Issue Brief

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KEY POINTS

- Estimated savings to federal and state governments is $2.7 billion throughout five years
- Average Manufacturer Price definition creation allowed for states to collect rebates on more expensive infused and injected drugs
- Implements extended rebates to covered outpatient drugs provided to beneficiaries enrolled in Medicaid managed care

CMS Issues Final Covered Medicaid Outpatient Drug Rule: Effective April 1, 2016

The Centers for Medicare & Medicaid Services has issued a final Covered Outpatient Medicaid Drug rule. The final rule implements provisions of the Affordable Care Act pertaining to Medicaid reimbursement for covered outpatient drugs. The final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program. The final rule is effective on April 1.

A copy of the 658-page document is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-01274.pdf. Publication is scheduled for Feb. 1.

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Social Security Act. Section 1903(a) of the Act provides for federal financial participation in state expenditures for these drugs.

Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for CODs, which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into a national rebate agreement as set forth in section 1927(a) of the Act.

CMS says this final rule will save federal and state governments an estimated $2.7 billion throughout five years.

THE AFFORDABLE CARE ACT

- Section 2501(a) of the ACA increased the minimum rebate percentage for most single source and innovator multiple source drugs from 15.1 percent of the average manufacturer price to 23.1 percent of AMP; established a minimum rebate percentage of 17.1 percent of AMP for certain single source and innovator multiple source clotting factors and single source and innovator multiple source drugs for pediatric indications; and specified that the amounts attributable to the increased rebate percentages be remitted to the federal government. The amendments made by section 2501(a) were effective Jan. 1, 2010.
- Section 2501(b) of the amended section 1927(c) of the Act by increasing the rebate percentage for noninnovator multiple source drugs from 11 percent of AMP to 13 percent of AMP, effective Jan. 1, 2010.

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- Section 2501(c) specified new conditions for managed care organization contracts, including that CODs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. The ACA also amended section 1903(m)(2)(A) of the Act to establish that MCO capitation rates shall be based on actual cost experience related to rebates and subject to federal regulations at 42 CFR 438.6 regarding actuarial soundness of capitation payments. The legislation also provided that MCOs are responsible for reporting to the state certain utilization data and such other data as the Secretary determines necessary for the state to access the rebates authorized by this provision.
- Section 2501(c) required manufacturers that participate in the MDR program to provide rebates for drugs dispensed to individuals enrolled with a MCO, if the MCO is responsible for coverage of such drugs. Finally, section 2501(c) modified section 1927(j)(1) of the Act to specify that CODs are not subject to the rebate requirements if such drugs are both subject to discounts under the 340B of the Public Health Service Act and dispensed by health maintenance organizations, including Medicaid MCOs. The amendments made by section 2501(c) were effective March 23, 2010.
- Section 2501(e) added a new subparagraph (D) and established a maximum on the total rebate amount for each single source or innovator multiple source drug at 100 percent of AMP, effective Jan. 1, 2010.
- Section 2501(f) made conforming amendments to section 340B of the PHSA, but those amendments are not addressed in this final rule.
- Section 2503(a)(1) revised the federal upper reimbursement limit to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Additionally, it specified that the Secretary shall implement a smoothing process for AMP which shall be similar to the smoothing process used in determining the average sales price of a drug or biological product under Medicare Part B.
- Section 2503(a)(2) revised the definition of AMP to now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.
- Section 2503(a)(3) amended the definition of multiple source drug to specify in the definition that the sales of such drugs shall be specifically within the U.S.
- Section 2503(a)(4) added to section 1927(k) definitions of retail community pharmacy and wholesaler for purposes of section 1927 of the Act.
- Section 2503(b) amended section 1927(b) of the Act by establishing a requirement that manufacturers report, not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly AMP for each COD. It also amended the preexisting requirement that the Secretary disclose AMPs, to instead

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require the Secretary to post, on a website accessible to the public, the weighted average of the most recently reported monthly AMPs, and the average retail survey price determined for each multiple source drug in accordance with section 1927(f) of the Act. The amendments made by section 2503(b) were effective Oct. 1, 2010.

- Section 2503(c) amended section 1927(f) of the Act by clarifying that the survey of retail prices described in such subsection applies to retail community pharmacies.
- Section 2503(d) specified that the amendments made by section 2503 were effective Oct. 1, 2010. Section 2503(d) further specified that the amendments made by section 2503 shall take effect without regard to whether final regulations to carry out such amendments have been issued by Oct. 1, 2010.
- Section 3301(d)(2) included a conforming amendment to the definition of best price (BP) under Medicaid at section 1927(c)(1)(C)(i)(VI) of the Act. This amendment provides that any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act are exempt from a manufacturer's best price calculation, effective for drugs dispensed on or after July 1, 2010.

CMS' FACT SHEET ON THE RULE NOTES THAT:

CMS says "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."

- Changes to rebate percentages 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, 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.
- 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 ACA 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.

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CMS says "the final rule clarifies many of the changes made to the Medicaid Drug Rebate Program by the ACA 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

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 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.

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. 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. CMS has requested additional comments on the definition of line extension drugs.

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.

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