidence-based Policy

- Established in 2003
- Based at Oregon Health & Science University
- Applying data and evidence to public policy challenges
- Evidence review, data analysis, stakeholder engagement, policy development
- 35 people - MPH, PhD, MD, RPh
- Not academic publishing focused (or interested)
Who We Are

Center for Evidence-based Policy

- Our work is driven by states, 90% in Medicaid
- We are not funded by industry or associations
- We have one foundation grant (LJAF)
- Worked with 25 states in the past two years
- We do not lobby
- We are nonpartisan
Center for Evidence-based Policy

Center Mission:

Addressing policy challenges with evidence and collaboration
Currently the Center works with 25 states:

- **Multi-state Collaborations**
  - MED
  - DERP
  - SMART-D
  - Medical Cannabis (work in progress)

- **Single-state Evidence Assistance & Data**
  - NY
  - OR
  - WA
  - P4P

- **Health Process Systems Engineering**
  - NH
  - WA ACH
  - TX

- **Others**
  - CO MPC
  - EiHP
Who We Are

Our two largest programs:

- MED – 20 states
  - Research, evidence, policy for Medicaid (largely excluding pharmacy)
- DERP – 13 states
  - Research, evidence, comparative effectiveness for Medicaid pharmacy
Drug Effectiveness Review Project

Self-governing collaboration of organizations that:

• Obtains and synthesizes global evidence on the comparative effectiveness, safety, and effects on subpopulations of drugs within classes.
• Supports policy makers in using evidence to inform policies for local decision making.
• Produces recently expanded evidence products to meet changing needs
• Refined focus in July 2012
  – Focus on high-impact, specialty drugs
  – Proprietary beginning in July 2012
  – Expanded evidence products to meet changing needs
DERP Mission

• The Drug Effectiveness Review Project (DERP) is a *trailblazing* collaborative of 13 state Medicaid and public pharmacy programs
• DERP produces concise, comparative, evidence-based products that assist policymakers and other decision-makers grappling with difficult drug coverage decisions
• Collaborative founded in 2003
  - Under Gov. Kitzhaber’s Administration
  - Originally was 3 state collaboration that expanded to include up to 15 states
    • Oregon
    • Washington
    • Idaho
  - Was the building block for the Center for Evidence-based Policy
DERP Participating States

- Washington
- Oregon
- Idaho
- Montana
- Colorado
- Texas
- Minnesota
- Wisconsin
- Missouri
- Tennessee
- North Carolina
- New York
- District of Columbia
State Situation and Needs

- New high-cost therapies are increasing

- State budgets are finite – 49 states have balanced budget requirements

- States need better tools to provide access while managing costs.
  - DERP
  - SMART-D
Medicaid Pharmacy Program Dynamics

- State management tools are limited
  - States are required to cover if a federal rebate agreement exists
  - States cannot use closed formularies, although preferred drug lists are allowed;
    - Prescription limits are regulated
  - States can negotiate supplemental state rebates;
    - kept confidential.
  - States can use prior authorization criteria with the PDL

...but in the end, the states will have to pay – regardless of efficacy
MDRP Dynamics

- Medicaid “Best Price” provisions do not necessarily get triggered by Medicaid
  - Supplemental rebate negotiated by state Medicaid agencies will not trigger “Best Price”; “Best Price” is a lever in commercial negotiations
- 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 so it is less expensive than a new generic equivalent
Other Federal and State Requirements

- 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):

Project Overview
SMART-D Project Goals

CEbP 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.
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
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
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 Plans for Alternative Purchasing Models

**PHASE THREE: IMPLEMENT**
(MAY 2017 – APRIL 2018)

Three to Five States Implement Alternative Purchasing Models
*scope based on implementation plans*
SMART-D Website and Phase 1 Reports

- See [www.smart-d.org](http://www.smart-d.org)
- Research and reports tab:
  1. Summary Report
  2. Legal Brief
  3. Economic Analysis
  4. APM Brief
  5. MED Policy Report
SMART-D Technical Assistance

- Center’s goal is to support states with technical assistance resources for development of APM implementation plans

- SMART-D team has identified technical assistance needs and opportunities in four areas:
  1. Economic Analysis of High Cost Drugs
  2. Legal and Compliance Framework
  3. APM Development
  4. Communication and Engagement
SMART-D Economic Analysis of High Cost Drugs

- Found 64 high-cost specialty drugs accounted for 32.6% of Medicaid drug reimbursement spending and 3.1% of overall Medicaid spending in 2015

- 64 drugs reimbursed at over $600 per prescription = $72m in annual Medicaid expenditure

- There are at least 110 additional drugs in the pipeline in the next two years that are likely to meet this same criteria and have a similar budget impact
Legal and Compliance Analysis Framework

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

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
Pathway Eight: 340B with Innovative Care Delivery Models
State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D):

Initial Experience Working with SMART-D States
Drugs & Conditions Prioritized for Potential APM Development

- Hemophilia
- Diabetes long acting insulin
- Anti-coagulants
- Anti-inflammatories
- Oral chemotherapy
- Atypical Antipsychotic - Long-Acting Injectables
- Multiple Sclerosis
- Cystic Fibrosis
- Orphan drugs (SMA)
- Hepatitis C
State Opportunities: Pathways Currently Under Exploration by SMART-D States

- **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
- **Pathway Eight:** 340B with Innovative Care Delivery Models
SMART-D APM Characteristics To Date

*Alternative models that generate viable discussions have certain characteristics, such as:*

**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 the Medicaid program can organize patient care into a center of excellence model including wrap-around patient care services to improve clinical outcomes, drug adherence, and data gathering for clinical outcome measures.

**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.
Questions and Discussion