



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

Drug Effectiveness Review Project (DERP)



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Today's Presentation

- Center for Evidence-based Policy (CEbP): Overview of the Center
- CEbP Work with States
- Drug Effectiveness Review Project (DERP)
 - Project Overview
- State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D):
 - Project Overview
 - Initial Experience Working with States
 - Next Steps



Center for Evidence-based Policy: Overview of the Center and Our Work with States



Who We Are

Center for Evidence-based Policy (CEbP)

- 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
- Non academic publishing focused (or interested)



Who We Are

Center for Evidence-based Policy

- Our work is driven by states, 90% in Medicaid
- Work with 25 states in some capacity
- We are not funded by industry or associations
- We have a grant funded by Laura and John Arnold Foundation
- We are nonpartisan and do not lobby



The Center's Mission

Addressing policy challenges with evidence and collaboration



Center for Evidence-based Policy

CEbP utilizes evidence and collaborative discourse

- **Multistate Collaboratives**
 - Medicaid Evidence-based Decisions Project (MED)
 - Drug Effectiveness Review Project (DERP)
 - SMART-D
- **Single-State Evidence Assistance and Data**
 - New York
 - Oregon
 - Washington
- **Health Process Systems Engineering**
 - New Hampshire
 - Texas
 - Washington Accountable Communities of Health
- **Other Work**
 - Colorado Multi-Payer Collaborative
 - Evidence-informed Health Policy workshops



Who We Are

Our two largest programs are the collaboratives:

- Drug Effectiveness Review Project (DERP)
 - 14 states
 - Research, evidence, comparative effectiveness for Medicaid pharmacy

- Medicaid Evidence-based Decisions (MED)
 - 19 states
 - Research, evidence, policy for Medicaid (largely excluding pharmacy)



DERP's Mission

- The Drug Effectiveness Review Project (DERP) is a *trailblazing* collaborative of 14 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



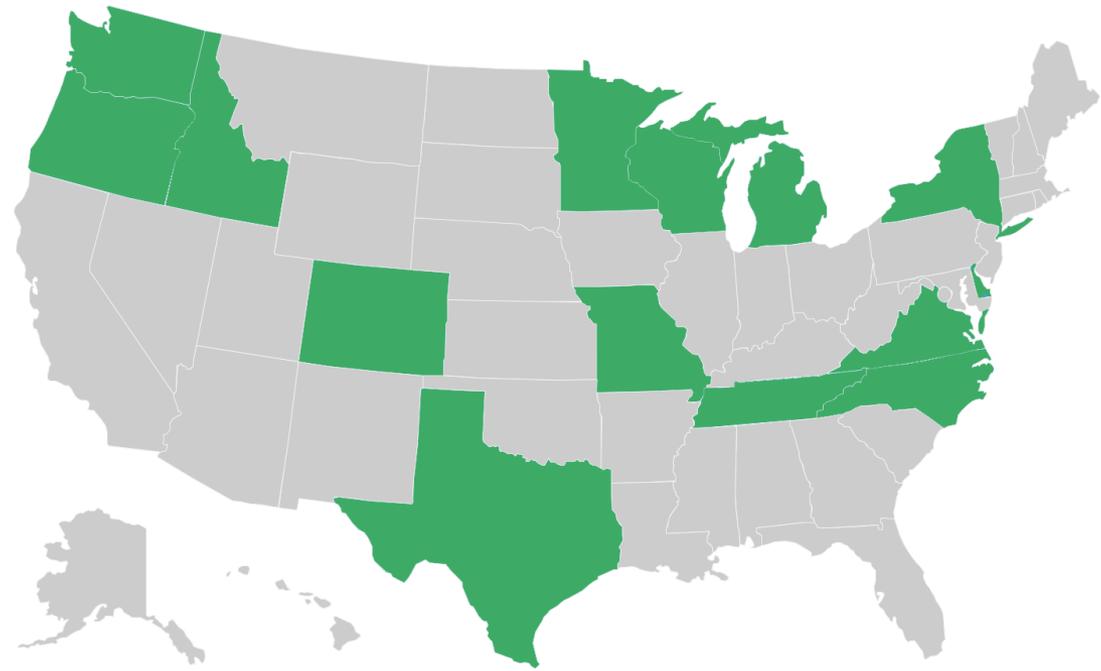
Drug Effectiveness Review Project

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

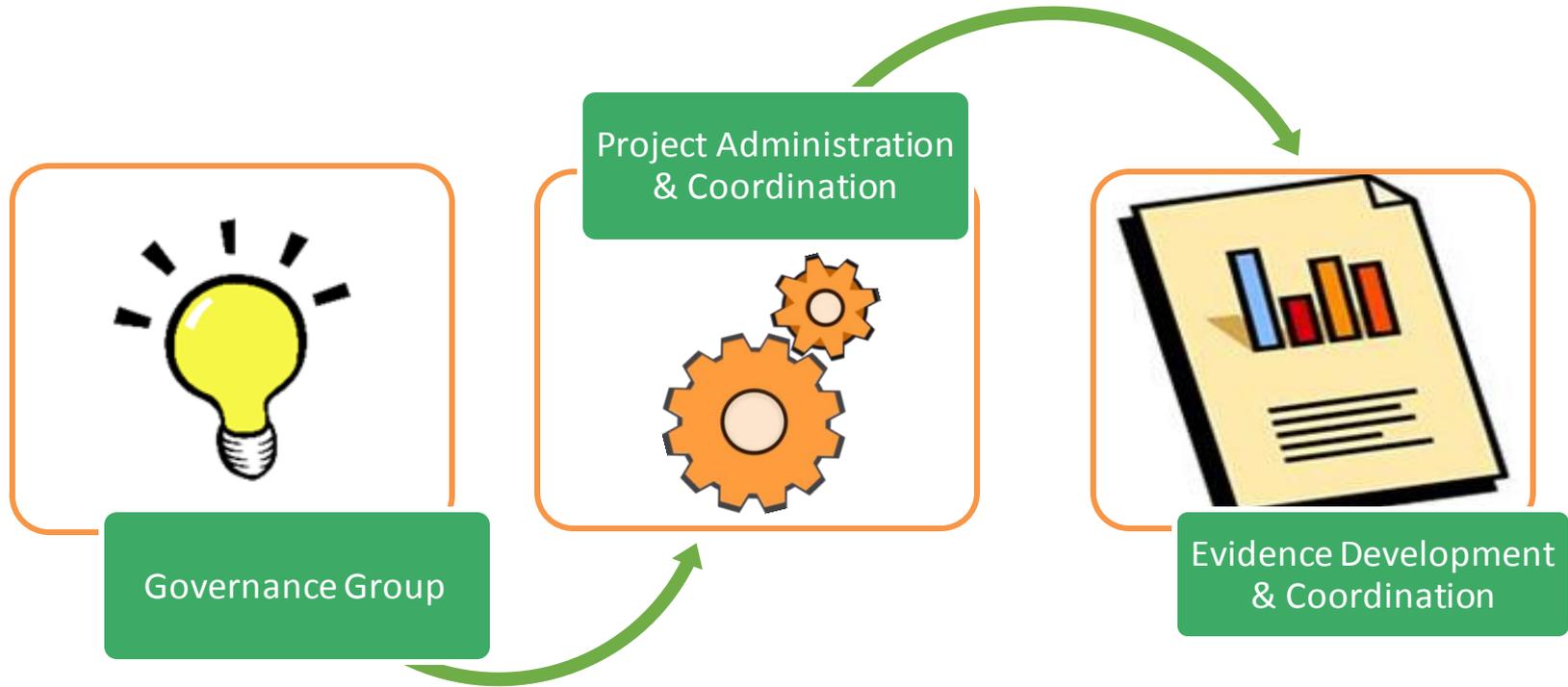


DERP Participating States



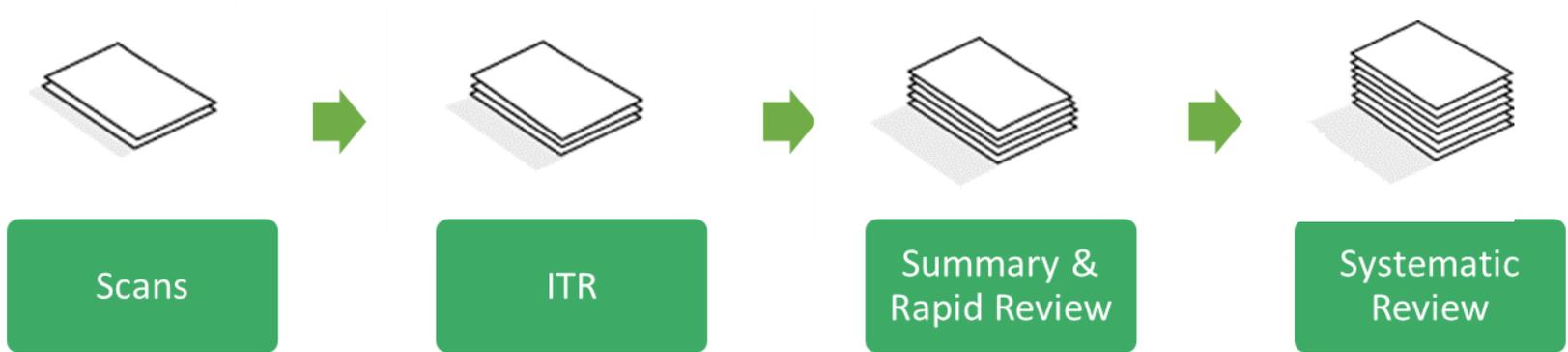
- Colorado
- Delaware
- Idaho
- Michigan
- Minnesota
- Missouri
- New York
- North Carolina
- Oregon
- Tennessee
- Texas
- Virginia
- Washington
- Wisconsin

DERP Program Structure





DERP Research Product Types





DERP Proprietary Policy

- All reports and materials are proprietary for exclusive use by DERP participants and staff
- Selection of products or reports for public dissemination can occur at any time during development, but requires additional steps including majority consensus.



Recently Completed Reports

- Compounded Topical Analgesics
- Benzodiazepines
- HIV Antiretrovirals
- Emflaza
- Exondys 51
- Keytruda
- Non-alcoholic Fatty Liver Disease/Weight Management
- Opioid Use Disorder Treatment and Acute Pain Management
- Kymriah
- Luxturna

Topics for Commissioned Reports – In Progress on Work Plan

- Injectable and Implantable Buprenorphine
- CGRP Inhibitors
- Migraine Prevention & Treatment
- Oncology
- PCSK9's
- CAR T-Cell Therapy
- Pharmacy Lock-in/PDMP Utilization





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

Project Overview



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
 - Medicaid Drug Rebate Program (MDRP)
 - 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



SMART-D Project Objectives

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 under existing regulatory framework, 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 payments for a drug(s) to an agreed-upon measure
- Our research has highlighted two pathways of APMs in Europe and the US:
 - Financial-based
 - Health outcome-based



Alternative Payment Models

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

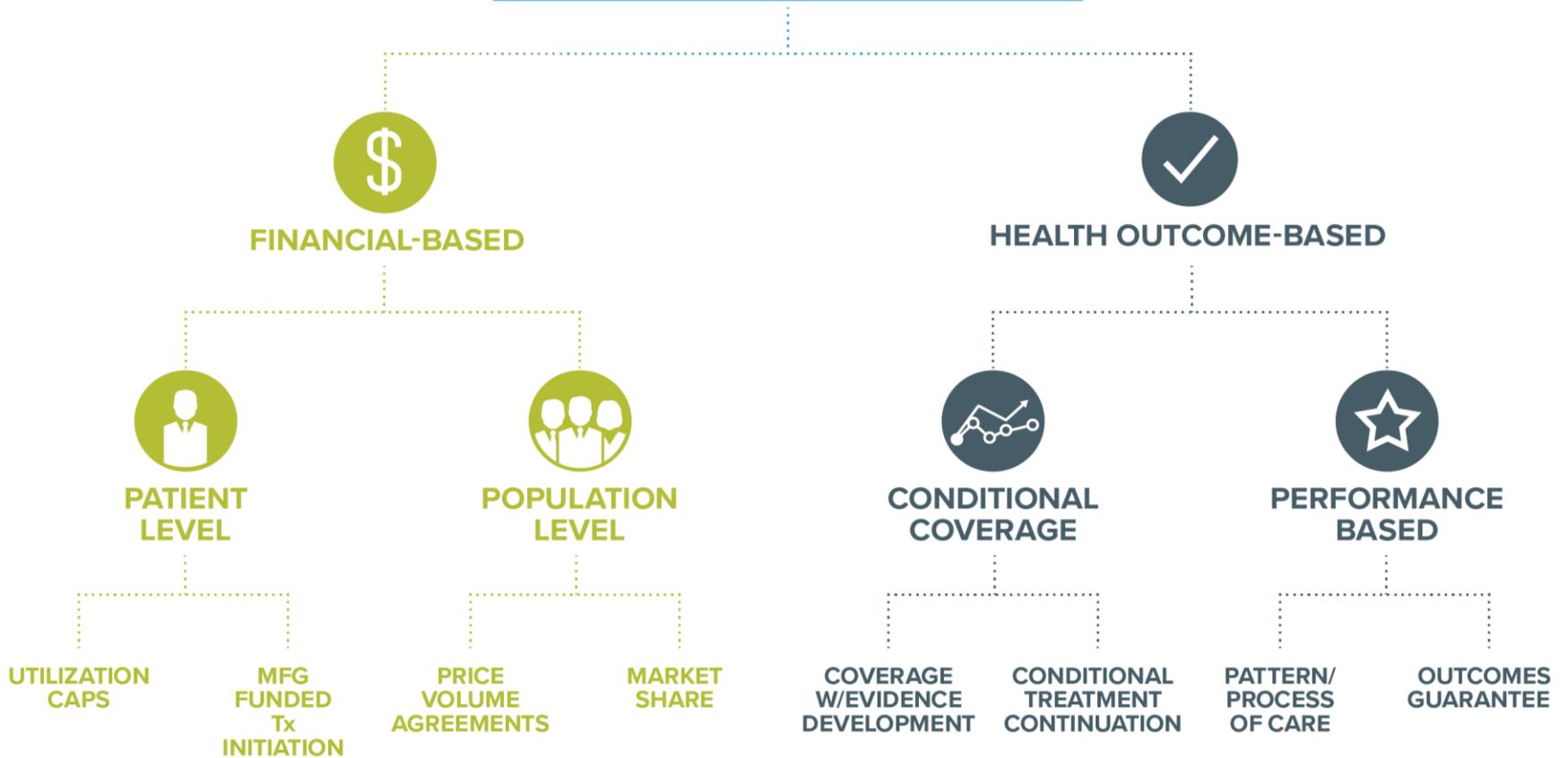
Health outcome-based APMs

- 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

Alternative Payment Models



ALTERNATIVE PURCHASING MODELS





Summary of Project Phases To Date

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

The screenshot shows the homepage of the SMART-D website. At the top left is the Evidence-Based Policy Center for logo. The main heading reads "STATE MEDICAID ALTERNATIVE REIMBURSEMENT AND PURCHASING TEST FOR HIGH-COST DRUGS (SMART-D)". Below the heading is a navigation menu with links for "ABOUT SMART-D", "HIGH-COST SPECIALTY DRUGS AND MEDICAID", "RESEARCH AND REPORTS", "NEWS", and "CONTACT". The page features three images: a stethoscope on a prescription form, a pharmacist at a counter, and a hand pouring pills from a container onto a dollar bill. A blue text box on the right contains the following text: "OUR PURPOSE IS TO HELP BRING CLARITY TO THE COMPLICATED LANDSCAPE OF DRUG PURCHASING FOR STATE MEDICAID PROGRAMS AND PROVIDE ALTERNATIVE PAYMENT MODELS (APMS) TO HELP IMPROVE PATIENT ACCESS TO EVIDENCE-BASED THERAPIES WHILE ALLOWING STATES TO PREDICT AND MANAGE PRESCRIPTION DRUG COSTS. LEARN MORE ABOUT SMART-D".

- 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



SMART-D Accomplishments

- Broke ground on viable pathways for state Medicaid agencies
- Engaged states in pharmacy APM concepts
 - 14 states contributed to research
 - 4 states received technical assistance (TA)
 - More are interested in APMs and engaging in TA
- Developed an outcome-based supplemental rebate contract for state use
 - State SPA submitted and approved for contract June 2018



SMART-D Accomplishments

- Accelerating drug manufacturer engagement with Medicaid
 - 4 manufacturers actively negotiating; others showing interest and contacting states and SMART-D
- Informed national conversation with expert input regarding Medicaid Drug Rebate Program and drug purchasing
 - Centers for Medicare & Medicaid Services (CMS)
 - Medicaid and CHIP Payment and Access Commission
 - National Association of Medicaid Directors
 - Academy Health
 - American Drug Utilization Review Society
 - National Conference of State Legislatures



SMART-D Technical Assistance

- Center's goal is to continue to support states with technical assistance resources for development of APM implementation plans
- SMART-D team has identified technical assistance opportunities in five areas:
 1. Public Purchaser and/or Multi-Payer Partnerships
 2. Outcomes-based Supplemental Rebate Agreements
 3. Targeted Use of 1115 Waiver Strategy
 4. Assessing Use of Single PDL in Managed Care States
 5. Leveraging 340B Prices in a Care Management Model



State Opportunities: Technical Assistance Supported by Legal 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



Initial Drugs & Conditions Targeted for Potential APM Development

- Hemophilia
- Newer Diabetes Drugs/Insulins
- Anti-coagulants
- Biologics/Anti-inflammatories
- Oral chemotherapy
- Atypical anti-psychotics long acting injectables
- Multiple Sclerosis
- Cystic Fibrosis
- Orphan drugs (SMA)
- Hepatitis C



SMART-D Next Steps

- Phase 4 proposal being submitted to LJAF
- Opportunity for:
 - 5 to 10 slots for states to engage in varying levels of Technical Assistance
 - states must commit now
 - indicate pathways of interest
- Timeline: Fall 2018

Questions and Discussion

