
Covered Outpatient Drugs Final Rule with Comment (CMS-2345-FC) Fact Sheet

Overview

Today, the Centers for Medicare & Medicaid Services (CMS) released the Covered Outpatient Drugs final rule with comment that addresses key areas of Medicaid drug reimbursement and changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. This final rule assists states and the federal government in managing drug costs, establishes the long term framework for implementation of the Medicaid drug rebate program, and creates a more fair reimbursement system for Medicaid programs and pharmacies. The final regulation:

Assists States and the Federal Government in Managing Drug Costs

As described in the final rule, changes to rebate percentages in the Affordable Care Act (ACA) have resulted in increased Medicaid rebates being paid to the federal and state government by manufacturers of covered outpatient drugs, including higher cost brand name drugs. In addition, the final rule takes several steps to ensure that the federal and state government will save money in managing Medicaid drug costs.

- The final rule creates a regulatory definition for Average Manufacturer Price (AMP), a key concept underpinning the Medicaid drug rebate program, which is the program's key metric both for the determination of manufacturer rebates as well as pharmacy reimbursement for certain generic drugs that are subject to the Federal Upper Limit (FUL).
- By establishing a definition of AMP for inhalation, infusion, instilled, implanted, or injectable drugs, (5i drugs), which are not generally dispensed through a retail community pharmacy, states can collect rebates on more expensive infused and injected drugs, which are an increasing expense to the Medicaid program.
- The final regulation updates the FUL formula for the payment of certain generic drugs, which creates an incentive for pharmacies to utilize generic drugs because pharmacy costs for these drugs will be regularly updated.
- The final regulation also implements the Affordable Care Act provision that extended rebates to covered outpatient drugs provided to beneficiaries enrolled in Medicaid managed care organizations.
- The final rule revises the definition of "states" to include U.S. territories (Puerto Rico, Virgin Islands, Guam, American Samoa and the Northern Mariana Islands) in the rebate program so that territories can also achieve savings in their drug expenditures.

Establishes Sustainability of the Medicaid Drug Rebate Program

The final rule clarifies many of the changes made to the Medicaid Drug Rebate Program by the Affordable Care Act and provides drug manufacturers with the regulatory guidance necessary to ensure proper calculation and reporting of drug product and pricing information. More specifically, the final rule:

- Clarifies the definition of what constitutes a manufacturer's "best price" and aligns it, where applicable, to the definition of AMP.
- Clarifies the definitions of other key terms used in the determination of AMP:

- Retail Community Pharmacy
- Wholesaler
- Establishes regulatory definitions of terms used to classify drugs with special rebate calculations:
 - Pediatric Indication
 - Clotting Factor

Creates Fairer Pharmacy Reimbursement System

The final rule is designed to ensure that pharmacy reimbursement is aligned with the acquisition cost of drugs and that the states pay an appropriate professional dispensing fee. The final rule:

- Creates an exception to the FUL calculation, which allows for the use of a higher multiplier than 175% to calculate the FUL based on acquisition costs for certain multiple source drugs.
- Establishes actual acquisition cost (AAC) as the basis by which states should determine their ingredient cost reimbursement so payments are based on a more accurate estimate of the prices available in the marketplace, while still ensuring sufficient beneficiary access.
- Implements the use of the term professional dispensing fee to ensure that the dispensing fee paid to pharmacies reflect the cost of the pharmacist's professional services and cost to dispense the drug product to a Medicaid beneficiary.
- Clarifies that states are required to evaluate the sufficiency of both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either of these components.
- Requires states to specify in the Medicaid state plan that reimbursement methodology to pharmacies that purchase drugs through the Federal Supply Schedule and the 340B Drug Pricing Program is consistent with overall AAC requirements.

Seeks Additional Comments on Line Extension Provision

At this time, CMS is still considering the comments received on the definition of line extension and has decided not to finalize that portion of the regulation. At this time, manufacturers are to rely on the statutory definition of line extension at section 1927(c) (2) (C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. We have also requested additional comments on the definition of line extension drugs as we may consider addressing this definition in future rule making.

However, CMS is finalizing two aspects of the line extension provision:

- The provision which specifies the rebate calculation requirements for line extension drugs; and
- The provision which requires the alternative rebate be calculated if there is a corporate relationship between the manufacturer of the line extension drug and the manufacturer of the initial brand name listed drug.