Implementation of Executive Order 22-164; Pharmacy Benefits Managers

Senate Health Policy Committee

February 6, 2023

Executive Order 22-164

On July 8th, 2022 Governor Ron DeSantis issued Executive Order 22-164 to increase transparency and accountability in the Pharmaceutical Industrial Complex.

- ❑Prohibits the use of spread pricing and financial clawbacks.
- ❑Includes requirement to report data regarding rebates and payments from drug manufactures, insurers, and pharmacies.
- ❑Directs State Agencies to amend contract language to include provisions in all existing and future contracts.
- ❑Requires an Agency Audit of all PBM's that provided services for SMMC in the last 5 state fiscal years.

Agency for HealthCare Administration Implementation of Executive Order 22-164

What is Medicaid?

Medicaid is a federal program through which states partner with the federal government to provide health care coverage to low-income children, families, elders, and people with disabilities.

The federal government establishes basic mandatory program requirements.

States choose whether to participate.

Jointly financed: federal and state governments share the cost.

Each state develops a unique Medicaid program based on federal rules – subject to federal Centers for Medicare and Medicaid Services (CMS) approval.

Florida Medicaid Delivery System

- A majority of Florida's Medicaid population receives Medicaid services through a managed care delivery system.

SMMC: Multiple Managed Care Program Components

Managed Medical Assistance (MMA)

COVERAGE:
Preventive, acute, behavioral, and therapeutics services, including pharmacy and transportation services.

ENROLLMENT:
Most Medicaid recipients must enroll in an MMA plan.

Long-Term Care (LTC)

COVERAGE:
Nursing facility, assisted living, and Home and Community-Based services.

ENROLLMENT:
65 years of age or older, or age 18 or older and eligible for Medicaid by reason of a disability.

Requires Nursing Facility level of care or Hospital level of care for individuals diagnosed with cystic fibrosis.

Dental

COVERAGE:
Preventive and therapeutic dental services.

ENROLLMENT:
All Medicaid recipients in managed care and all fully Medicaid eligible fee-for-service individuals.

Pharmacy Benefit Manager Overview

- A Pharmacy Benefit Manager (PBM) administers prescription drug benefits on behalf of a health plan and/or payer and is primarily responsible for processing and paying claims and creating or maintaining a network of participating pharmacies.
  - In some cases (Not in the Medicaid program), a PBM may also set formularies, negotiate rebates, and implement other utilization management.

Florida Medicaid Pharmacy Benefits

- The Agency maintains a Medicaid preferred drug list (PDL), which is a listing of cost-effective, safe and clinically efficient medications for each of the therapeutic classes on the list.
  - Drugs on the PDL generally do not require prior authorization.

Medicaid health plans must provide medically necessary prescription drugs to all their Medicaid members.

The same pharmacy benefit is available to all Florida Medicaid recipients, whether they are in the fee-for-service delivery system or the SMMC program.

Health plans must follow the Agency's PDL.

Florida Medicaid Pharmacy Benefit

Statewide Medicaid Managed Care program (SMMC) plans are:

- Paid a capitated rate, which is a per-member, per-month amount that covers the cost of providing the required care and administering the contract.
- Responsible for maintaining a network of providers sufficient to meet the needs of their enrollees, based on network standard established by the Agency.

Required Pharmacy Network Standards for Health Plans			
	Maximum time (minutes)	Maximum distance (miles)	Providers per Enrollee
Pharmacy	15	10	1:2,500 enrollees

Manufacturer Rebates

The State recoups a significant part of the retail cost of prescriptions reimbursed by Florida Medicaid through rebates paid by pharmaceutical manufacturers for each time their drug is dispensed.

- Rebates required by the federal government
- AHCA-negotiated supplemental rebates

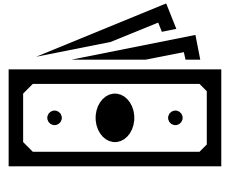
AHCA negotiates rebates on Medicaid prescriptions paid for through fee-for-service and SMMC.

SMMC plans and PBMs are not permitted to negotiate or collect any drug rebates.

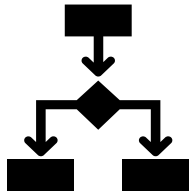
AHCA bills the manufacturers for the agreed upon rebate for every prescription filled that has a rebate contract. The cash rebate goes into a trust fund that helps pay for the cost of Medicaid prescriptions.

Pharmacy Benefits Managers In Florida Medicaid

PBMs are utilized in all lines of health care business—commercial, Medicare, and Medicaid



They work on behalf of insurers to negotiate better rates with pharmacy suppliers.



They administer pharmacy benefits according to the benefit structure dictated by the insurer.

PBMs in Florida Medicaid Do NOT:

The services PBMs provide in Florida Medicaid are different than the services PBMs provide in the commercial and Medicare markets.

Create or maintain a formulary of drugs .

The Agency maintains the Preferred Drug List, which is recommended by the Pharmaceutical and Therapeutics Committee.

Negotiate or collect drug rebates from drug manufacturers

The Agency does this for all Medicaid-funded drugs.

Agency Implementation

- AHCA amended all Managed Care Plan contracts to comply with Executive Order 22-164, effective July 1st, 2022 .
  - Amendments executed October 2022.
- Amendments:
- Required plans to amend all PBM contracts within 180 days, of contract execution, to comply with the Executive Order, to:
  - ❑Prohibit Spread Pricing Model
  - ❑Require Pass-through Pricing Model
  - ❑Prohibit Financial Clawbacks/ Prohibit Reconciliation of Offsets
- Required plans to submit Annual and Quarterly Reconciliation Reports
- Requiring Inspection and Audit of Financial Records
- Additional Liquidated Damages

Requiring Pass-Through Pricing Model:

Agency Contracts between the Managed Care Plan and the PBM must be based on a Pass-Through Pricing model. Spread pricing model is prohibited.

- Pass-Through Pricing model: Managed Care Plan's payment to the PBM for prescription drugs and any related dispensing fees are equivalent to the PBM payment to the dispensing pharmacy or provider.

Prohibits Reconciliation of Offsets:

- Under the prohibition of “Financial Clawbacks” or Reconciliation Offsets:
- The Managed Care Plan or its PBM is prohibited from recuperating any fees paid to a pharmacy via reconciliation, or any other monetary recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction fees and any other instance where a fee may be recuperated from a pharmacy and/or provider.
- Fee can be recouped in instances of fraud or abuse, claims adjudicated in error, or payments tied to value based purchasing agreements based on quality outcomes.

Requiring Annual and Quarterly Reconciliation Reports:

- The Managed Care Plan and PBM shall provide Annual and Quarterly Reconciliation Reports.
  - The Quarterly Reconciliation Report shall be provided by the 25th of the first month following the last day of the prior quarter to the Agency.
  - First Quarterly report is due July 2023.

Requiring Inspection:

- Managed Care Plan's are required to disclose to the Agency all financial terms and arrangements for payment of any kind that apply between the Managed Care Plan or the Managed Care Plan's Pharmacy Benefits Manager and any provider of outpatient drugs, any prescription drug manufacturer, prescription drug wholesaler, or labeler.
- Managed Care Plan must also disclose copies of its PBM pharmacy provider agreement and notate any differences among commercial, preferred, or independently owned pharmacies.

Audit of Financial Records

- The Agency entered into a contract with third party vendor Meyers and Stauffer to investigate the organizational structures and contractual arrangements, including payment terms, of the pharmacy benefit managers (PBM) utilized by the health plans participating in the Statewide Medicaid Managed Care (SMMC) program.
- Three phases:
  - Risk Assessment
  - Detailed Analysis
  - Detailed Investigational Analysis

Requiring Additional Liquidated Damages

- Within 180 days following execution of this amendment all Managed Care Plan PBM subcontracts must be updated to reflect Executive order 22-164 provisions.
- Managed Care Plan found in violation of updating their contracts will be subjected to Liquidated damages, contractual sanctions, or other actions deemed necessary by the Agency.
- Failure to provide the necessary data/ reports to the Agency will result in immediate action by the Agency that may include (but not be limited to) sanctions, application of liquidated damages, or reduction of capitation payments in the amount of estimated combined federal and supplemental rebates.