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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

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Background & Summary

On May 24, the Centers for Medicare & Medicaid Services (CMS) issued a Proposed Rule to implement policies to address drug misclassification issues and other program integrity and program administration policies, including revising and proposing key definitions, used in the Medicaid Drug Rebate Program (MDRP). Also, the Proposed Rule clarifies and establishes requirements for state fee-for-service (FFS) pharmacy reimbursement, codifies conditions related to states claiming Federal Financial Participation (FFP) for physician-administered drugs (PADs), and designates drug price verification and transparency through data collection, among other changes. CMS also proposes to rescind changes provided in a December 2020 final rule regarding the determination of best price and determination of average manufacturer price (AMP) sections.

Comments are due **no later than July 25, 2023**. Vizient looks forward to working with provider members to help inform our letter to the agency.

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

According to CMS, under the MDRP, a covered outpatient drug (COD) is generally defined as a prescribed drug that is FDA approved and used for a medically accepted indication. CMS notes that since the diagnosis is not included on prescriptions, it can be difficult to determine whether a drug is being used for a medically accepted indication and therefore, potentially rebate-eligible.

CMS seeks comment on 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. Also, CMS requests comment on the patient care, clinical, and operational impact of requiring that a patient's diagnosis be included on a prescription as a condition of a state receiving FFP for that prescription. The agency is particularly interested in understanding any operational implications, privacy-related concerns, the burden associated, and how to negate any foreseeable impact on beneficiaries and providers, including what steps would be needed by states to successfully implement a Medicaid requirement for diagnosis on prescriptions.

Proposal to Accumulate 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 proposes to make clear that the 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.

Proposal Regarding Drug Price Verification and Transparency through Data Collection

CMS notes that since the start of the MDRP, the Secretary has had authority to survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify reported manufacturer prices, if required to make payment. Prices that may be included in the survey include a manufacturer's AMP, best price, Average Sales Price, and in some cases, Wholesale Acquisition Cost (WAC) for a drug. The reported information is used by CMS programs, such as Medicare Part B and Medicaid, and the rebate calculation under the MDRP.

CMS notes that distribution methods have evolved (e.g., PBM-owned specialty pharmacy distribution) and launch prices for several types of products (e.g., cell and gene therapy drug treatments) have increased dramatically, which impacts prices reported to CMS. As a result, CMS proposes rules to identify the situations when it is necessary for surveys to be sent to manufacturers and wholesalers to verify prices and charges. Also, CMS proposes rules regarding the information that would be requested to verify prices or charges so that payments can be made. In addition, CMS proposes to post non-proprietary information on its website so stakeholders could comment on public information as part of the verification process. As provided in the Proposed Rule, manufacturers who do not comply would have cases referred to the Office of the Inspector General for potential civil monetary penalties.

CMS requests comment on these proposals. CMS also requests specific feedback on whether the agency should consider surveying manufacturers of certain CODs that are granted accelerated approval by the Food and Drug Administration.

MDRP Program Administration Proposed 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 on the basis of the unit rebate amount (URA).

The formula used to calculate the rebate depends on how the drug is classified: (1) single source drug (S drug) or innovator multiple source drug (I drug, also called brand name drugs); or (2) other drugs, such as noninnovator multiple source drugs (N drug, also called generic drugs).

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[1] In the Proposed 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.
[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.

Prior rulemaking, specifically the 2016 Medicaid Covered Outpatient Drug Final Rule, also provided policy regarding classification of products. Despite clarification provided in the 2016 Final Rule, CMS notes that manufacturers have continued to misreport drugs marketed under New Drug Applications as noninnovator multiple source drugs for periods prior to April 1, 2016. The Medicaid Services Investment and Accountability Act of April 2019 (MSIAA), provided definitions for "single source drug,"[3] "innovator multiple source drug."[4] and "noninnovator multiple source drug."[5]

In the Proposed Rule, CMS implements and codifies several statutory changes in regulation. For example, CMS proposes to modify or add several definitions used for the MDRP, including COD, manufacturers, market date, noninnovator multiple source drug, drug product information, and vaccine. CMS also clarifies the required collection of all National Drug Codes (NDC) for single and multiple source PADs to receive FFP and secure manufacturer rebates.

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

CMS notes that generally, PADs may satisfy the definition of a COD, with some exceptions, and that states are required to collect and submit certain utilization data on certain PADs in order for FFP to be available for these drugs, and for states to secure rebates. CMS proposes to require states to collect NDC information on all covered outpatient single and multiple source PADs and to specify that states should be invoicing for rebates for all covered outpatient PADs to receive FFP and manufacturer rebates.

Proposal Related to Managed Care Plan Standard Contract Requirements

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

CMS reminds readers that 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).

Despite this information, CMS provides that it is difficult to determine if a beneficiary is covered under a Medicaid managed care plan or non-Medicaid coverage (e.g., employer-sponsored group health plan or individual market insurance) if offered by the same insurance provider that offers the Medicaid managed care plan. CMS believe this issue arises because Medicaid-specific BIN, PCN and group numbers are not always on a Medicaid managed care plan identification card. Also, the agency notes that resolving this identification issue would help states and their managed care plans identify claims for drugs paid under the 340B Drug Pricing

[3] "A single source drug as a covered outpatient drug which is produced or distributed under an original new drug application." (34239 of the Proposed Rule).
[4] "an innovator multiple source drug as a multiple source drug that was originally marketed under an original new drug application" (34239 of the Proposed Rule).
[5] "A noninnovator multiple source drug was defined at Section 1927(k)(7)(A)(iii) of the Act as a multiple source drug that is not an innovator multiple source drug" (34239 of the Proposed Rule).

Program and avoid invoicing for rebates on 340B drugs; this would also help avoid duplicate discounts[6] in the MDRP.

As a result, CMS proposes to require 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 seeks comment on the implementation time frame and other possible operational issues of requiring unique Medicaid BIN, PCN, and group numbers to be on Medicaid managed care beneficiary identification cards.**

Drug Cost Transparency in Medicaid Managed Care Contracts

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 PBM for services such as claims adjudication and processing prior authorization requests). To increase transparency, CMS proposes 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. Examples of information to be reported include reimbursement for the covered outpatient drug, 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 seeks comment on the potential burden and unintended consequences of the proposed reporting changes. CMS also requests comment on alternatives for how MCOs, PIHPs, and PAHPs should require information from their subcontracts and how they should structure payment or billing arrangements to increase transparency.**

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

In accordance with the American Rescue Plan Act, CMS proposes regulatory changes to remove the maximum rebate amounts 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.

What's Next?

It is unclear when CMS will publish a final regulation. The comment period closes on July 25, 2023.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, AVP Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.

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[6] Duplicate discounts occur when a state erroneously bills a manufacturer for a Medicaid drug program rebate involving a drug that was purchased under the 340B Drug Pricing Program. That occurs because the claim was not identified as a 340B claim before it was sent to the state.