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CMS Finalizes Changes to Advance Drug Price Transparency and Promote Efficient Operation of the Medicaid Drug Rebate Program

On September 20th, the Centers for Medicare & Medicaid Services (CMS) released the Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program final rule, which finalizes policies that aim to promote efficient operation of the Medicaid Drug Rebate Program (MDRP). See the fact sheet here. In this rule, CMS finalizes proposals to:

- Establish a new definition of "misclassification,"
- Implement a process to settle unpaid rebates under the MDRP,
- Rescind "accumulator" program changes related to its December 2020 Medicaid rule,
- Remove the manufacturer rebate cap for drugs effective December 31, 2023,
- Establish a procedure to suspend a manufacturer's National Drug Rebate Agreement (NDRA) if the manufacturer fails to report certain information in a timely manner,
- Limit manufacturers audits of state utilization data on rebate invoices to 12 quarters,
- Require that states collect National Drug Code (NDC) information on all covered outpatient physician-administered drugs,
- Mandate Medicaid managed care plans to use unique Medicaid information on beneficiaries' cards and modify contracts with subcontractors to ensure reporting of drug claim costs and administrative fees starting November 19, 2025,
- Require that state changes to pharmacy reimbursement under Medicaid fee-for-service must be based on pharmacy-established cost data,
- Clarify several definitions to improve transparency and consistency within the MDRP.

CMS is not finalizing its proposal to require stacking of price concessions to determine the Medicaid Best Price and will instead collect additional information from manufacturers related to Best Price stacking methodologies to better understand and inform future rulemaking. Additionally, CMS is not moving forward with its proposal to implement an annual manufacturer survey for high-cost drugs. The agency is reviewing the feedback received from commenters, which may influence future rulemaking on this subject.

This final rule is scheduled to be published in the *Federal Register* on September 26, 2024. The rule will be effective 60 days after publication of the final rule on November 19, 2024, with the exception of two provisions in the Standard Medicaid Managed Care Contract Requirements section which will be effective November 19, 2025.

CMS INTRODUCES NEW DEFINITION OF "MISCLASSIFICATION" AND PROCESS TO SETTLE UNPAID REBATES IN THE MDRP

Manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) must submit certain product and pricing information for covered outpatient drugs (CODs) to CMS on a monthly and/or quarterly basis. This information includes the classification of each drug as either brand-name or generic, which helps determine the rebate amounts that manufacturers pay to states. Brand-name drugs are subject to higher rebate rates compared to generic drugs.

The Medicaid Services Investment and Accountability Act of 2019 (MSIAA) amended Medicaid statute to address situations in which manufacturers incorrectly report or misclassify their drugs in the MDRP, which may allow manufacturers to take advantage of lower rebate obligations. To implement the provisions from the MSIAA, CMS finalizes several proposals.

Definition of "Misclassification"

CMS will define "misclassification" in the MDRP as a situation where a manufacturer reports a drug category or product information for a COD that does not comply with relevant laws or regulations. Additionally, "misclassification" will encompass cases where a manufacturer accurately reports its drug classification but pays rebates to states that do not align with the applicable statutory or regulatory requirements. CMS emphasizes that a misclassification can occur regardless of whether the manufacturer knowingly or unknowingly made the error.

Manufacturer Notification of Drug Misclassification

Once a misclassification is identified, CMS will issue both written and electronic notices to the manufacturer, which may include a notification that past rebates are due. Upon notification, the manufacturer will have 30 calendar days to provide CMS with any information necessary to correct the misclassification of the COD and calculate rebate obligations.

Commenters requested a dispute resolution process in the regulations, arguing it is unfair for CMS to solely determine misclassifications. They suggested a collaborative approach that allows manufacturers to validate misclassifications before the 30-day correction period begins. CMS noted that the current framework set by Congress lacks such a process but will consider this suggestion for future rulemaking.

Payment of Unpaid Rebates

Manufacturers must pay states, for each period during which the drug was misclassified, the difference between the per unit rebate amount (URA) paid by the manufacturer for the COD and the per URA that the manufacturer would have paid if the COD were classified correctly, multiplied by the total units of the COD paid for under the state Medicaid plan in each period.

Manufacturers will have 60 calendar days from the date of notification to settle outstanding rebate payments and provide documentation to CMS that all past due rebates have been paid.

Enforcement

CMS will implement enforcement procedures in the event that a manufacturer does not correct misclassifications within 30 days of notification, fails to certify pricing and drug product data, or does not pay overdue rebates within 60 days of notification. In such cases, CMS may use any pricing and product information provided by the manufacturer to correct the misclassification or take further actions, such as suspending the drug's COD status, excluding it from Federal Financial Participation (FFP), or imposing civil monetary penalties for each rebate period (up to a specified limit). Additional penalties may include referrals to the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and potential termination from the MDRP. CMS clarifies that suspension of a drug as a COD under the MDRP due to a misclassification would not affect its status as a reimbursable drug under Medicare Part B or a drug covered under the 340B Program.

Transparency of Manufacturer Misclassification

To comply with statutory obligations which requires information on misclassified CODs be annually reported to Congress and made publicly available on a designated website, CMS will issue an annual report listing the CODs identified as misclassified in the preceding year. The report would include information on any actions taken by CMS to reclassify these CODs and ensure manufacturers settle any extra rebate amounts owed due to the misclassifications.

In response to a commenter's concerns, CMS clarifies that the report will not contain proprietary drug pricing information; rather, it will focus on the CODs identified as misclassified, the actions taken for reclassification and payment of overdue rebates, and the disclosure of associated expenditures.

CMS DOES NOT FINALIZE ANNUAL MANUFACTURER SURVEY FOR CERTAIN HIGH-COST DRUGS

In its proposed rule, CMS proposed to implement section 1927(b)(3)(B) of the Social Security Act (the Act), which authorizes the Secretary of the HHS to survey manufacturers and wholesalers for information about the prices of CODs reported to CMS. This would include Average Manufacturer Price (AMP), Average Sales Price (ASP), Wholesale Acquisition Cost (WAC), and Best Price (BP)), along with charges, distribution and utilization data, product and clinical information, as well as costs related to production, research, and marketing, among other details as determined by the Secretary. Non-proprietary data would be shared with states and the public and CMS indicated it may request manufacturers to address published information publicly. This survey would be intended to confirm reported prices and understand if reimbursements paid based on these prices are adequate and appropriate, and to support states in negotiating supplemental and/or value-based rebates for these drugs.

However, in response to commenters, CMS is not finalizing this policy at this time. The agency indicates it is continuing to review the feedback provided by commenters, which may inform future rulemaking on this topic

ACCUMULATOR PROGRAM CHANGES RELATED TO PRIOR MEDICAID RULE RESCINDED IN LIGHT OF 2022 COURT DECISION

In its December 2020 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*,[1] which impacts Medicaid, CMS finalized its proposed requirement for manufacturers to guarantee that the full value of assistance provided by patient assistance programs reached the consumer or patient, without being diverted by intermediaries through "accumulator" programs. Given the U.S. District Court for the District of Columbia's May 2022 decision[2] to vacate this rule in *Pharmaceutical Research and Manufacturers of America vs. Becerra*, CMS finalizes its proposals to rescind its prior patient assistance exclusion rule revisions that would have impacted Best Price and AMP calculations in connection with Pharmacy Benefit Manager (PBM) accumulator adjustment programs. As such, regulations will use language that has been in place since 2016.

PROPOSAL FOR STACKING OF PRICE CONCESSIONS FOR MEDICAID BEST PRICE NOT FINALIZED

Medicaid statute §1927(c)(1)(C)(i) defines "Best Price" to be "the lowest price available from the manufacturer during the rebate period to any" Best Price eligible entity. The proposed rule included a proposal to require manufacturers to "stack" or aggregate discounts, rebates, or other arrangements for a single transaction for the purposes of determining best price for a particular unit of a covered outpatient drug, including discounts, rebates or other arrangements provided to different best price eligible entities. Currently, stacking is only required when multiple concessions are provided to the same entity on the same unit of product.

However, in a May 2024 press release[3], CMS indicated that it will not be finalizing the proposal regarding stacking and will instead collect additional information from manufacturers related to Best Price stacking methodologies to better understand and inform future rulemaking. Accordingly, CMS does not finalize this provision in this final rule and notes that it will collect this information through a separate Paperwork Reduction Act (PRA) request. No timeline is given for the release of the PRA.

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[1] 85 FR 87000

[2] https://fingfx.thomsonreuters.com/gfx/legaldocs/zjpqkgjdwpx/PhRMA v Becerra opinion.pdf

[3] https://www.cms.gov/newsroom/press-releases/cms-statement-misclassification-drugs-program-administration-and-program-integrity-updates-under

MANUFACTURER REBATE CAP REMOVED EFFECTIVE DECEMBER 31, 2023

The American Rescue Plan Act of 2021 removes the cap on Medicaid drug rebates for single source and innovator multiple source drugs, currently 100 percent of AMP, beginning January 1, 2024. AMP is the average price paid to manufacturers by wholesalers and retail community pharmacies that purchase drugs directly from the manufacturer and is used to calculate drug rebates under the MDRP. Under current law, once a brand drug reaches the 100 percent AMP, the brand drug manufacturer is effectively receiving zero net revenue from Medicaid use of the drug, and in some instances, may be providing the drug to states at no cost. With the removal of the cap on Medicaid drug rebates, for certain manufacturers where Medicaid rebates exceed or equal 100 percent AMP, the manufacturer may have to pay Medicaid when the drug is used. In line with this requirement, CMS finalizes its proposal to amend relevant regulatory provisions to state that the current limit on maximum rebate amounts for drugs ends on December 31, 2023.

CMS OUTLINES PROCESS FOR SUSPENSION OF MANUFACTURERS' MEDICAID NATIONAL DRUG REBATE AGREEMENT FOR LATE REPORTING

Section 1927(b)(3)(C)(i) of the Act permits CMS to fine and suspend manufacturers that do not timely provide price and drug product information as required for participation in the MDRP. CMS finalizes its proposal to establish a procedure whereby a manufacturer's National Drug Rebate Agreement (NDRA) will be suspended if the manufacturer fails to report this information in a timely manner. Specifically, CMS will provide written notification to the manufacturer if timely information is not provided. Failure to comply within 90 calendar days of receiving such notice will result in the agency suspending the manufacturer's NDRA for all supplied CODs. Consequently, the manufacturer's CODs will no longer be eligible for Medicaid coverage, reimbursement, or Medicaid FFP until the required information is fully reported and certified, with a minimum suspension period of 30 calendar days. Prolonged suspension may lead to termination from the MDRP. During a suspension, the NDRA will remain in effect for Medicare Part B reimbursement and the 340B Drug Pricing Program.

MANUFACTURERS' ABILITY TO AUDIT UTILIZATION DATA ON REBATE INVOICES LIMITED TO 12 QUARTERS

Section 1927(b)(2)(A) of the Act requires states to invoice manufacturers for rebates based on utilization of the manufacturer's drugs within a specific quarter no later than 60 days after the quarter ends. Subsequently, manufacturers have the option to audit state utilization data for their CODs. If there are inconsistencies on the invoice, the manufacturer can submit a Reconciliation of State Invoice (ROSI) form or a Prior Quarter Adjustment Statement (PQAS) to the state, providing explanations for any adjustments.

Currently, there are no time limits on manufacturers initiating disputes regarding state utilization data on rebate invoices. To streamline dispute resolution and resource allocation, CMS proposed to restrict manufacturers' ability to initiate audits and other processes for adjusting utilization data to within 12 quarters from the end of the quarter of the state invoice. Upon reviewing public feedback, CMS has determined referencing the invoice postmark date, rather than the date of the state invoice, offers clarity to states and Manufacturers for timeline initiation and aligns with previous policy. Thus, CMS is finalizing as proposed with the caveat of referencing "postmark date" as opposed to "the date of the State invoice."

CMS TO REQUIRE THAT STATES COLLECT NDC INFORMATION ON ALL PHYSICIAN-ADMINISTERED DRUGS

States are only required to collect utilization data and coding, such as Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Codes (NDCs), for single-source CODs or multiple-source CODs that are listed among the top 20 high-dollar volume physician-administered drugs under Medicaid. This information is required in order for FFP to be available for these drugs, and for states to collect manufacturer rebates. In this final rule, CMS finalizes its proposal to require that states collect NDC information on all covered outpatient single and multiple source physician-administered drugs. CMS also specifies that states should invoice for rebates for all covered outpatient physician-administered drugs to receive FFP and secure manufacturer rebates. CMS anticipates the administrative burden posed by these policies to be minimal, as most state Medicaid programs already require providers to report NDCs for all single- or multiple-source physician-administered drugs that are CODs.

MEDICAID MANAGED CARE PLAN CONTRACT AND BENEFICIARY CARD REQUIREMENTS MODIFIED EFFECTIVE NOVEMBER 19, 2025

Many managed care organizations (MCOs) engage subcontractors, such as PBMs, to oversee the administration of the Medicaid drug benefit. Frequently, MCOs lack visibility into the costs incurred for CODs dispensed to patients and the administrative fees paid to PBMs for managing the COD benefit. The difference between what PBMs charge MCOs for drug claims and what they pay pharmacies, known as "spread" or "spread pricing," is typically undisclosed unless mandated by a state Medicaid program or the plan itself.

To enhance transparency and accountability concerning COD payments, CMS will mandate Medicaid MCOs, prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs), covering CODs to structure contracts with subcontractors (including PBMs) responsible for delivering or managing the COD benefit to require the subcontractor to report separate amounts for:

1. Incurred claims, including reimbursement for CODs, payments for additional patient services, and fees paid to providers or pharmacies for dispensing or administering CODs; and

2. Administrative costs, fees, and expenses of the subcontractor.

CMS expects this requirement will improve state transparency regarding subcontractor costs and fees, addressing concerns about PBMs engaging in spread pricing practices that may not accurately reflect revenue in the plans' medical loss ratios.

Additionally, CMS will require states to direct Medicaid managed care plans to use a specific Medicaid Bank Identification Number/Processor Control Number (BIN/PCN) combination and group number on beneficiaries' cards. CMS believes this will ensure appropriate benefit allocation and helps prevent duplicate discounts under the 340B Drug Discount Program.

The effective date for these provisions is the first rating period for contracts beginning on or after November 19, 2025.

CMS FINALIZES POLICY REQUIRING STATES TO BASE PHARMACY REIMBURSEMENTS ON ACTUAL COSTS

To protect pharmacy access for Medicaid beneficiaries, CMS finalizes its policy on State Plan Requirements, Findings, and Assurances.[4] The finalized policy introduces important clarifications to ensure that Medicaid Fee-For-Service (FFS) reimbursements for pharmacies accurately reflect the real costs of providing prescription drugs. Under the new rules, states must use cost-based data when establishing or modifying their reimbursement formulas, which consist of two components: the ingredient cost of the drug (based on the actual acquisition cost, or AAC) and the professional dispensing fee (PDF), which covers the pharmacy's costs to dispense the drug. Importantly, these costs must be based on actual pharmacy data, not market-based research or what third-party payers reimburse. States are required to provide this cost-based data when proposing any changes to their reimbursement methodologies through the State Plan Amendment (SPA) process.

The policy also emphasizes that states must periodically review their reimbursement rates to ensure they reflect current pharmacy costs, though no specific timeline for these reviews is mandated. States are encouraged to conduct regular assessments, especially when making changes to ingredient cost reimbursements. Additionally, the policy allows for enhanced professional dispensing fees for certain drugs, such as 340B prescriptions, provided these meet federal requirements.

CMS CLARIFIES DEFINITIONS TO IMPROVE TRANSPARENCY IN THE MDRP

The final rule clarifies several key definitions to improve program administration and ensure compliance with statutory requirements. Notably, CMS updates definitions for various terms including CODs, market date, and non-innovator multiple source drug. These changes are

[4] § 447.518

designed to provide clear guidance for rebate calculations, drug classifications, and reporting requirements.

Covered Outpatient Drugs

Drugs and biologics that qualify as CODs fall under manufacturer price reporting and rebate requirements, and state Medicaid programs must cover them. However, Medicaid law excludes certain products from the "COD" definition—and from rebate eligibility—if they are provided "as part of, or as incident to, and in the same setting as" specific healthcare services. This exclusion applies only when payment can be made for the listed service or setting, and not as direct reimbursement for the drug. This means currently a product that would otherwise qualify as a COD and be subject to Medicaid rebates is excluded from the definition if it is administered in certain settings and not directly reimbursed.

To clarify the distinction between direct reimbursement for a drug and when it falls within the COD exclusion (thus subject to rebates), CMS proposed to modify the definition of "COD" to clarify what constitutes "direct reimbursement." Specifically, CMS proposed to define "direct reimbursement" as including cases where the drug and its cost are separately identified on a Medicaid claim form.

To clarify concerns raised by commenters, CMS is refining the definition of "direct reimbursement" such that in order for a payment to be considered direct reimbursement for a drug, the claim must include the charge for the drug, the number of units utilized, and the payment made to the provider must include an amount directly attributable to the drug and is based on a CMS approved reimbursement methodology. Meeting these criteria would mean the drug is considered directly reimbursed and may be subject to Medicaid rebates.

Manufacturer

Under the MDRP, states offer coverage for all CODs of a participating manufacturer in exchange for rebates. In the proposed rule, CMS initially proposed a broader definition of "manufacturer" to include all affiliated entities under a rebate agreement. This change aimed to ensure that all associated entities comply with the rebate requirements under the NDRA. However, after considering public feedback, CMS is not finalizing this change, leaving the door open for future rulemaking.

Market Date

A COD's market date is used for determining the base date AMP, Medicaid inflation rebates, and the Inflation Reduction Act's (IRA's) Medicare Part D inflation rebates. In this final rule, CMS officially defines the term "market date," for the purpose of establishing the base date AMP quarter, as the date on which the COD was first sold by any manufacturer. CMS clarifies that "sold" implies that the drug has been transferred, including during transit, to a purchasing entity. This new definition for "market date" will impact how inflation rebates may be applied to products under the MDRP and Medicare Part D.

Drug Product Information

In its proposed rule, CMS proposed a new definition for "drug product information" to comply with section 1927(b)(3)(A)(v) of the Act, which requires manufacturers to report specific information for each COD within 30 days after the end of a rebate period. The proposal aimed to standardize the data manufacturers must submit, ensuring clarity and closing loopholes in MDRP reporting.

While many commenters supported the proposal for enhancing transparency and accuracy, some raised concerns about the inclusion of data fields not explicitly mentioned in the statute. In response, CMS asserts that certain data elements, like unit type, are essential for accurate AMP calculations, even if not specifically listed in the statute. The final rule removes open-ended language such as "includes but is not limited to" to clearly delineate which data elements must be reported. Therefore, "drug product information" will now be defined as NDC, drug name, units per package size (UPPS), drug category ("S", "I", "N"), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA-approved application number or over-the-counter monograph citation (if applicable), market date, and COD status.

CMS clarifies that this new definition does not require repetitive or burdensome monthly reporting, and manufacturers need to report drug product information only once, when entering a rebate agreement or introducing a new drug.

Noninnovator Multiple Source Drugs

Noninnovator multiple source drugs, or "N drugs," were historically multiple source drugs that were either unapproved or approved under an Abbreviated New Drug Application (ANDA). CMS clarifies that that while all CODs other than "S" or "I" drugs should be categorized as "N" drugs whether or not they satisfy the definition of a noninnovator multiple source drug at §447.502, not all "N" drugs are multiple source.

In this rule, CMS updates the definition of "noninnovator multiple source drug" to align with statutory amendments. This change replaces the phrase "was originally marketed" with "is marketed," ensuring that the regulatory definition of a noninnovator drug matches the updated statutory language. The amendment helps maintain clear distinctions between innovator drugs (brand-name drugs) and noninnovator drugs (generic drugs) for rebate purposes.

Internal Investigation

MDRP regulations generally limit a manufacturer's ability to restate AMP and Best Price to a 12-quarter window, unless under specific circumstances, which include restatements as a result of an internal investigation. In this final rule, CMS finalizes a formal definition for "internal investigation" to provide clarity on situations where manufacturers can revise drug pricing data beyond the standard 12-quarter reporting limit. The new definition specifies that revisions are permitted if the pricing change relates to potential fraud, abuse, or violations of law uncovered

during internal investigations. This clarification is important for consistent reporting and compliance, allowing manufacturers to correct pricing data when necessary.

Vaccine

Vaccines are currently excluded from the definition of COD and from Medicaid rebate liability. As there is no statutory or regulatory definition of vaccine, CMS initially proposed a specific more limited definition of "vaccine" for the MDRP which defined vaccine to mean a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States. This proposed definition would have excluded therapeutic vaccines and was intended solely for the MDRP and was not meant to apply to other federal programs such as the Vaccines for Children (VFC) Program. However, CMS has decided not to finalize this definition at this time, pending further review and potential future rulemaking.

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