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Manatt on Medicaid: Evolving Trends in the Pharmaceutical Benefit and the Role of Medicaid Managed Care

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Introduction

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Agenda

- **Medicaid Pharmaceuticals Overview**
  - Coverage of Drugs Under Medicaid
  - Requirements of §1927 of Social Security Act
  - Rules of the Road for States: Covering Drugs in Managed Care
- **Medicaid Managed Care**
  - Why States Are Shifting to Managed Care
  - Formulary Development
  - Best Practices for States
  - Impact on MCO Rate Setting
- **The Future of Pharmaceuticals in Medicaid – The Search for Savings and Value**
  - Federal Efforts
  - Pharmacy Benefit Managers and Medicaid
  - Value Based Payment Models
  - Coverage of Expensive Therapies

Medicaid Pharmaceuticals Overview

Coverage of Drugs Under Medicaid

Prescription drug coverage is an optional benefit, but all states provide such coverage

States must follow Section 1927 of the Social Security Act (SSA) in regards to "covered outpatient drugs"

- "*Covered outpatient drugs*" are drugs that are reimbursed separately from any other service. They include infused and injected drugs, and drugs provided in the outpatient setting
- If a state pays for a drug under a bundled payment, it is not a covered outpatient drug

Coverage rules may differ depending on age of beneficiary:

- For children (under 21), states must cover all medically necessary services – including drugs – under the Early Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit
- Adults may be subject to prescription limits

SSA §1927 Imposes Coverage & Reimbursement Requirements With National Drug Rebate Agreement

Coverage Requirements

- State must cover every FDA approved drug, subject to limited exceptions (e.g., weight loss, fertility, hair loss, vitamins)
- State must cover all drugs immediately after FDA approval *(though rarely followed)*
- State may subject drugs to prior authorization, but cannot deny access for medically-accepted indications
  - Must respond to request for prior authorization within 24 hours and provide at least a 72-hour supply in case of emergency

Reimbursement Requirements

- Manufacturer must pay minimum rebate, specified by formula
- Rebate depends on average manufacturer price (AMP) and best price
  - AMP: Average price paid to manufacturer by wholesalers/ pharmacies *(differs for 5i drugs)*
  - Best Price: Lowest price available from manufacturer, subject to exceptions
- No requirement to cover cost paid by pharmacy. But rates must be "sufficient to enlist enough providers" so that Medicaid beneficiaries have same access as the general population

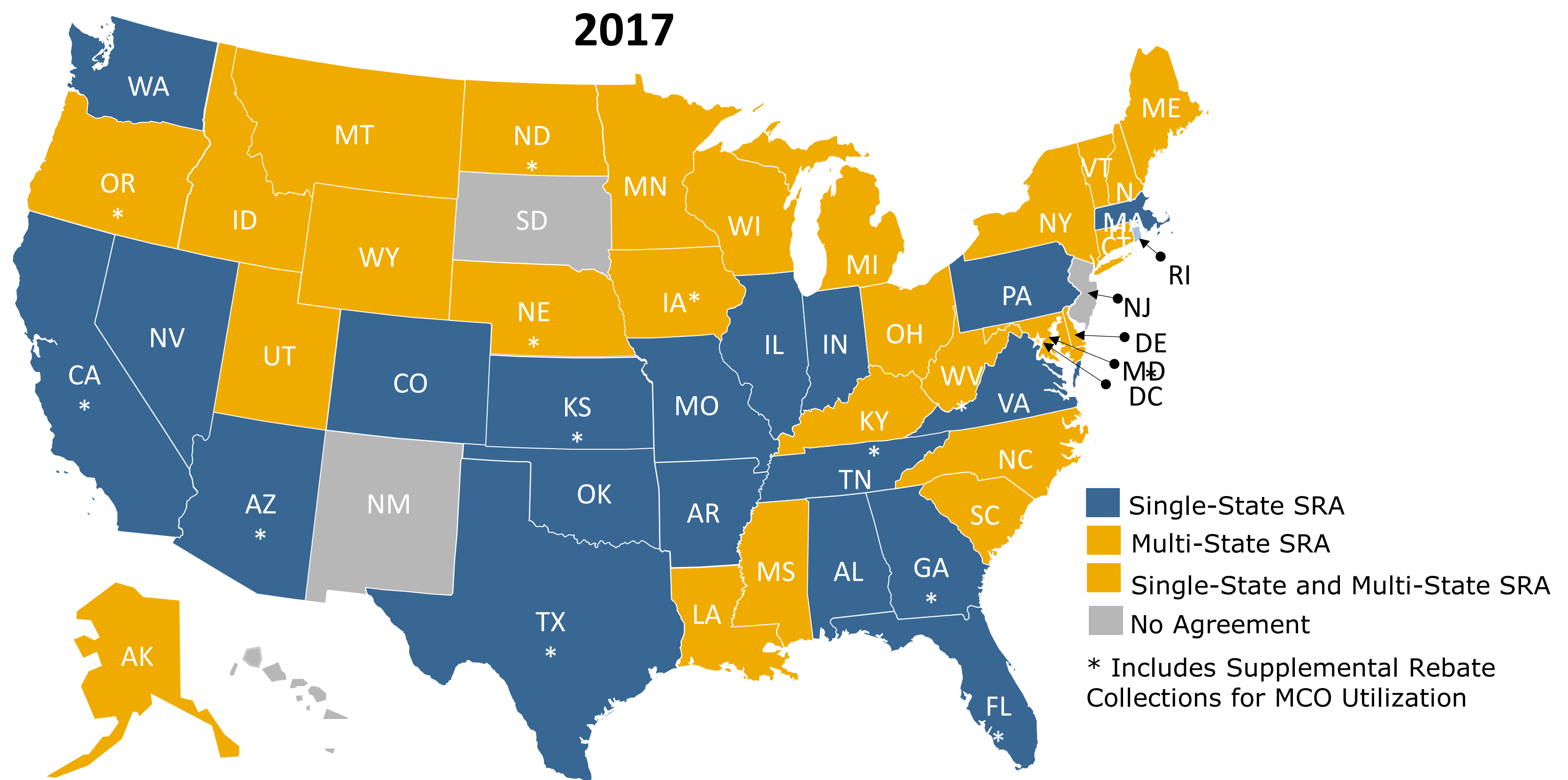
Types of Medicaid Drug Rebates

Type of Rebate[1]	MFG Obligation	MFG Incentive	FFS	Managed Care
Federal Basic Rebate	Mandatory	Required for inclusion in state Medicaid drug benefit	Pre-ACA: > of 15.1% of AMP or Best Price Post-ACA: > of 23.1% of AMP or Best Price	Pre-ACA: N/A Post-ACA: > of 23.1% of AMP or Best Price
Federal Inflation-based Rebate	Mandatory	Required for inclusion in state Medicaid drug benefit	Pre- and Post-ACA: "Additional Rebate Calculation"[2]	Pre-ACA: N/A Post-ACA: "Additional Rebate Calculation"[2]
State-specific Supplemental Rebates	Voluntary	Supports inclusion on state's preferred drug list eliminating need for prior authorization	State negotiates with manufacturer for drug utilization under FFS	State may negotiate with manufacturer for drug utilization under managed care[3]
Managed Care Rebates	Voluntary	Supports preferential placement on managed care formulary	N/A	Private contract negotiations with Medicaid managed care entity

1. *MACPAC. "Issue Brief: Medicaid Payment for Outpatient Prescription Drugs" March 2017. p. 7-10*
2. *CMS. "Unit Rebate Amount (URA) Calculation for Single Source or Innovator Multiple Source Drugs." 2015. [Note: same formula pre- and post-ACA. Post-ACA, same formula applied to drugs provided under FFS or managed care. Accessed on 9/20/17 at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/ura-for-s-or-i.pdf*
3. *Medicaid Pharmacy Supplemental Rebate Agreements (SRA) as of March 2017. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf*

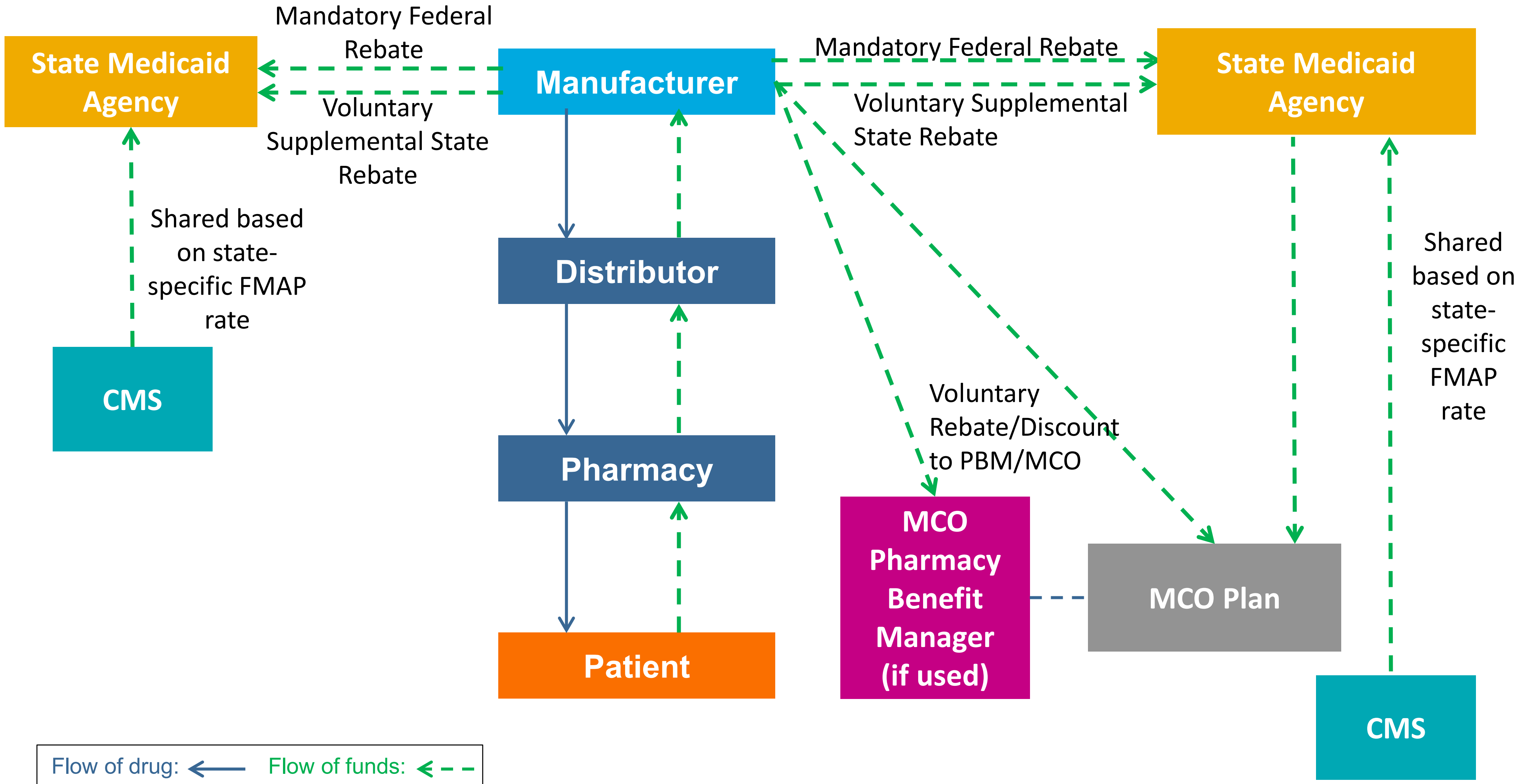
States Negotiate Supplemental Rebates Individually and as Groups

Supplemental rebate agreements (SRAs) are typically executed between states, manufacturers, and pharmacy benefit managers, depending on the specific arrangement. They can be negotiated by a single or multiple states



Medicaid Pharmacy Supplemental Rebate Agreement (SRA). March 2017. Accessed on 9/20/17 at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf

Medicaid Pharmaceutical Funds Flow For Fee-for-Service and Managed Care



State Medicaid Programs Use Multiple Strategies to Manage Drug Utilization

Strategies to Influence Drug Utilization Patterns

Utilization Management

- These tools, and others, are often specified on formularies and can impact access to products
- They are being increasingly implemented in states
- States can use PDLs and UM to guide drug use in crowded classes

Formularies/PDLs

- Managed care organizations use formularies to prefer some drugs over others and control utilization
- MCOs often require supplemental rebates to control tier placement on a formulary
- States often prefer drugs with supplemental rebates and have less restrictive UM requirements

Generic Drug Requirements

- Many states require a prescribed brand drug to be substituted with a generic product when available
- However, generic dispensing rates are typically high, especially in managed care

Prior Authorization

- Overriding a generic substitution requirement can be complex, and most states require a physician to get PA before a brand drug will be dispensed over an available generic version
- Drugs that are preferred are usually subject to more favorable PA requirements, separate and apart from preferring generics over brand name

Step Therapy

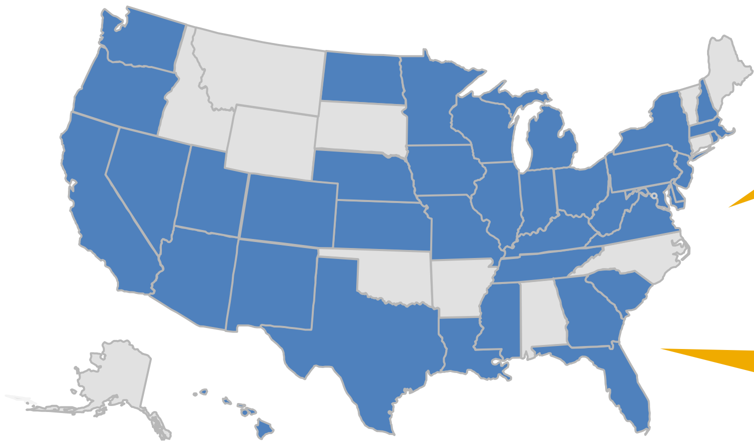
- Patient first “try and fail” on other medications before access to some therapies
- Many policies require trying generic or preferred products first

Quantity Limits

- Typically include limits on the number of prescriptions allowed each month, number of days that can be dispensed at a time, and caps on refills

Medicaid Managed Care

States Continue to Shift to Managed Care For A Variety Of Reasons



38 states + D.C. contract with comprehensive MCOs

90% of all U.S. Medicaid beneficiaries live in these states

States are increasingly using managed care as a vehicle to cover comprehensive benefits for complex populations

83% of Medicaid's costliest beneficiaries have at least three chronic conditions

- Severe mental illness
- Dual eligibles
- HIV/AIDS
- Developmentally disabled

State goals include:

- Addressing physical health, behavioral health, and long-term care silos
- Improving quality and consumer experience mechanisms and oversight capacity
- Transitioning to population health – focusing on the person, not diagnosis
- Bending the cost curve

Medicaid Managed Care Drug Coverage Requirements

Key Requirement: Medicaid MCO beneficiaries are entitled to the same protections as FFS beneficiaries. This means:

- MCOs may establish their own formularies, but beneficiaries must have access to same drugs as FFS beneficiaries. This means that if drug is off formulary, either:
  - MCO must provide access to the drug through an exceptions process, or
  - The FFS program must cover the drug

MCOs must cover a drug immediately after FDA approval, assuming the drug is not carved out

MCO prior authorization programs are subject to the same restrictions as FFS prior authorization programs

Most States Require MCOs To Take on the Risk of Covering Drugs Within Their Benefits Package

Carve-In

States include prescription drug benefit in managed care contracts

Requires the MCO to take on the financial risk of coverage

Carve-Out

States carve out the prescription drug benefit from managed care contract and require coverage through the state's FFS program

Requires the state to take on the financial risk of coverage

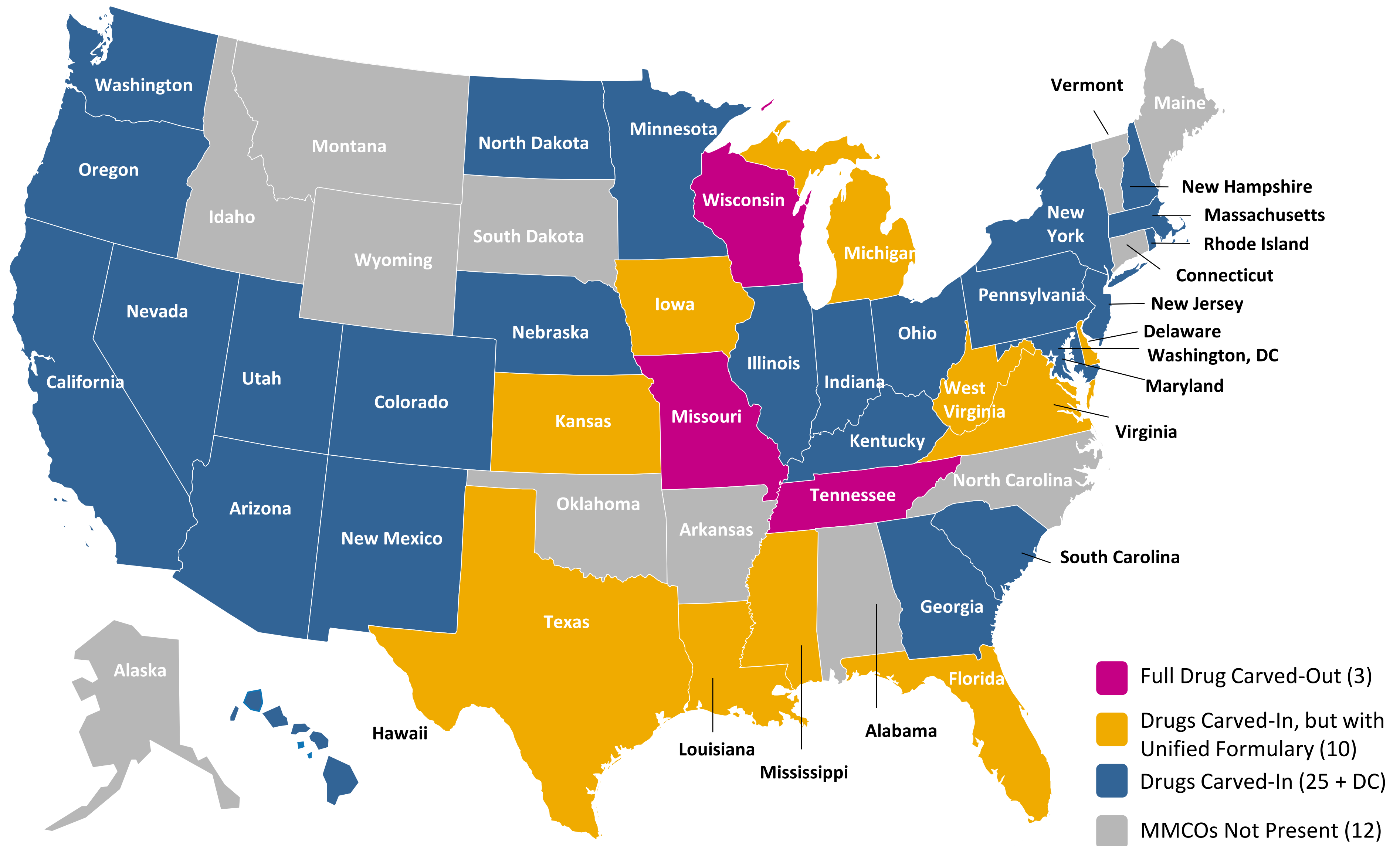
Unified Formulary

Several states have executed a more unified approach, requiring MCOs to take on the financial risk of prescription drug coverage, while requiring those MCOs to use the state's PDL

Condition-Specific

Some states have carved out specific classes of drugs for conditions such as HIV/AIDS, substance abuse, hemophilia, mental health, and hepatitis C

Drug Coverage Strategies in MCOs Vary Across States



Manatt research, updated September 2018

States Have Taken A Range Of Approaches In Managing Drugs Within their Medicaid Programs

State	Medicaid MCO Penetration	MMCO Carved-In	Medicaid Unified Formulary	Condition-Specific Carve-Outs	Medicaid Expansion
California	79%	Y	N	Y	Y
Florida	92%	Y	Y	Y	N
Illinois	63%	Y	N	N	Y
New York	83%	Y	N	N*	Y
Texas	92%	Y	Y	N	N

*New York provides additional protection for coverage of medically necessary prescription drugs in several therapeutic classes, mostly behavioral health related.

States Have Also Taken A Range Of Approaches In Allowing MCOs Flexibility In Prior Authorization/Exceptions

Oklahoma

- ***MCOs have no flexibility***
- May only PA drugs that the state requires to have PA
- Must follow criteria established by the OK DUR Board

Florida

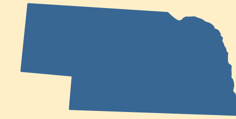
- ***MCOs maintain flexibility***
- MCO may adopt the Medicaid prior authorization criteria posted on the Agency website, or develop its own criteria
- Prior authorization, step-edit therapy protocols for PDL drugs may not be more restrictive than that used by the State Medicaid Agency

Nebraska

- ***MCOs maintain flexibility***
- The MCO may manage utilization of drugs through procedures that may include, but are not limited to, prior authorization and utilization and clinical edits

Streamlining Medicaid Managed Care UM Processes

- Utilize a common prior authorization form developed by the State
- Require MCOs to have a dedicated toll free number for both pharmacy providers and prescribers
  - 24/7 staffing requirement
  - During daytime hours, operations must be located in the state and must be no less generous than current operations
- Require MCOs to accept electronic prescribing
- Require MCO-developed web-based prior authorization processes



Nebraska

E-Prescribing and Single PA Form

- MCO must support e-prescribing transactions, including, but not limited to member eligibility, formulary and benefit, and medication history
- MCO must allow submission of pharmacy PA requests through a common written form within 30 calendar days of it being developed and approved by the Administrative Simplification Committee and Managed Long Term Care Pharmacy Program

Pharmaceutical Benefit Important Drivers in MMCO Rates

- Pricing
- Utilization Management
- Generic Dispensing Rates
- Plan Negotiated Rebates
- Program Changes
- Copays
- New Brand Drugs/Transitions to Generics
- Managed Care "Savings"
- Administrative Costs and Underwriting Gain

Financing Approaches for New Blockbusters in MCOs

	Prospective Trend	Prospective Trend with Risk Pool, Reinsurance, and/or Risk Corridor	Supplemental Payment	Pass-Through Payment, Reconciliation, or Carve-Out
Administrative Complexity	Low	Moderate	Moderate	High
State Budget Predictability	Predictable	Predictable	Varies	Unpredictable
State Risk Exposure	Exposes States and Plans to Over/Under Payment Risk	Mitigates Over/Under Payment Risk	Mitigates Over/Under Payment Risk	Mitigates Over/Under Payment Risk
Impact on Plan Incentives	Maintains Incentive to Manage Cost and Utilization	Limits Incentive to Manage Cost and Utilization	Maintains Incentive to Manage Cost; Diminishes Incentive to Manage Utilization	If Fully Employed – Removes Incentive to Manage Cost and Utilization
Impact on Experience Prior to Rate Inclusion	Doesn't Allow Experience Prior to Including in Rates	Doesn't Allow Experience Prior to Including in Rates	Allows Experience Prior to Including in Rates	Allows Experience Prior to Including in Rates
Impact on Premium Allocation Among Plans	May Enhance Premium Allocation	Enhances Premium Allocation	Enhances Premium Allocation	None
Examples	Many States	Massachusetts New York	California Florida	New York

Source: American Academy of Actuaries

The Future of Pharmaceuticals in Medicaid – The Search for Savings and Value

American Patients First: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

There are five major Medicaid-related themes from the Blueprint and RFI

- Drug Pricing Transparency
- Medicaid Drug Rebate Reform
- Innovation Through Demonstrations
- Spurring Competition
- Reducing Patient OOP Costs – Gag Clauses

President's Budget Includes Demonstration to Waive Medicaid Best Price; Grants Flexibility to Exclude Drugs from Formularies

The proposal envisions that in exchange for increased flexibility for states, manufacturers would no longer be required to provide rebates

(Rebates currently set at a minimum of 23.1% of average manufacturer price for brand name drugs)

- ❑ **Proposal includes up to five states (yet to be identified) to participate in the demonstration**
- ❑ **CMS has not yet announced whether it will proceed with the demonstration without legislation**
- ❑ **CMS would likely need to waive portions of Section 1927 and Best Price**
  - CMS denied MA's request to waive §1927 to permit the State to exclude drugs from its formulary and retain full federal rebates
  - CMS could use demonstration authority to grant a full waiver of Section 1927 in the five demonstration states and limited waiver of the Section 1927 provisions noted above in the remaining states

MACPAC Favors Grace Period For State Medicaid Programs Before Covering New Drugs

Unlike in Medicare, state Medicaid programs must cover outpatient drugs upon FDA approval

- Medicare plans have 90 days to make coverage decisions for drugs in the six protected classes and 180 days to determine coverage requirements for all other drugs

MACPAC supports giving states a grace period before covering newly approved drugs and lifting Medicaid rebate cap

- Wary of letting states use closed formularies or to increase rebates on either expensive drugs or drugs granted fast approvals
- Like idea of basing drug reimbursement on performance, but value-based pay is unproven and seldom-used

Commissioners considering giving Medicaid either 180 days or 90 days to do clinical reviews

- Grace period policy could be paired with requirement to place drugs on formulary
- Commissioners also open to increasing rebate caps
    - Rebates capped at 100% of drug’s average manufacturer price to avoid inflationary rebates leading to total rebates greater than drug prices

Ohio Medicaid Is Taking Several Innovative Steps to Address Costs

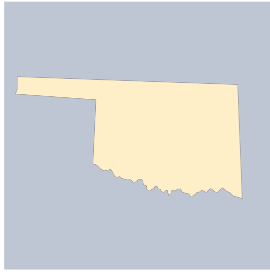
Value-Based Payment Reform

- Providers are given a report card that assesses their charges, quality of care, and patient outcomes
  - If they deliver value-based care, they are financially rewarded with a $4 per patient per month bonus
  - If their care is over-priced and poor quality, compared to their peers, they get bad reviews and no rewards
- This approach has reduced acute asthma treatment costs by 21 percent and acute COPD treatment costs by 18 percent in 1 million Medicaid enrollees over a two-year period

Canceling PBM Contracts in Favor of Transparency

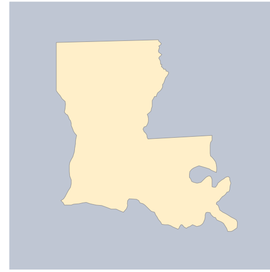
- Ohio Medicaid requiring MCOs to quit contracts with PBMs because of opaque pricing practices
- "Analysis commissioned by Medicaid department found that CVS Caremark and OptumRx billed managed-care plans $223.7 million more for prescription drugs than they paid pharmacy providers in one year"
- Ohio Medicaid wants to move to a pass-through pricing model

Alternative Payment Arrangements for High Cost Therapies in State Medicaid Programs



Oklahoma

- CMS approved state's request to allow amount of rebate vary based on value
- State to receive higher rebates from Melinta for skin infection antibiotic (Orbactiv) if it fails to keep patients out of the hospital
- Other contract ties rebates for schizophrenia drug to patient adherence



Louisiana

- State's "Netflix Model" is billed as appropriate only for: (a) therapies with competitors; and (b) therapies addressing a public health crisis. Only targeting HCV therapies at the moment
- Unclear if model will be implemented under the existing Medicaid program structure or through a state-level demo

➢ Michigan and Colorado have also reportedly been moving in a similar direction

Will The State Pay For Expensive Therapies as Outpatient Drug or as a Drug Bundled into a Hospital Service?

Coverage and reimbursement for gene therapy within the Medicaid program is a decision left up to the states. Once coverage of the therapy is determined, the state must decide how to reimburse for the cost of the product – as a drug or as a hospital service

Drug

If a state pays for the gene therapy as a drug, the state will make a payment for the drug only, in addition to any payments paid for the hospital's services (e.g., paying the hospital for infusing the drug into the patient)

Service

If a state pays for the gene therapy as a hospital service, the state will provide a bundled payment to the hospital, which is intended to reimburse the hospital both for the cost of the drug and for the services

New Models Are Emerging to Help Medicaid Programs Pay for Products Like Gene Therapy and CAR-T

	New York	Massachusetts
Applicable Setting	Inpatient and Outpatient	Inpatient and Outpatient
Drugs Subject to Carve-Out	Kymriah, Yescarta, and Luxturna	Kymriah and Yescarta
Payment Rate for Carve-Out	Actual Acquisition Cost	Lesser of (1) actual acquisition cost (net of all price concessions); (2) WAC; and (3) Medicare rate
Role of VBP	VBP optional	Hospital must enter into outcome-based arrangement if manufacturer offers it
Applies to MCOs?	No	Technically no, but EOHHS expected to require MCOs to pay at 100% of FFS rates

Presentation developed by:

Thank You!