Medicaid Drug Rebate Program: How it Works

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Medicaid Drug Rebate (MDRP) Program

- Prescription drugs are an optional benefit in Medicaid programs
- More than 600 drug manufacturers participate in the MDR program
- Manufacturers must sign an agreement with the Secretary of HHS in order for their drugs to be covered by Medicaid, with the exception of certain drugs cited in the rebate statute.
- Manufacturers are required to pay statutory rebates to states on a quarterly basis as a condition of Medicaid reimbursement for their drugs dispensed to Medicaid fee-for-service (FFS) and MCO individuals, and for physician administered drugs.
- MCOs may negotiate their own rebates, but states also collect statutory rebates on MCO drugs.

History of the MDRP

- MCCA 88
  - Rx drug benefit - groundwork for OBRA 90
- OBRA 90
  - Created MDRP, DUR program and E-claims processing
  - Part of Andrews Budget Deal
  - Saved $3.4 billion over 5 years
- Veterans Health Care Act of 1992
  - Created Master Agreement, VA, 340B and DOD pricing
- OBRA 93
  - Allowed states to use Medicaid formularies

History of the MDRP

- 2002
  - CMS issues guidance on state supplemental rebate negotiations
- MMA 2003
  - Moved dual eligibles to Medicare Part D
- DRA 2005
  - Required use of AMPs to set FULs
  - Permitted CMS to conduct surveys of pharmacy prices
- ACA/2010
  - Changed calculation for FULs
  - Extended Rebates to MCO Claims
  - Clarified Definition of AMP and Retail Pharmacies
  - AMP for 5i Drugs

History of the MDRP

- 2012
  - NADAC File published to assist states with reimbursement
- Budget Act of 2015
  - Generic Drug Inflation penalty
- 2016
  - CMS published final regulation with comment on COD regulation
  - CMS publishes final regulation on managed care plans

Controlling Costs and Promoting Quality Key Points

- Medicaid controls drug costs primarily through the Federal MDR program and supplemental rebates negotiated by states.
- Medicaid sets broad parameters for state Medicaid pharmacy reimbursement.
- States manage appropriate drug use and leverage better manufacturer rebates through Prior Authorization (PA), Preferred Drug List (PDL), and Drug Utilization Review (DUR).

Rebate Amount

The rebate amount due for each unit of a drug is based on statutory formulas:

- **Innovator Drugs** – the greater of 23.1 % of the AMP or difference between AMP and best price and adjusted by the Consumer Price Index-Urban (CPI-U). Prior to the Affordable Care Act, the percentage was 15.1%.
- **Blood Clotting Factors and Drugs Approved by FDA Exclusively for Pediatric Indications** – the greater of 17.1 % of AMP or difference between AMP and best price and adjusted by CPI-U. Prior to the Affordable Care Act, the percentage was 15.1%.
- **Non-innovator Drugs** – 13 % of the AMP. Prior to the Affordable Care Act, the percentage was 11%.

Supplemental Rebates

- With CMS' approval via their State Plan Amendment, states may enter into single-state and multi-state supplemental drug rebate pools that generate rebates that are at least as large as the rebates as set forth in the national rebate agreement with drug manufacturers.
- States use Prior Authorizations (PA) and Preferred Drug Lists (PDL) to leverage further "supplemental" rebates from drug manufacturers, further lowering their costs.
- Some states extend these supplemental rebates to MCO claims.

Rebates for Drugs Dispensed Through Managed Care Organizations (MCOs)

- The Affordable Care Act required and the final rule implements (at **447.509(b)**) the requirement that manufacturers participating in the MDR program pay rebates for CODs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for covering such drugs.
- Manufacturers are exempt from the requirement if such drugs are:
  - Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and
  - Discounted under section 340B of the Public Health Service Act.

State Drug Management Options

- **Cost-Sharing** – encourage Medicaid beneficiaries to request less expensive drugs; implement different co-pays for generic and brand drugs, or implement different co-pays based upon drug price.
- **Prescription Limits** – state could impose limitations on number of monthly prescriptions (through a PA for override when necessary).
- **Adjust the Dispensing Fee for Drugs** – states could adjust dispensing fee to adjust to surrounding states if surrounding states have dispensing fees that are reasonable and adequate to cover the cost to dispense a drug to a beneficiary. States would have to provide justification if they revise their dispensing fee.
- **Establish Disease Management Programs** – these programs provide educational and disease specific information to beneficiaries. The programs often use targeted communication to help beneficiaries comply with treatment regiments and take a more active role in the management of their condition. These services can give the state more control over prescription costs and better oversight of drug therapies.

State Drug Management Options

- **Expand PA** – states could expand their PA program to include more categories of drugs, particularly those categories that include higher-priced drugs.
- **Enter into Supplemental Rebate Agreements** – negotiate with manufacturers to increase cash rebates that are already provided under federal law.
- **Implement a PDL** –used in conjunction with supplemental rebates, PDL involves state selecting medications that they consider to be most clinically effective and cost-effective drugs in a particular class. Drugs not on PDL would be subject to PA. Manufacturers could have their drugs added to the list if they agreed to pay supplemental rebates beyond those that are provided under the national rebate agreement.
- **Obtain 1915(b) waiver for Specialty Drug Contracting –** allows states to waive freedom of choice and any willing provider to promote competition in contracting with select entities to provide high cost drugs to Medicaid beneficiaries.
- **Mandatory Generic Substitution**

DUR Program

States use a DUR program to ensure that:

- Drugs are appropriate,
- Medically necessary, and
- Not likely to result in adverse medical results.

DUR is a two-phase process that is conducted by the Medicaid state agencies

- First phase (prospective DUR), state Medicaid agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse.
- Second phase (retrospective DUR) involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed.

Questions?