Proposed Rule to Advance Medicaid Prescription Drug Transparency

On May 26, 2023, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule, "Misclassification of Drugs, Program Administration, and Program Integrity Updates Under the Medicaid Drug Rebate Program (MDRP)," aimed at **lowering prescription drug costs** in Medicaid and building on President Biden's executive order to lower prescription drug costs for Americans. This proposed rule introduces efforts to increase transparency in prescription drug costs, strengthen the management of pharmacy benefits, and bolster program integrity in Medicaid.

CMS is accepting public comments on this proposed rule through July 25, 2023.

Increase Transparency of Medicaid Prescription Drugs

High-Cost Prescription Drug Costs for Rebate Negotiations (42 CFR 447.510(k))

The proposed rule introduces an annual Medicaid Drug Price Verification Survey. The survey is intended to **verify prices** charged by manufacturers of covered outpatient drugs (CODs) supplied and sold by manufacturers that have a National Drug Rebate Agreement with the US Department of Health and Human Services. Prices subject to survey verification include Average Manufacturer Price (AMP), best price, Average Sales Price (ASP), and Wholesale Acquisition Cost (WAC) for a drug. While WAC charges are often publicly available, other prices reported, such as AMP, best price, and ASP, are generally not available. CMS also notes in the proposed rule preamble that drug price transparency resources (such as the National Average Drug Acquisition Cost file) are limited to retail pharmacy, and similar, transparency resources do not exist for physician-administered drugs (PADs).

Using a process to select high-cost drugs to Medicaid, CMS anticipates that three to ten National Drug Codes (NDCs) will be identified for the annual survey. Information collected from the surveys will be made public and states will be able to negotiate supplemental rebates better.

Drug Spending with Managed Care Plans (42 CFR 438.3)

There is growing concern that pharmacy benefit managers (PBMs) are increasing their profit margins through *spread pricing* — a practice by which the PBM charges the Medicaid managed care plans more than the amount that is paid to a dispensing pharmacy. The proposed rule would shine a light on this practice by requiring Medicaid managed care contracted PBMs to report on incurred claims and administrative costs for drug administration. Under the proposed rule, Medicaid managed care subcontracted PBMs would be required to separately report:

1. Incurred claims such as the reimbursement cost of the COD, payments for other patient services, and fees paid to pharmacies or providers for dispensing or administering drugs.

2. Administrative costs, fees, and expenses paid to the subcontractor.

This new reporting requirement will provide states information to evaluate whether spread pricing is occurring.

Drug Classifications for Rebate Accuracy (42 CFR 447.509 and 42 CFR 447.510)

The Medicaid Services Investment and Accountability Act of 2019 (MSIAA) established oversight and enforcement authority to support compliance with drug manufacturer reporting on drug product and pricing information. The law established compliance oversight of drug classification for purposes of determining drug rebates owed to state Medicaid programs. The proposed rule would codify these statutory changes in regulation.

MSIAA and the proposed regulation aim to address situations where manufacturers incorrectly report or misclassify their drugs for the MDRP. The proposed rule would:

1. Define situations where a drug is considered misclassified or a manufacturer is paying an incorrect rebate amount.

2. Develop a process and timeline to correct the misclassification.

3. Clarify that the manufacturer is responsible for paying unpaid rebates to a state due to the misclassification.

4. Describe the enforcement actions that CMS may take against a manufacturer that does not correct the misclassification. Manufacturers would have **30 days** after notification to correct the misclassification and **60 days** to pay rebates to the states due to the misclassification.

The goal of this provision is to ensure that states receive the appropriate rebates to which they are entitled. Drugs classified as brands have a higher rebate percentage than generic drugs. These changes will allow states to determine if a drug is misclassified and CMS can enforce correction of the misclassification.

Enhance MDRP Operations

Definitions (42 CFR 447.502)

To improve efficiency and reduce ambiguity, CMS proposes new definitions to clarify certain terms associated with the MDRP, including:

- **Manufacturer**: defined to be inclusive of all labelers of a manufacturer.
- **Vaccine**: defined to clarify which products are considered vaccines in the MDRP, as vaccines are not CODs and not subject to rebates.

- **Best price**: clarified to be cumulative of discounts, rebates, and other arrangements, including those provided to other best price eligible entities, such as those listed in 42 CFR § 447.505(a).
- **Market date**: defined for establishing a baseline AMP.
- **Direct reimbursement**: defined to clarify that a drug, when the drug is reimbursed as part of a single payment, is eligible for rebates if the drug and its cost can be separately identified on a claim for payment.
- **Non-innovator multiple source drug**: defined as all other drugs that do not meet the definition of single source drug or innovator multiple source drug to clarify the rebates owed to states.

Policy Clarification (42 CFR 447.510)

CMS proposes changes to various MDRP policies, including clarification that:

- Manufacturers may only initiate rebate disputes, hearings, or audits up to 12 quarters from the last day of the quarter from the date of the state's invoice.
- Within the fee-for-service program, ingredient cost and professional dispensing fee reimbursement must be based on pharmacy-established cost data. Ingredient cost and professional dispensing fee reimbursement cannot be based on market-based research (such as third-party payments accepted by pharmacies).

Collection of NDCs for All PADs (42 CFR 447.520)

CMS proposes to require states to require providers to submit NDCs on claims for all PADs. These NDCs would be used to secure rebates and receive Medicaid Federal Financial Participation (FFP). The proposed rule would require states to collect NDCs for PADs in order to receive FFP, including PADs dispensed by managed care plans.

Request for Information on Potential Requirement of Diagnosis Codes on Prescriptions

CMS is seeking comments on a potential requirement of adding diagnosis information on prescriptions as a condition to receive FFP. This information would allow states to identify drug expenditures that qualify for enhanced Federal matching funds, such as drugs used for family planning. In addition, there are opportunities for clinical benefits and utilization management enhancement with the diagnosis codes. CMS is soliciting specific comments on impacts on stakeholders and operations and potential mitigation strategies for burdens created by this requirement.

Other Provisions

Highlights of the Proposed Rule

This proposed rule also contains other provisions to address previous legislation and enhance Medicaid operations. Highlights include:

- Medicaid-specific Bank Identification Number (BIN), Processor Control Number (PCN), and group numbers on pharmacy benefits cards for all Medicaid managed care beneficiaries.

- Modify third-party liability rules to conform with the statutory exception to standard coordination of benefits cost avoidance and allow states to *pay and chase* for pediatric preventive service claims and medical child support service claims.

Considerations for Medicaid Programs

This proposed rule contains numerous changes and clarifications that have large impacts on Medicaid pharmacy programs. **States will need to consider the impact of these proposals**, such as:

- Utilizing the results of the Medicaid Drug Price Verification Survey to improve negotiating for supplemental rebates.
- Incorporating required managed care pharmacy benefit reporting in capitation rate setting. Work with the state's actuary to plan on utilizing the required managed care reporting to determine the appropriate allocation for the medical loss ratio calculations.
- Collecting rebates owed due to manufacturer misclassification of drugs.
- Capitalizing on definitions to maximize rebate collections, such as identification of direct reimbursement drug claims that are subject to rebates.
- Reviewing ingredient cost and dispensing fee rate setting to ensure compliance with the updated policy clarification that such reimbursement rates cannot be based on market-based research.
- Adjusting processing of PAD claims to ensure claims without NDCs are rejected for missing information.
- Providing feedback to CMS regarding the requirement for diagnosis codes on prescription drug claims as a condition for receiving FFP.
- Include the Medicaid-specific BIN, PCN, and group number on the member pharmacy benefit cards to assist with identifying 340B claims to include a modifier and avoid duplicate discounts.

CMS is accepting public comments on this proposed rule **through July 25, 2023**. Contact your Mercer pharmacy consultants to talk through the implications of these proposed provisions to your specific program.

Caveats and limitations

Questions for your specific state?

Please contact Mark England, James Shin, or your Mercer consultant to discuss the impact for your specific state programs. You may also email us at mercer.government@mercer.com.

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