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Medicaid Benefits and Health Programs Group

July 24, 2025

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 121**

For Manufacturers

The Centers for Medicare & Medicaid Services (CMS) is issuing this Manufacturer Release to provide additional guidance on items contained in the Medicaid Program's "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" final rule (CMS-2434-F), 89 FR 79020 (September 26, 2024) (Final Rule). The Final Rule's effective date was November 19, 2024.

Definition of Covered Outpatient Drug

In this Release, CMS is providing additional guidance on the definition of Covered Outpatient Drug (COD) and the clarifications provided to that definition in the Final Rule. In the Final Rule, we modified the definition of COD to clarify the term "direct reimbursement," which is contained in the statutory and regulatory definitions of COD. The statute references "direct reimbursement" but does not define it. In section 1927(k)(3) of the Social Security Act (the Act), the term COD does not include any drug, biological product, or insulin provided as part of, or incident to, and in the same setting as, any of the listed services for which payment may be made under Title XIX as part of payment for those services and not as direct reimbursement for the drug.

In the Medicaid Program's "Covered Outpatient Drug" final rule with comment (CMS-2345-FC), 81 FR 5170 (February 1, 2016) (2016 COD Final Rule), we finalized a regulatory definition of COD that substantially mirrored the statutory definition. The relevant portion is as follows:

> A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug): (i) Inpatient Services; (ii) Hospice Services; (iii) Dental Services, except that drugs for which the state plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs; (iv) Physician services; (v) Outpatient hospital services; (vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities; (vii) Other

laboratory and x-ray services; or (viii) Renal dialysis.

As we noted in the preamble of the Final Rule, stakeholders have raised questions and concerns regarding the statutory and regulatory definition of a COD, particularly concerning when a payment is considered to be a direct reimbursement for a drug. This issue has become increasingly relevant for drugs that are included on inpatient and outpatient hospital claims. Recent implementation of newer reimbursement methodologies has prompted questions about whether the drugs reimbursed through these new methodologies are CODs. Given these concerns, CMS determined it was important to clarify the portion of the statutory definition of COD related to direct reimbursement.

In the Final Rule, we added paragraph (4) to the definition of COD in 42 CFR 447.502 to define direct reimbursement to be (i) reimbursement for the drug alone; or (ii) reimbursement for a drug plus the service in a single inclusive payment if:

(A) the drug, charge for the drug, and number of units of the drug are separately identified on the claim, and
(B) the inclusive payment includes an amount directly attributable to the drug, and
(C) the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the state plan.

CMS provided clarification in the preamble about the distinction between direct reimbursement and bundled payments. CMS further notes that there is a distinction between those reimbursement methodologies that incorporate the cost of the drug into the final payment amount (which includes outpatient hospital payment methodologies such as Enhanced Ambulatory Patient Group [EAPG]-like methodologies), which can qualify as a direct reimbursement, and those bundled payments where the cost of the drug is not a direct component of the final payment (such as inpatient hospital Diagnosis-Related Group [DRG] models). In other words, "not directly reimbursed" in the context of bundled rates means not separately identified or itemized with an amount associated with payment for the drug.

This clarification aligns with previous Office of Inspector General (OIG) findings. On October 22, 2020, the OIG published its audit of the Massachusetts Executive Office of Health and Human Services to determine whether Massachusetts complied with Federal Medicaid requirements related to invoicing manufacturers for rebates for physician-administered drugs.[1] By reviewing claims for physician-administered drugs in 2016 and 2017, OIG determined that Massachusetts did not always comply with requirements related to invoicing manufacturers for rebates for physician-administered drugs. Specifically, the audit found that the state did not invoice for rebates for physician-administered drug claims identified as hospital outpatient. Massachusetts had transitioned to a new hospital outpatient payment methodology in 2016, which was the adjudicated payment per episode of care (APEC) methodology. The OIG

[1] Office of Inspector General (2020, October). Massachusetts claimed unallowable federal reimbursement for some Medicaid physician-administered drugs. https://oig.hhs.gov/reports/all/2020/massachusetts-claimed-unallowable-federal-reimbursement-for-some-medicaid-physician-administered-drugs/#:~:text=What%20OIG%20Found,)%20in%20physician%2Dadministered%20drugs

determined that drugs paid through this methodology met the definition of CODs and that manufacturers should be invoiced for these drugs.

For physician-administered drugs reimbursed using the APEC or the EAPG methodology, there are typically identifiable amounts attributable to drugs and other components within a payment for an episode of care. Drugs reimbursed through these kinds of methodologies therefore provide sufficiently identifiable reimbursement amounts attributable to those drugs to qualify as direct reimbursement; as such they are CODs and rebate-eligible, and states should invoice manufacturers for these drugs.

By contrast, the final reimbursement for the drugs in the DRG methodology typically is not separately identified and the final reimbursement for the patient's care does not vary based on which drugs are administered. In those situations, the drugs reimbursed through this methodology do not meet the definition of direct reimbursement.

If a single payment is made for a service that includes a drug (bundled payment), and that drug would have otherwise satisfied other portions of the definition of COD, that drug would not be eligible for a rebate because it was not directly reimbursed. However, "direct reimbursement" for a drug would include a single payment to a provider when the provider's claim identifies the drug and an amount directly attributable to the drug and such arrangements are therefore eligible for a rebate.

States may also employ payment methodologies that include an outlier payment for inpatient and/or outpatient services. For example, a state may use a methodology in which, if the payment for an inpatient stay exceeds the standard cost by a certain threshold or the patient stay extends beyond a certain number of days, an outlier payment may be triggered. In these situations, additional services and costs are typically not separately identified. Rather, there may be a percentage of the total additional costs that is paid to the provider. In this situation, the drug is not sufficiently identified, nor is the outlier payment directly tied to the cost of the drug in a way that the payment would be considered a direct reimbursement for the drug. If states structured an outlier payment that was directly tied to the cost of the drug and met all other requirements for outlier payments, this might be sufficient to be considered direct reimbursement for the drug.

CMS also notes that there are states that already carve out drugs from inpatient and/or outpatient hospital claims for separate payment and acknowledge that these drugs would constitute direct reimbursement. States can pay for these drugs using their pharmacy reimbursement methodologies or other methodologies, as long as they are detailed in the state plan and result in an amount paid that is directly attributable to the drug.

Manufacturers must pay rebates to the states for CODs, including those that are directly reimbursed as outlined in this Release.

Definition of Market Date

Prior to the Final Rule, CMS provided guidance and instruction to report the market date for S (single source), I (innovator multiple source), and N (noninnovator multiple source) drugs marketed under a U.S. Food & Drug Administration (FDA) approved application as the earliest date the drug was first marketed, or first available for sale, under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the market date was to equal the market date of the original product.

In the Final Rule, CMS finalized a regulatory definition of market date as the *date on which the covered outpatient drug was first sold by any manufacturer*. The purpose of the market date is to establish the base date Average Manufacturer Price (AMP) quarter.

While the Final Rule established a regulatory definition for market date, the concept of the market date, as used for the establishment of the base date AMP quarter, is not new. The market date must be tracked back to the drug, dosage form, and strength of the product, as well as when it was first sold by any manufacturer. The only change to the determination of market date from previous guidance is that , manufacturers should now use the date that the drug was first sold by any manufacturer as the market date instead of using the date that the drug was first available for sale.

If a market date is established by an earlier marketed drug, a Purchased Product Date (PPD) may be appropriate. The PPD field is only required in certain situations. A PPD is the date on which the company currently holding the legal title to the NDC first marketed the drug under their labeler code. However, the PPD field is only required when the drug was previously marketed under a different labeler code. This situation may occur, for example, due to the purchase of a drug by one company from another company, the re-designation of an NDC from one labeler code to another within the same company, or cross-licensing arrangements. If a PPD is provided in the PPD field, the manufacturer will owe quarterly pricing data to CMS beginning with the quarter in which the PPD falls. A PPD should never be the same date as the market date.

Several earlier manufacturer program releases addressed the effect of the market date for N drugs at the time the additional inflation-adjusted rebate requirement became effective for N drugs. See Manufacturer Release No. 97, Manufacturer Release No. 101, and Manufacturer Release No. 106. Additional information may also be found in the Medicaid Drug Rebate Data Guide accessed through a link on the bulletin page in the Medicaid Drug Programs (MDP) application.

As noted in those releases, manufacturers may report a market date using reasonable assumptions. If the market date of a drug is reported using reasonable assumptions and there have not yet been sales, there may be no actual data to use to calculate an AMP. In this case, when price reporting is due at the end of the month, the manufacturer should advance the market date to report the market date as one month later than the originally reported date. Advancing the date by one month should be done every month until the date of the first sale of the drug. This will prevent MDP from expecting pricing data for a month and quarter in which there have been no sales. Once the first sale has occurred, the market date should be updated one final time to

reflect the actual date of the sale and the associated pricing data should be submitted. Also, as noted in the Final Rule, sales used to establish the market date of a drug are not limited to AMP-eligible sales. The first date of sale, and therefore the market date, does not depend on what entity is making the purchase.

When a manufacturer makes an initial request to enter into a Medicaid National Drug Rebate Agreement (NDRA), they provide CMS with much of the drug product information for their NDCs, including the market date and, if applicable, the PPD. CMS understands that if the drug has never been marketed by any manufacturer prior to the request for a new NDRA, the market date for the purpose of determining the base date AMP may not yet be established. In such cases, the manufacturer should report the anticipated market date when requesting a new NDRA. This information can be updated as needed if the actual date differs from the reported anticipated date.

For drugs that were certified in the MDP application prior to the effective date of the regulatory definition, manufacturers are not required to change an established market date if that date was established based on the date the drug was first available for sale, rather than the date on which it was first sold, to comply with the new regulatory definition. However, if a manufacturer misreported a market date for any NDC in the MDP application by reporting the date they began marketing the drug, instead of reporting the date the drug was first marketed by any manufacturer, they must correct the market date to establish the correct base date AMP quarter and provide the required pricing for that quarter.

As a reminder, once certified, a market date that is more than three years in the past may not be changed without CMS review and approval. If a manufacturer identifies a market date that needs to be changed and the date is more than three years in the past, the manufacturer should follow the instructions in the Medicaid Drug Rebate Program Change Request process.

CMS encourages manufacturers to evaluate the reported market date for all their NDCs and submit a change request if they determine that a change is required to correct previously reported inaccurate data. 42 CFR 447.502 includes market date in the definition of drug product information and 42 CFR 447.509(d)(1) includes that misclassification occurs when a manufacturer has reported inaccurate drug product information. 42 CFR 447.509(d)(2) states that if CMS determines that a misclassification has occurred, we will send a notification to the manufacturer, after which the manufacturer has 30 calendar days to correct the misclassification and report and certify the corrected information. As described in section 1927(c)(4)(B)(ii) of the Act, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency that the drug is misclassified, CMS has the authority to take any or all of the following actions: (1) correct the misclassification, using drug product information provided by the manufacturer, on behalf of the manufacturer; (2) suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from Federal Financial Participation (FFP); and, (3) impose a civil money penalty (CMP) for each rebate period during which the drug is misclassified subject to certain limitations. The Act expressly provides that the

imposition of such penalties shall be in addition to other available remedies, such as termination from the Medicaid Drug Rebate Program (MDRP), or CMPs under Title XI.

12-Quarter Rebate Audit Time Limitation

Effective November 19, 2024, the Final Rule at 42 CFR 447.510(i) limits the time period during which manufacturers may initiate disputes, hearing requests, or audits of state-invoiced utilization units to 12 quarters from the last day of the quarter in which the state invoice postmark date occurs. CMS explained in its Response to Comments that manufacturers should, within 12 quarters from the invoice postmark date, initiate a dispute, hearing or audit of a state invoice for any disputes that may arise regarding 340B duplicate discounts. This time limitation was finalized to help ensure that discrepancies are identified and resolved, thereby promoting the efficient operation of the MDRP. The limitation applies to all newly initiated rebate disputes, hearings, or audits, regardless of when the claim was processed. However, any claim currently in the dispute resolution process would not be affected by the finalization of this provision. With respect to the audit authority, we clarified that it is intended to refer to any process a manufacturer is using to seek an adjustment to utilization data under section 1927(b)(2)(B) of the Act. That audit authority encompasses many processes for seeking adjustments in utilization data, including assessments and reviews, and may involve paper procedures, informal phone calls, and emails or other mechanisms. This provision is intended to provide a 12-quarter timeline for any of those processes that result from a manufacturer seeking an audit.of the state's drug utilization data.

Under the 12-quarter time limit, a manufacturer may only initiate a dispute, request a hearing, or seek an audit of a state regarding state drug utilization data during a period not to exceed 12 quarters from the last day of the quarter in which the postmark date of the state invoice occurs. Thus, upon receipt of a quarterly invoice, the period for manufacturers to initiate audits, request hearings or initiate disputes concerning state drug utilization data begins on the last day of the quarter in which the state invoice's postmark date occurs.

After publication of the Final Rule, CMS received requests for clarification regarding how ongoing disputes that were started more than 12 quarters ago should be treated if the state newly adds more units to the dispute. We clarify that if the state changes units on an invoice, this adjustment will restart the 12-quarter clock, but only for the specific NDC where the units were modified, not for the entire invoice. We believe that the 12-quarter time limit should continue to apply to any existing disputes and the addition of new units should not result in an exception to this 12-quarter time limit requirement for the existing units. As all disputes must be resolved on a unit basis only, changes to the invoice based on modifications to the unit rebate amount (URA) or any other factor would not qualify for an exception to restart the 12-quarters clock. CMS also received a request to clarify what happens if a state invoices for a new rebate for units on a claim that is more than three years old. If it is a new rebate invoice, the manufacturer may audit and dispute the units even if the claim is more than three years old.

The time period to initiate an audit or a dispute ends 12 quarters after the last day of the quarter in which the postmark date occurs. For electronic invoicing via email, CMS considers the postmark date to be the date on which the email is sent. Similarly, when a state sends an email

with the invoice attached, then the postmark date is the date on which the email is sent. For example, if the email was sent in the fourth quarter of 2024, then the time period to initiate an audit or dispute ends 12 quarters after the last day of the fourth quarter of 2024, which would be the last day of the fourth quarter of 2027. Importantly, we also noted that while all audits and disputes must be initiated within the 12-quarter time period, they do not need to be resolved within this timeline. CMS recognizes that in certain instances, the resolution of a dispute may extend beyond this time period, and in the Final Rule, we clarified that we are not requiring that disputes be resolved within this 12-quarter time period.

CMS continues to believe that manufacturers and states need to communicate as soon as possible on suspected drug unit issues to prevent and resolve disputes, preferably even before rebates are due. As stated in the NDRA, both the state and the manufacturer are expected to use their best efforts to resolve a dispute within a reasonable timeframe after the state's receipt of the manufacturer's Reconciliation of State Invoice (ROSI) or Prior Quarter Adjustment Statement (PQAS). Manufacturers and states need to work in partnership to resolve outstanding units in dispute. The prompt notice of disputes should encourage states to resolve these issues in a timely manner.

If you have any questions or concerns regarding this release, please contact CMS at RxDrugPolicy@cms.hhs.gov.

Sincerely,

/s/

Melissa Harris
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