Medicaid Outpatient Drug Rule

Medicaid and CHIP Payment and Access Commission
Chris Park

Introduction

- CMS just released final rule on Medicaid outpatient drugs
  - Proposed rule was published February 2012
- Implements and clarifies provisions of ACA
- Revises other requirements related to covered outpatient drugs, including key aspects of payment
- Although rule is final, CMS soliciting comments on one issue
- MACPAC not required to comment

Overview

- Refresher on Medicaid payment for drugs
- Overview of Medicaid Drug Rebate Program
- Highlight major provisions of final rule
  - Important dates
  - Definitional changes and clarifications
  - Payment limits and requirements
  - State requirements

Medicaid Outpatient Drugs

- Optional benefit but provided by all states
- Typically dispensed from a pharmacy
- Drug manufacturers must enter into a rebate agreement with Medicaid in order to have their products recognized for federal Medicaid match
- Outpatient drug spending reflects the state's payment to the pharmacy and manufacturer's rebate

Medicaid Drug Payment

Payment to Pharmacies

- Ingredient cost covers the pharmacy's cost of acquiring a drug
  - Typically based on a published benchmark price such as Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC)
  - Several states have moved to actual acquisition cost (AAC)
- Dispensing fee covers costs associated with the professional services to dispense the drug
- Beneficiary may pay some cost sharing
- Managed care plans typically use similar structure but use a pharmacy benefit manager to negotiate payment terms with pharmacies

Limits on Payment

- Federal upper limit (FUL) for certain multiple source drugs (e.g., generic drugs)
  - ACA establishes the FUL as no less than 175 percent of the Average Manufacturer Price (AMP)
- State Maximum Allowable Cost (MAC)
- States typically pay lowest of:
  - ingredient cost plus dispensing fee
  - FUL plus dispensing fee
  - MAC plus dispensing fee
  - pharmacy’s usual and customary charge

Medicaid Drug Rebates

Federal Medicaid Drug Rebate Program

- Drug manufacturers must provide rebate in order for their products to be recognized for federal Medicaid match
- States must generally cover a participating manufacturer's products
- States may limit use (e.g., prior authorization, preferred drug lists)
- Statutorily-defined rebate based on Average Manufacturer Price (AMP)
  - Separate from the state's payment to the pharmacy

Rebate Formulas

- Single source and innovator, multiple source (e.g., brand drugs)
  - Basic rebate calculated as the greater of (a) 23.1 percent of AMP or (b) AMP minus “best price”
  - Additional inflationary rebate
- Non-innovator, multiple source (e.g., generic drugs)
  - 13 percent of AMP
  - Bipartisan Budget Act of 2015 adds inflationary rebate to generic drugs one year after enactment
- Alternative rebate for line extension drugs

Federal Rebate Offset

- ACA increased federal rebate formulas
  - Brand drugs increased from 15.1 percent of AMP to 23.1 percent of AMP
  - Generic drugs increased from 11 percent of AMP to 13 percent of AMP
- Federal government keeps all rebate dollars above and beyond the old rebate formula
  - 0 to 8 percent of AMP for brand drugs
  - 2 percent of AMP for generic drugs

Provisions of Final Rule

Important Dates

- Final rule effective April 1, 2016
- Comments due 60 days after publication
- State Medicaid agencies have four quarters to submit a State Plan Amendment to implement AAC methodology
  - Last date is June 30, 2017 to be effective April 1, 2017
- Provisions of final rule applied prospectively from effective date

Implementing ACA Provisions

- Change rebate formulas
  - Increase in rebate formulas and federal offset
  - Alternate rebate for line extension drugs
  - Maximum rebate of 100 percent of AMP
- Extend rebates to managed care
- Amends AMP and best price definitions
- FUL is no less than 175 percent of AMP

Territories

- Revised definition of “States” and “United States” to include the territories, effective April 1, 2017
- Previously, territories were not included in Medicaid Drug Rebate Program, but they may receive territorial government-mandated price concessions and other discounts
- Territories can use waiver authority and choose not to participate in Drug Rebate Program

Average Manufacturer Price

- Implementing AMP definition from ACA
  - Clarify which entities are considered wholesalers and retail community pharmacies and what prices and discounts are included in calculation
- AMP calculation for inhalation, infusion, instilled, implanted, or injectable drugs (known as 5i drugs)
  - Manufacturer will make determination if 5i drug
  - Standard on what qualifies as not generally dispensed from retail community pharmacy

Line Extension Drugs

- Rule does not define line extension drug
  - Seeking comments on what should be included
- Alternative rebate for line extension will only be calculated if there is a corporate relationship between the manufacturer of initial product and manufacturer of line extension
- Finalizing formula for calculating alternative rebate

Federal Upper Limit

- Implementing FUL at 175 percent of AMP
- Will make any FUL that is less than the average acquisition cost from a national survey equal to the average acquisition cost
- FUL will not apply to 5i drugs
- No smoothing mechanism in the FUL calculation at this time

Pharmacy Payment

- Establishes AAC as standard for ingredient cost
  - May use NADAC, state surveys, AMP, or other benchmark if state can demonstrate relationship to actual acquisition cost
- Amends “dispensing fee” to “professional dispensing fee”
- Payment consistent with efficiency, economy, and quality of care and provide for sufficient access
- MCOs do not need to use AAC methodology but payment must be sufficient to provide appropriate access

State Requirements

- Must consider and demonstrate overall payment adequacy (ingredient cost and dispensing fee) when proposing change to either component
- Must submit payment methodology for:
  - 340B entities and associated 340B contract pharmacies
  - Indian Health Service/tribal/urban Indian pharmacies

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