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CMS' Final Rule Advances Policies to Promote the Efficient Operation of the Medicaid Drug Rebate Program

Overview

On September 20, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a long-awaited final rule "Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program ("MDRP")" (the "Final Rule"). The Final Rule is intended to promote the efficient operation of the MDRP which includes implementing new statutory authorities as well as enhancing MDRP integrity.

One primary goal of the Final Rule is to implement newly granted statutory authorities in identifying and correcting misclassified drug information as well as addressing late reporting of drug product and pricing information by manufacturers. Manufacturers that participate in the MDRP must report certain drug related product and pricing information upon participation in the MDRP and through required monthly and quarterly submissions to CMS. This information includes the classification of a manufacturer's drug as a brand-name or generic drug, which helps to determine the rebates that manufacturers pay to the states for their drugs. In this final rule, CMS is implementing statutory authorities to address issues related to incorrect reporting by drug manufacturers of drug product information in the Medicaid Drug Program (MDP) system, as well as the misclassification of drugs.

Additionally, the Final Rule includes several provisions designed to ensure states can obtain the required manufacturer rebates so they can effectively operate their pharmacy programs and enhance access to necessary prescription medications.

- Define "market date" of a drug.
- Limit the period for manufacturers to initiate disputes.
- Specify that both ingredient cost reimbursement and dispending fee reimbursement under Medicaid Fee-for-Service (FFS) must be on pharmacy-established cost data.
- Require states to collect national drug code (NDC) information on all physician-administered drugs and specify that states should be invoicing for rebates for all physician-administered drugs to receive federal matching funds and secure manufacturer rebates.
- Modify the definition of a covered outpatient drug; as a result, "direct reimbursement" includes reimbursement for a drug that is part of an inclusive payment.
- Specify the conditions that constitute an "internal investigation" of pricing data.
- Specify that for the purposes of manufacturer drug rebates, the drug category "'N' represents "other drugs."

Additional provisions of the Final Rule include improving pharmacy benefit operations in Medicaid Managed Care. CMS requires that states, via their managed care contracts, instruct Medicaid managed care plans to assign and exclusively use a Medicaid-specific Bank Identification Number/Processor Control Number (BIN/PCN) combination and group number on Medicaid managed care beneficiaries' cards, to help ensure the appropriate scope of benefits are delivered and to help avoid duplicate discounts under the 340B Drug Discount Program. CMS is also requiring state managed care contracts that include pharmacy benefit managers (PBM) to be transparent about spread pricing.

Lastly, CMS is implementing other provisions related to legislative changes to the Medicaid Drug Rebate cap: sunsetting maximum rebate amount, court-ordered changes: vacated Accumulator Adjustment Rule of 2020, and third-party liability: allows states to "pay and chase" for certain types of care.

Strategies for State Medicaid Programs to Consider

State Medicaid programs should review the Final Rule and ensure compliance with and/or program optimization related to the manufacturer provisions. In particular, states should:

- Ensure managed care contracts require Medicaid managed care plans to assign and exclusively use a Medicaid-specific BIN/PCN combination and group number on Medicaid managed care beneficiaries' cards.
- If utilizing PBMs in managed care contracts, require PBMs to be transparent about spread pricing.
- Verify that both ingredient cost reimbursement and professional dispensing fee reimbursement, under Medicaid FFS, are based on pharmacy-established cost data rather than market-based research.
- Confirm collection of NDC information on all physician-administered drugs and that the State is invoicing for rebates for all physician-administered drugs to receive federal matching funds and secure manufacturer rebates.
- Evaluate inclusive payments for opportunities to collect federal rebates and update the State plan with a reimbursement methodology accordingly. The inclusive payment must have the number of units of the drug that were dispensed or administered to the patient, and the amount paid that is attributable to the drug.
- Review the Final Rule provisions for opportunities for greater consistency and accuracy of drug information reporting, timely data collection, and efficient operation of the MDRP. Even though these are largely manufacturer-directed, states may have opportunities to direct manufacturers to the Final Rule provisions including but not limited to current disputes or rebate collection procedure discussions.

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Questions for your specific state?

Please contact Ryan Ferguson, Dr. Bethany Holderread, or your Mercer pharmacy consultant to discuss the impact for your specific state programs.

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