799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

Vizient Office of Public Policy and Government Relations

Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

October 16, 2024

Background & Summary

On September 20, the Centers for Medicare & Medicaid Services (CMS) issued a Final Rule (fact sheet available here) to implement policies to address drug misclassification issues and matters related to incorrect reporting by drug manufacturers of drug product information used in the Medicaid Drug Rebate Program (MDRP). Also, the Final Rule includes other policies related to the MDRP, such as requiring manufacturers who participate in the program to report certain drug-related product and pricing information and providing a process and timeline that CMS will use to notify the manufacturer when it is determined that a misclassification of a covered outpatient drug (COD) has occurred. In addition, the Final Rule also rescinds changes provided in a December 2020 Final Rule ("Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements") regarding the determination of best price and determination of average manufacturer price, among other changes.

Also, CMS did not finalize several proposals, including the proposal to accumulate price concessions and discounts ("stacking") when determining best price under the MDRP.

Most provisions in the Final Rule will go into effect on November 19, 2024.

Key Provisions of the Final Rule

Accumulation of Price Concessions and Discounts ("Stacking") when Determining Best Price

As defined under statute, the term "best price" means with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, subject to certain exceptions and special rules.[1] CMS proposed to make clear that manufacturers have to stack all applicable discounts that they offer on a single sale of a covered outpatient drug, including if multiple price concessions are provided to two entities for the same drug transaction. In the Final Rule, CMS did not finalize this "stacking" proposal and stated they will continue to review the input provided by commenters. CMS intends to collect additional information related to manufacturers' stacking methodologies, which may inform future rulemaking on this issue.

[1] In the Final Rule, CMS notes that the term best price includes the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act.

MDRP Program Administration Changes

The Medicaid program is jointly funded and administered at the state and federal levels. CMS administers the program, while each state administers its Medicaid program as provided in a state plan that CMS approves. Under the Medicaid program, states have the option to provide medical assistance for CODs. If a state provides such assistance, then the statutory requirements for the Medicaid Drug Rebate Program (MDRP)[2], which also addresses payment for CODs, must be met. Generally, for payment to be made available for CODs, manufacturers must enter into a National Drug Rebate Agreement (NDRA) where rebates paid by manufacturers help offset the federal and state costs of outpatient drugs dispensed to Medicaid beneficiaries. Manufacturers pay rebates to states for each unit of the drug dispensed and paid for under the state plan based on the unit rebate amount (URA).

The formula used to calculate the rebate depends on how the drug is classified. Although there was prior rulemaking related to drug classification, Congress ultimately passed the Medicaid Services Investment and Accountability Act in 2019 (MSIAA), which provided definitions relevant to drug classification. Consistent with the MSIAA, the Final Rule modifies or adds several definitions used for the MDRP, including:

- Covered Outpatient Drug (COD) – CMS noted, as background, that the Public Health Service (PHS) Act provides a definition of the term "covered outpatient drug" (COD) which incorporates a limiting definition. The limiting definition functions to exclude certain products from the definition of COD. The limiting definition exclusion does not apply when there is "direct reimbursement" for the product, however, CMS provides that in prior regulation, the agency did not clarify the meaning of "direct reimbursement".[3] In the Proposed Rule, CMS sought to clarify "direct reimbursement" and in response to stakeholder feedback regarding the agency's proposal, CMS finalized a revised definition. According to CMS, under the finalized definition, states will be able to more effectively collect rebates on certain drugs administered in certain settings that may not have been identified under the prior definition. Additionally, while the scope of CODs is relevant for purposes of the 340B Program, CMS notes because 340B issues are outside the scope of this rule, it is not addressing those stakeholders' comments.
- Vaccine – CMS did not finalize the proposed definition of specifying which products are considered vaccines and thus excluded from the definition of COD. CMS will continue to review the input provided by commenters, which may inform future rulemaking on this topic.
- Manufacturer – CMS proposed to refine this definition by specifying that a manufacturer must have entered into and have in effect a rebate agreement with the Secretary in order for payment to be available for their CODs under Medicaid, among other changes. CMS did not finalize the proposals and is continuing to review the input provided by commenters, which may inform future rulemaking on this topic.
- Market date – CMS amended this definition to reflect the date of first sale of the drug, rather than the date the drug was first available for sale, by any manufacturer; and codified the historical policy that the market date does not change if a drug is purchased or otherwise acquired from another manufacturer.

---

[2] Also, the MDRP provides specific requirements for manufacturer rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for states for CODs.
[3] In the Final Rule, CMS notes that clarifying the interpretation of "direct reimbursement" in the COD definition also impacts the "situations under which a State could bill a manufacturer for a rebate for a COD when the COD is part of an inclusive payment for the COD and related services."

Proposals to Implement the MSIAA and Federal Financial Participation (FFP): Conditions Related to PADs

Section 6002 of the Deficit Reduction Act of 2005 (DRA) requires states to collect and submit certain utilization data on certain PADs as a condition for FFP to be available in payments for these drugs, and to facilitate state collection of manufacturer rebates. More specifically, states had to provide for the collection and submission of utilization data and coding (such as J-codes and NDCs) for all single source PADs (after January 1, 2006) and multiple source drugs (after January 1, 2008) that are a top 20 high dollar volume PAD that appears on a published list (based on highest dollar volume dispensed under Medicaid identified by the Secretary, after January 1, 2007) in order for FFP to be available. CMS proposed to require states to require providers to submit NDCs for all multiple source PADs that are CODs, which would then be subject to manufacturer rebate invoicing, and not limit such rebate invoicing to those on the top 20 high dollar volume PADs. CMS finalized the policy as proposed.

Proposal Related to Managed Care Plan Standard Contract Requirements

Requirement of BIN/PCN Inclusion on Medicaid Managed Care Pharmacy Identification Cards

To allow pharmacies to process and bill claims to Medicare managed care plans in real-time, health plans use two codes on beneficiary insurance cards to identify a patient's prescription health insurance and benefits - the National Council for Prescription Drug Programs (NCPDP) Processing Bank Identification Number (BIN) and Processor Control Number (PCN). This information, along with a group number, can specify that a beneficiary is part of a specific patient insurance group (e.g., a Medicaid managed care beneficiary).

While the use of Medicaid-specific BIN, PCN, and group number identifiers does not assist in identifying claims for drugs purchased under the 340B Drug Pricing Program, CMS believes it may help states and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid.

CMS proposed to require Medicaid managed care plans (i.e., managed care organizations (MCOs), pre-paid inpatient health plans (PIHPs), and pre-paid ambulatory health plans (PAHPs)) that provide coverage of CODs to assign and exclusively use unique Medicaid BIN, PCN, and group identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits. CMS thought this change would help to reduce the incidence of 340B Program duplicate discounts by identifying Medicaid managed care plans. The agency received comments suggesting the policy would be more effective with a BIN and PCN group combination, instead of requiring separate unique Medicaid-specific BIN, PCN, and group number identifiers. In the Final Rule, CMS agreed with these comments and amended the proposal to require a unique BIN and PCN combination, along with a group number identifier, to be assigned for Medicaid managed care enrollees' identification cards.

Drug Cost Transparency in Medicaid Managed Care Contracts

According to CMS, to correctly report the Medical Loss Ratio (MLR), a Medicaid managed care plan is required to distinguish expenses that are for covered benefits (e.g., drug costs) and administrative expenses (e.g., fees paid to its pharmacy benefit manager (PBM) for services such as claims adjudication and processing prior authorization requests). To increase transparency, CMS proposed that MCOs, PIHPs and PAHPs that provide CODs structure any contract with any subcontractor (e.g., PBMs) to require the subcontractor to report specified information (e.g., reimbursement for the COD, payments for other patient services, and fees paid to providers or pharmacies for dispensing or administering a COD). Such information is to be reported separately from any administrative costs, fees, and expenses of the subcontractor. CMS largely finalized this provision as proposed and set the applicability date for this

requirement as the first rating period for contracts with managed care plans starting on or after November 19, 2025, which is one year after the effective date of the Final Rule.

Removal of Manufacturer Rebate Cap (100 percent Average Manufacturer Price (AMP))

In accordance with the American Rescue Plan Act, CMS finalized regulatory changes as proposed to remove the maximum rebate caps for the rebate periods beginning on or after January 1, 2024. As a result, no maximum rebate would apply to rebate periods beginning on or after January 1, 2024. CMS notes that Medicaid savings (approx. $14.21 billion over 10 years) would be generated by removing the manufacturer rebate cap.

Drug Price Verification and Transparency through Data Collection

To create a centralized process to collect specific data from manufacturers (or wholesalers) to verify prices that manufacturers report to CMS, the agency proposed several policies, including identifying the situations when it is necessary for surveys to be sent to manufacturers and wholesalers to verify prices and charges. CMS also proposed rules regarding the information that would be requested to verify prices or charges so that payments can be made. In addition, CMS proposed to post non-proprietary information on its website so stakeholders could comment on public information as part of the verification process. Without providing further detail regarding the comments received, CMS ultimately did not finalize any of the proposals surrounding the drug price verification and transparency through data collection and is continuing to review comments, which may inform future rulemaking.

Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payments

In the Proposed Rule, CMS provided a Request for Information (RFI) regarding the potential impact of a requirement that a patient's diagnosis be included on a prescription as a condition of receiving Medicaid FFP (i.e., the federal government's share of a state's expenditures under the Medicaid program) for that prescription. In the Final Rule, CMS indicates it received an overwhelming number of comments that were opposed to this policy as a potential requirement. CMS noted that due to overwhelming opposition to the request, it is not going to pursue rulemaking at this time, however, the agency may decide to address this issue in future rulemaking if appropriate.

What's Next?

Most provisions in the Final Rule will go into effect on November 19, 2024. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Final Rule. Please direct your feedback to Jenna Stern, AVP Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.