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

October 30, 2017

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 107**

For Participating Drug Manufacturers

This release provides the information that was included in State Release No. 184 pertaining to the use of the Centers for Medicare & Medicaid Services' (CMS's) drug product data to determine drug coverage by states under the Medicaid Drug Rebate (MDR) Program.

In addition, this release provides manufacturers with the following operational guidance: 1) reminds manufacturers of the requirement for timely submission and certification of pricing data; 2) reminds manufacturers of the process for submitting change requests; and 3) provides a comprehensive list of CMS's resource mailboxes and their uses to ensure the questions and concerns are routed to the correct resource.

Use of CMS's Drug Product Data to Determine Drug Coverage by States Under the MDR Program

CMS is aware that there are many external sources of drug product data available to stakeholders for use in determining whether a drug is a covered outpatient drug. However, those sources may contain conflicting information as compared to CMS's drug product data. While the external data sources may be a valuable tool in administering a state's Medicaid drug program, we remind states that CMS's drug product data takes precedence when there are conflicts. Drug product data reported to the Drug Data Reporting for Medicaid (DDR) system is submitted to CMS by manufacturers participating in the MDR Program and the drug product data file can be found on Medicaid.gov at https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data. Manufacturers are required to certify the accuracy of the drug product data they report monthly and quarterly, as well as when any update is made.

This information reinforces previous guidance provided to states concerning the utilization of drug product data from CMS for the purposes of the MDRP. CMS previously provided guidance in State Release No. 130 (April 30, 2004), State Release No. 137 (May 13, 2005), State FAQs in Manufacturer Release No. 69 (May 13, 2005), and in the Covered Outpatient Drug final rule with comment period, 81 Fed. Reg. at 5189, regarding the use of product data from external compendia for the purposes of the MDR Program.

We remind states that CMS's drug product data should be the primary source of information used in developing a state's drug file. States are responsible for operating their programs in accordance with the requirements of the MDR Program. States have flexibility to use external compendia to supplement the information provided by CMS. However, utilizing data from external compendia that conflicts with drug product data reported to CMS may result in a state inappropriately administering its program, such as, providing coverage of products that do not meet the statutory definition of a covered outpatient drug, or, in the denial of coverage for drugs that do meet the statutory definition of covered outpatient drug, and for which coverage is required.

Additionally, CMS's drug product data should be the primary source of information for prescription drug coverage provided to all Medicaid beneficiaries, whether they receive their prescription drug coverage via fee-for-service or Medicaid managed care.

If a state questions the accuracy of manufacturer-certified drug product data, we encourage the state to reach out to the manufacturer to clarify the information that was provided to CMS and copy CMS at MDROperations@cms.hhs.gov so that we are aware of these suspected errors and we can follow up with the manufacturer, if necessary.

If you have any questions regarding this topic, please contact MDROperations@cms.hhs.gov.

Timely Submission and Certification of Pricing Data

Recently, CMS has noticed an increased number of manufacturers who have reported their monthly average manufacturer price (AMP) data in the DDR system by the due date but have not certified that data submission. We want to remind manufacturers that in order to comply with the timely reporting requirements found in §447.510, pricing data must not only be submitted but also certified by the due date in order to be compliance. Until the data is certified, it is not considered to be reported. If pricing data are submitted but are not certified by the due date, submission is considered late and CMS will notify the Office of the Inspector General (OIG) for possible imposition of civil monetary penalties.

Submission of Change Requests

We would like to remind manufacturers to submit all change request templates to CMS for review and processing to the Drug Policy Resource Mailbox at rxdrugpolicy@cms.hhs.gov rather than sending them to an individual staff member. This will ensure that all requests are properly tracked and routed to the correct staff member for review and processing.

Resource Mailbox Information

To determine the resource mailbox that can best address your questions or concerns, please consult the list below. We encourage you to send your inquiry only to the appropriate mailbox, and not unnecessarily send a copy to other mailboxes as it may result in a delayed response.

DDR@cms.hhs.gov
DDR System Administration

- Obtaining DDR access
- DDR Login assistance (**Not for password assistance. See Service Desk info below for password assistance.)
- Annual certifications
- Submitting 367d and 368 contact change forms for processing
- Assistance with submitting a request for a new CMS User ID and access to DDR using the EFI system

**For questions regarding EUA passwords, please call the CMS IT Service Desk at 1-800-562-1963.

DRP@cms.hhs.gov
Dispute Resolution Program (DRP)

- For states and/or manufacturers with unresolved DRP related issues that remain after first contacting the appropriate Regional Office DRP Coordinator. NOTE: The DRP pertains only to Medicaid units in dispute, and not to rate changes or unpaid rebate amounts not officially disputed.

DrugRebateAgreement@cms.hhs.gov
Drug Rebate Agreement

- Requests for new rebate agreement or reinstatement
- Request for termination of rebate agreement

DURPolicy@cms.hhs.gov
Drug Utilization Review (DUR) Program

- For inquiries regarding the Medicaid Drug Utilization Review (DUR) Survey and State Comparison/Summary Report

FUL@cms.hhs.gov
Federal Upper Limit (FUL) Program

- For states, pharmacy providers, and other stakeholders to request information regarding the FUL program.

MDRIACS@cms.hhs.gov

- Access to Medicaid Drug Rebate (MDR) state exchange mailboxes
- For states and fiscal intermediaries to request “MDR State Exchange” access in order to submit/receive their respective state drug utilization data (SDUD) files via Gentran and/or for any issues associated with their current User IDs/access for the MDR state exchange mailboxes

MDROperations@cms.hhs.gov

- For states and labelers to make URA-related inquiries and to ask operational questions about the Medicaid Drug Rebate Program and DDR (e.g., labeler questions regarding error and alert messages received in response to a data submission, state questions concerning information on a quarterly rebate file, etc.).

MDRUtilization@cms.hhs.gov
State Drug Utilization Data (SDUD) or Electronic File Transfer (EFT) Questions

- For email inquiries pertaining to the SDUD posted in the Drug Data Reporting for Medicaid (DDR) System or on Medicaid.gov, or state reporting of any EFT issues for which they need assistance.

MedicaidBPD@cms.hhs.gov
Branded Prescription Drug (BPD) Program

- For Manufacturer email inquiries pertaining to dispute prevention and data used in calculating their Medicaid Sales Fee for the Internal Revenue Service BPD Program

RxDrugPolicy@cms.hhs.gov
Medicaid Prescription Drug Programs policy questions

- For manufacturers and states to request guidance and assistance related to policy matters within the MDR Program (such as clarification on regulations and the rebate statute).
- For manufacturers to submit change requests (for example: COD Status change requests, Market Date change requests, Base Date AMP change requests, and 5i Drug Indicator change requests).
- For manufacturers to request guidance and assistance with unit type and units per package size (UPPS) reporting.

RPS@cms.hhs.gov
Survey of Retail Prices and NADAC

**For questions regarding EUA passwords, please call the CMS IT Service Desk at 1-800-562-1963.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group