

Center for Medicaid and CHIP Services

June 29, 2017

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 105

For

Participating Drug Manufacturers

The following release details specific Medicaid drug rebate program operational issues and guidance that are important to manufacturers and states.

First, this release ensures manufacturers are apprised of the same information and guidance that was issued to states through State Release #181, including: 1) information on the notification process for suspected errors in manufacturer-reported covered outpatient drug pricing data and unit of measure information; and 2) the Center for Medicare and Medicaid Services' (CMS's) request for state assistance with identifying nonresponsive manufacturers and delinquent rebate payments.

Second, this release provides manufacturers with the following operational guidance: 1) reminds manufacturers about the threshold for Medicaid drug rebate write-offs; 2) reminds manufacturers of the State Hearing mechanism option available to states and manufacturers when dispute resolution has ceased to be productive; 3) provides information on edits to existing adjustment/dispute codes reported on the Reconciliation of State Invoice (ROSI) and the Prior Quarter Adjustment Statement (PQAS); and 4) reminds manufacturers that managed care organization (MCO) invoicing is to be based on date of service (DoS) beginning with 3Q2017 invoice.

1. Notification Process for Suspected Errors in Manufacturer-Reported Covered Outpatient Drug Pricing Data & Unit of Measure Information

The following item was included in State Release #181 regarding reporting suspected manufacturer unit of measure product data reporting errors.

Occasionally, the CMS receives notifications from states that a national drug code's (NDC's) calculated unit rebate amount (URA) derived from manufacturer-reported pricing and product data, and/or the manufacturer-reported unit type and units per package size (UPPS) data fields, collectively referred to as the unit of measure (UOM), appear to be incorrect. For example, a state may compare the amount of total reimbursement by Medicaid plus any applicable third-party payers to the total amount of rebate owed (by multiplying the state's rebate units by the URA). When the result of such a comparison seems atypically low or high compared with the state's historical experience for rebates, states have notified CMS and/or the manufacturer of the discrepancy in various ways (e.g., by emailing requests to CMS to explore the issue, forwarding

email communications from manufacturer inquiries to CMS, calling CMS, calling manufacturers, etc.).

Effective immediately, in order to keep a record of each inquiry and to promote better efficiency, we are requesting that suspected errors of the nature described above be emailed to the state's manufacturer contact, with a copy to CMS at mdoperations@cms.hhs.gov. We advise that, if the state's manufacturer contact is not the manufacturer's technical contact (TC), the state should copy the TC on the email as well because CMS's communications about manufacturer-submitted data must include the TC. Manufacturer's technical contact information can be found at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> under the Contact Information. The list of technical contacts is updated on quarterly basis. Whenever possible, we encourage states to include details and examples within such emails, while also being mindful to encrypt any sensitive or confidential data. Copying CMS will make us aware of these suspected errors so that we can follow up, if necessary. If you have any questions regarding this information, please email mdoperations@cms.hhs.gov.

2. Nonresponsive Manufacturers and Delinquent Rebate Payments

CMS has recently received several communications from states regarding manufacturers that have been nonresponsive to repeated requests regarding outstanding rebate payments and applicable interest. In accordance with section 1927(b)(1) of the Social Security Act and the terms of the Medicaid National Drug Rebate Agreement (NDRA), manufacturers are required to calculate and pay quarterly rebates to states to offset some of the cost of the covered outpatient drugs that each state paid for during the invoiced quarter/year. The NDRA states that, within 30 days of receiving a quarterly invoice, manufacturers should provide written notification to states if they are disputing some or all of the units included on the invoice. Manufacturers that fail to pay rebates or appropriately dispute utilization within 60 days of receipt of a state invoice are considered to be in violation of the NDRA. Such violations, if not rectified, may lead to the manufacturer's termination from the Medicaid Drug Rebate Program and/or other penalties.

In order to assist the states with outstanding rebate payment issues, and if necessary, to take appropriate compliance actions against those manufacturers that are in violation of the NDRA, CMS issued guidance in State Release #181 that requests states to provide us with information and supporting documentation regarding each instance of delinquent rebate payments. Such information could include, for example, a timeline of the state's communication attempts with the delinquent manufacturer, documentation of any responses received from the manufacturer, and total amounts of unpaid rebates.

Upon receipt of a state request for assistance regarding outstanding rebate amounts, CMS will review the supporting documentation provided and take steps (including compliance action, if necessary) to address the violations with the delinquent manufacturer.

If you have any questions regarding the process for addressing outstanding rebate payments and unresponsive manufacturers, please feel free to contact us at mdoperations@cms.hhs.gov.

3. Threshold (Write-off) Reminders for Medicaid Drug Rebate

CMS would like to remind both manufacturers and states of the current thresholds regarding drug-rebate write-offs for cases in which states are unable to collect rebates from manufacturers.

Please note that there are different thresholds depending upon whether the uncollected rebates were officially disputed and the disputes were never resolved, or whether the uncollectable rebates were invoiced, never paid, and also never disputed by the manufacturers.

- For disputes, [State Release #19](#) mentions that states do not need to pursue further dispute resolution with a manufacturer if the disputed amount in any quarter is less than \$10,000 per manufacturer, and less than \$1,000 per product code, and further dispute attempts would not be cost-effective. States may also want to consider the cost-effectiveness of a state hearing in such situations, per section V(c) of the NDRA and 42 CFR §447.253(e).
- For uncollected rebate invoicing, [State Release #19](#) notes that states should not invoice manufacturers for rebate amounts that are less than the administrative costs associated with preparing a quarterly invoice (i.e., rebate amounts of \$10 or less). [State Release #45](#) later increased this rebate threshold to \$50 per labeler code per quarter, and also stated that the threshold could be applied to utilization changes for any quarter's invoice.

As always, CMS expects manufacturers and states to work in partnership to resolve outstanding units in dispute, and we encourage either party to reach out to the CMS Dispute Resolution Program (DRP) Team at DRP@cms.hhs.gov for any dispute-related issue with which they may need assistance.

In addition, states are encouraged to notify CMS of any active manufacturers with outstanding uncollected rebate amounts (i.e., those that are not in dispute and have never been paid) that have not responded to the state's attempts to collect such rebates and interest. Such notifications can be sent via email to the MDR Operations team at MDROperations@cms.hhs.gov.

4. Reminder: State Hearing Mechanism Option Available

As a reminder, under Section V of the NDRA (in accordance with 42 CFR §447.253(e)) states can make a state hearing mechanism available to the manufacturer. Most manufacturers and states prefer to engage in the dispute resolution process; however, the state hearing option is available to both states and manufacturers when they have reached an impasse through the normal dispute resolution process, or when one of the parties is not being responsive to another's efforts to engage in dispute resolution. Therefore, we have issued State Release #181 to states recommending that states make manufacturers aware of what the process is to request such a hearing in the state as the processes will likely vary by state.

Once a hearing has taken place and a finding is issued, states and manufacturers are expected to act in accordance with the finding. For example, one state recently shared with CMS that it opted to invoke its hearing mechanism option, and that the finding was decided in the state's favor with respect to the rebates that had previously been in dispute. After the decision was issued that all rebates formerly in dispute were to be paid to the state, the manufacturer was expected to pay the rebates and any applicable interest; otherwise, the manufacturer risked being out of compliance under the terms of the NDRA. Such non-compliance may subject the manufacturer to potential termination from the Medicaid Drug Rebate Program; therefore, we urge both states and manufacturers to comply with any decision issued via the state hearing mechanism. Please contact DRP@cms.hhs.gov if you have any questions.

5. Updates/Additions to Existing Adjustment/Dispute Codes Reported on the Reconciliation of State Invoice (ROSI) and the Prior Quarter Adjustment Statement (POAS)

When completing the ROSI (form CMS-304) or the PQAS (form CMS-304a), manufacturers must enter the appropriate code(s) to explain any adjustments and/or disputes, as necessary. It was brought to CMS's attention that a few scenarios were not adequately represented with the current adjustment/dispute codes, so we are providing the following clarification and (where applicable) revisions in order to address those situations.

First, low utilization/rebate billing is not being recognized and disputed nearly as much as high utilization/rebate billing. In either case, manufacturers should identify suspected utilization errors and work with states to correct the cause of the under- or over-billing (i.e., unit of measure issues, such as milliliter (ML) vs. Each, decimals vs. whole numbers, etc.). Note: There is no limit on the timeframe for updating and correctly paying on under-billed rebates; therefore, CMS strongly encourages states and manufacturers to review quarterly utilization to identify such understated and overstated utilization discrepancies. We have highlighted some of the current dispute codes that could be used in identifying high or low rebate units:

- C.** Units invoiced adjusted through mutual agreement between labeler/state. Adjustments to be reflected to labeler and in utilization reporting to CMS.
- D.** Unit Type and/or Units Per Package Size (UPPS) reported on state invoice is different than unit of measure (UOM) reported to CMS by labeler for NDC. Labeler and state to follow up to discuss the need for conversions prior to rebate invoice billing or labeler change in reported UOM.
- E.** State is invoicing a decimal value for whole number value (UPPS) reported by labeler.
- Q.** Utilization/quantity is inconsistent with the number of prescriptions.
- R.** Utilization/quantity is inconsistent with pharmacy reimbursement levels, including Third Party Payments. (This dispute code should be used in conjunction with another code or other supporting documentation.) *
- S.** Utilization/quantity is inconsistent with state historical trends or current state program information. (Documentation should include trend/program information.) *
- T.** Utilization/quantity is inconsistent with lowest dispensable package size.

A complete listing of the Adjustment/Dispute Codes (also located in the Drug Data Reporting for Medicaid (DDR) system's State & Labeler Data Guides) is attached to this release; however, we have also highlighted some specific changes in bold below, and provided a reason for each change:

Change #1: J. No state reimbursement reflected on claims level detail. **(Fee for Service only)**

Reason: Managed care utilization/claim level detail may or may not reflect any state reimbursement; therefore, zero may be a valid value to report in these fields at the time the drug is dispensed.

Change #2: N. Discontinued/terminated NDC for which the shelf life expired more than one year from the dispense date. (Documentation should support dispensed date.) **Note:** Since 2Q2014, per **Manufacturer Release #91 and State Release #168**, **manufacturers that report retroactive termination dates cannot dispute utilization of a terminated product until after the quarter in which they reported the retroactive termination date.** *

Reason: We became aware that some manufacturers were retroactively submitting product termination dates and then requesting credits from states for rebates that were paid prior to the submission of the retroactive termination date. Guidance addressing this situation (Manufacturer Release #91/ State Release #168) may be found in its entirety on Medicaid.gov at <https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html>.

We are adding a new adjustment code:

Y. State-invoiced managed care organization (MCO) claims based on date of payment (DoP) rather than date of service (DoS). (This adjustment code to be used only for MCO utilization beginning 3Q2017 or later. The labeler should pay using the URA that applies to the suspected date of service, such as the preceding quarter, and should request claim-level data (CLD) from the state in order to apply claims to the correct invoice period and close outstanding balances.)

Please email DRP@cms.hhs.gov if you have any questions.

6. Reminder of MCO Invoicing to be Based on Date of Service (DoS) Beginning with 3Q2017 Invoice and Use of New Adjustment Code

In [Manufacturer Release #100](#), CMS noted the requirement for states to begin to reflect invoicing for MCO utilization using the DoS rather than date of payment (DoP). As the 3Q2017 invoice cycle approaches, CMS encourages manufacturers to become familiar with each state's logic for reversals, rebills, etc., that go back to quarters prior to the state's transition to DoS invoicing in order to avoid disputes on valid claims that may appear to be duplicate billing. CMS has also issued State Release #181, which encourages states to share their logic with manufacturers, as well as the quarter that DoS invoicing was implemented in the state.

Should a manufacturer reasonably believe that a state is not submitting rebate invoices beginning 3Q2017 based on DoS, the previous item in this release introduces a new adjustment code to change the URA manufacturers use to pay MCO utilization to a previous quarter's URA. Some manufacturers and/or their invoice/dispute agents have made inquiries about disputing on the

* Supporting Documentation REQUIRED. Note: Some adjustment/dispute codes are specifically noted to require supporting documentation; however, supporting documentation can always be submitted, even for those instances where it is not specifically mentioned in this document.

basis of a state not using the DoS for MCO utilization. CMS reminds manufacturers that disputes must be unit-based, so for a manufacturer to pay nothing when units are not in dispute is not a valid dispute and will be considered to be non-payment of rebates, which is a violation of the Medicaid NDRA.

If you have further questions regarding the MCO DoS policy, please contact RxDrugPolicy@cms.hhs.gov. Please email MDRUtilization@cms.hhs.gov if you have any questions regarding use of the adjustment code.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group

Attachment 1***7.10.4 Adjustment and/or Dispute Codes for ROSI (Form CMS-304) and/or PQAS (Form CMS-304a)***

- A. Unit rebate amount (URA) has been revised by labeler and reported to CMS, as required.
- B. Labeler has calculated URA and/or rebate where none (a zero URA) was reported by state.
- C. Units invoiced adjusted through mutual agreement between labeler/state. Adjustments to be reflected to labeler and in utilization reporting to CMS.
- D. Unit Type and/or Units Per Package Size (UPPS) reported on state invoice is different than unit of measure (UOM) reported to CMS by labeler for NDC. Labeler and state to follow up to discuss the need for conversions prior to rebate invoice billing or labeler change in reported UOM.
- E. State is invoicing a decimal value for whole number value (UPPS) reported by labeler.
- F. Package size discrepancy (e.g., could include correction to package size by labeler). *
- G. Transferred NDC to another labeler code or company. (Labeler code is ultimately responsible for rebate payment.) *
- H. Utilization change from the state.
- I. URA amount adjusted through correspondence between labeler/state. USE THIS CODE ONLY when the state has reported a URA not based on the CMS file and code A is not applicable.
- J. No state reimbursement reflected on claims level detail. (Fee-For-Service only)
- K. J-Code to NDC crosswalk requires validation data (e.g., crosswalk to products with multiple NDCs and/or package sizes). *
- L. Generic Substitution.
- M. Duplicate claim.
- N. Discontinued/terminated NDC for which the shelf life expired more than one year from the dispense date. (Documentation should support dispensed date.) **Note: Since 2Q2014, per Manufacturer Release #91 and State Release #168, labelers that report retroactive termination dates cannot dispute utilization of a terminated product until after the quarter in which they reported the retroactive termination date.** *
- O. Invalid/miscoded NDC.
- P. State units invoiced exceed unit sales. (Documentation should include supporting methodology and data source.) *
- Q. Utilization/quantity is inconsistent with the number of prescriptions.
- R. Utilization/quantity is inconsistent with pharmacy reimbursement levels, including Third Party Payments. (This dispute code should be used in conjunction with another code or other supporting documentation.) *
- S. Utilization/quantity is inconsistent with state historical trends or current state program information. (Documentation should include trend/program information.) *
- T. Utilization/quantity is inconsistent with lowest dispensable package size.
- U. Product not rebate eligible (e.g., product was not reported to CMS because the product is not a covered outpatient drug, product is for a non-Medicaid state-only program, an HMO non-Fee-For-Service program, etc...). *
- V. No record of sales directly to state or state history of purchase from out-of-state provider (e.g., border pharmacies, mail order pharmacies, etc.). *

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- W. Closed out. All disputes resolved.
 - X. PHS entity not extracted from state data. (Documentation should include PHS provider number.) *
 - Y. State-invoiced managed care organization (MCO) claims based on date of payment (DoP) rather than date of service (DoS). (**This adjustment code to be used only for MCO utilization beginning 3Q2017 or later.** The labeler should pay using the URA that applies to the suspected date of service, such as the preceding quarter, and should request claims-level data (CLD) from the state in order to apply claims to the correct invoice period and close outstanding balances.

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