DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and CHIP Services

December 31, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 95**

For

Participating Drug Manufacturers

1) LABELER REQUEST FOR CLAIMS LEVEL DATA (CLD) FROM STATES

In order to resolve and prevent both fee-for-service (FFS) and managed care organization (MCO) disputes, labelers in good faith may request CLD from states. The Centers for Medicare & Medicaid Services (CMS) first addressed data sharing in State Release #108, and we continue to encourage states to respond to reasonable requests for CLD; however, it has come to our attention that some labelers are repeatedly asking for CLD for the same national drug codes (NDCs) each quarter, even though they ultimately agree to pay the amounts in dispute. We remind labelers that they should adjust (i.e., raise) their dispute thresholds once a state has provided CLD in this manner, unless a change to the state program has occurred that would reasonably affect the average utilization (e.g., expansion population or waivers, preferred drug list (PDL) changes, etc.). The CMS Dispute Resolution Program (DRP) Team continues to encourage labelers to share with states, upon request, the methodology applied to their dispute thresholds.

Similarly, labelers have brought to our attention that some states are reluctant to provide CLD, and/or provide responsive data elements to facilitate prevention or resolution, even when the labeler is acting in good faith. In a release to states, CMS continues to encourage states to provide reasonable CLD to further dispute resolution.

Any questions regarding this issue can be directed to the respective Regional Office DRP Coordinator, found on Medicaid.gov at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/rodrpcoordinators060113.pdf, and the Central Office DRP Team at drp@cms.hhs.gov.

2) DISPUTE RESOLUTION PREVENTION AND RESOLUTION-REMINDERS

The DRP Team would like to remind labelers to engage in dispute prevention and to work together with states to resolve disputes timely. State Release #168 and Manufacturer Release #91 provide dispute guidance on NDCs with retroactive termination dates. CMS

reiterates the information in State Release #55; that all disputes must be resolved on a unit basis, rather than on a monetary amount, percentages, or any other factor. State Release #156 and Manufacturer Release #82 remind labelers and states of the correct reporting of unit types and units per package size (UPPS). It is important for labelers to report this data correctly, and for states to communicate with labelers when the reported unit type and/or UPPS is incompatible with the units they are receiving from their providers. Labelers and states need to communicate as soon as possible on suspected unit of measure issues in order to prevent and resolve disputes. Labelers should provide states with conversion factors on those NDCs that require conversion before rebate billing occurs.

Any questions regarding this issue can be directed to the respective Regional Office DRP Coordinator, found on Medicaid.gov at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/rodrpcoordinators060113.pdf, and the Central Office DRP Team at drp@cms.hhs.gov.

3) CIVIL MONETARY PENALTY (CMP) ON DRUG PRICING REPORTING BY THE OFFICE OF INSPECTOR GENERAL (OIG)

The OIG has resolved CMP cases through a settlement agreement with certain drug manufacturers, and this information can be found on the OIG's website at http://oig.hhs.gov/fraud/enforcement/cmp/index.asp

4) REPORTING REQUIREMENTS REMINDER

We would like to remind manufacturers of the following reporting requirements:

- Report monthly and quarterly data timely, i.e., within 30 days of the end of a month/quarter.
    - In the event that quarterly pricing on one or more NDCs is reported late, the manufacturer must calculate the Unit Rebate Amount and pay rebates based upon the state invoice.

- Review product data for accuracy before reporting to Drug Data Reporting (DDR) system to prevent apparent errors.
    - If data is submitted via file transfer, manufacturers should always review the Edit Report that is generated in response to the data submitted (reports are available in DDR via the "File Transfer" tab and then "File Processing Reports").

- Report accurate and timely termination and reactivation dates
    - Manufacturers should report product Termination Dates accurately and timely (e.g., as soon as possible after the date that the drug was withdrawn from the market or as soon as the drug's last lot expiration date is known) in order to avoid reporting retroactive product Termination Dates.
    - If a manufacturer fails to report the Termination Date timely, manufacturers should not ask for credits or dispute state utilization on the basis that the NDC

  - was terminated if that utilization occurred prior to the date that the retroactive Termination Date was reported. See Manufacturer Release #91 for more information. Manufacturers should not enter a product Termination Date if an NDC should be deleted from the Medicaid Drug Rebate (MDR) program altogether. In those cases, manufacturers should contact us at mdroperations@cms.hhs.gov to request deletion.
  - If an NDC was not actually terminated, manufacturers should **not** report a Reactivation Date that falls one day after the product Termination Date; rather, remove the originally reported product Termination Date altogether via DDR.

- Communicate with regulatory department to ensure that only covered outpatient drugs are reported for inclusion in the MDR Program and that the product data reported are accurate.

The state and manufacturer releases referenced in this document may be found on our website at: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html. If you have any questions regarding this release, please send them to mdroperations@cms.hhs.gov.

/s/
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