DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 115**

For Participating Drug Manufacturers

Changes and Clarifications in Reporting Line Extension Fields

The final rule entitled 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 (Final Rule), published by the Centers for Medicare & Medicaid Services (CMS) in the December 31, 2020 **Federal Register** (85 Fed. Reg. 87,000), made several regulatory changes that affect how manufacturers report "line extension" drugs for purposes of the Medicaid Drug Rebate Program (MDRP) under section 1927 of the Social Security Act. Those regulatory changes went into effect on January 1, 2022, and include:

- **Definition of "line extension"** 42 C.F.R. § 447.502 (85 Fed. Reg. 87,034, 87,101)
  Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

- **Definition of "new formulation"** 42 C.F.R. § 447.502 (85 Fed. Reg. 87,044, 87,101)
  New formulation means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

- **Definition of "oral solid dosage form"** 42 C.F.R. § 447.502 (85 Fed. Reg. 87,045, 87,102)
  Oral solid dosage form means, an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

- **Requirement that only the initial drug must be an oral solid dosage form** 42 C.F.R. § 447.509(a)(4)(iii) (85 Fed. Reg. 87,034, 87,103)

In addition to the information above regarding regulatory changes made by the Final Rule, CMS is also providing information on some operational changes that will be made in the MDRP

system pertaining to line extension reporting. CMS anticipates that the changes in the MDRP system will be completed in time for first quarter (1Q2022) reporting. Manufacturers' technical contacts will receive an email from MDROperations@cms.hhs.gov with notification of the date that the system changes will be available.

The MDRP system currently prevents manufacturers from reporting a drug as either a line extension or an initial drug if the unit type identified is anything other than a *Tablet*, *Capsule*, *Gram*, or *Each*. Due to the regulatory changes made by the Final Rule, system changes will allow a drug with any unit type to be identified as a line extension for 1Q 2022 reporting. Additionally, consistent with the requirement that the initial drug must be an oral solid dosage form, the MDRP system will be updated so that a drug with a unit type of *Tablet*, *Capsule*, *Gram*, *Each*, *Millicurie*, or *Microcurie*, may be reported as an initial drug.

CMS is also making two operational changes to the system. The MDRP system will be updated to ensure that manufacturers are able to: (1) report a national drug code (NDC) as an initial drug if it is also identified as a line extension drug; and (2) report an NDC as either a line extension or an initial drug if the NDC's Covered Outpatient Drug (COD) Status is *02 - Biological License Application (BLA)*.

What you need to do:
Manufacturers should review each of your labeler's drugs to ascertain whether it is impacted by either the regulatory changes made by the Final Rule or the operational changes made to the MDRP system. Specifically, you should determine:

- Whether the drug must be identified as a line extension.

- Whether you need to request a product data override if your drug should or should not be identified as a line extension, but is currently reported otherwise (See note below.)

Manufacturers must certify all product data changes made by either you or by CMS. Until you certify an NDC's product record, you will be unable to report pricing for it.

NOTE: Line extension drug indicator (LEDI) changes may only be processed by CMS. Therefore, if your NDC requires an override, you must submit an override request (and the justification for that request) via the MDRPChangeRequests@cms.hhs.gov email resource box. Instructions and templates for requesting changes that must be implemented by CMS can be found here: Medicaid Drug Rebate Program Change Request | Medicaid.

Clarification on the Application of Interest on State Utilization Adjustments, Unit Rebate Amounts (URAs), and Prior Period Adjustments (PPAs)

It has come to our attention that some manufacturers have been interpreting our previous guidance to mean that manufacturers are not required to pay interest on adjusted rebate amounts or units. Specifically, State Release No. 121 and Manufacturer Release No. 58 (*Interest Clarification When Prior Period Adjustments (PPAs) Are Submitted*) state that, "Interest is applied to disputed or unpaid rebate amounts and late rebate payments. Interest is not applied to PPAs of unit rebate amounts or to state utilization adjustments." To clarify, while interest does

not accrue on PPAs, URAs, or state utilization adjustments themselves, such adjustments or amounts may result in updates to rebate amounts and subsequently generate rebate amounts due. If those rebate amounts due are not paid timely, interest accrues. Therefore, any data changes, regardless if they are due to pricing (e.g., PPAs / URAs) or state drug utilization updates, which result in adjustments to the original rebate amount due, should be paid within 37-days of receipt of the invoice containing the adjustment; otherwise, interest will begin to accrue on the 38th day.

Additionally, the Medicaid Drug Rebate Program Data Guide, *Section 11.6 Reconciliation of State Invoice (ROSI) (Form CMS-304)*, states that "In the event that labelers have adjusted their pricing since submitting it to CMS, resulting in a different URA than the state received from CMS, if they disagree with the utilization data submitted by states, or if they need to adjust the utilization billed on the current state invoice as agreed-upon, labelers are required to complete and submit a ROSI with their invoice payment…The ROSI is used for both unit adjustments and disputes. CMS expects labelers to pay the portion of the invoice for which there is no disagreement with the state."

Accordingly, we expect manufacturers to work with states to resolve any outstanding rebate obligations for which unpaid rebate amounts due remain. If you have any questions regarding this topic, please contact MDROperations@cms.hhs.gov.

Manufacturer Contact Information and System Access Requirements

Per Section II.(a) of the National Drug Rebate Agreement (NDRA), for each of their labeler code(s), manufacturers must identify an individual point of contact for the legal, invoice, and technical contacts at a United States address. Note that one individual may perform multiple contact functions for a manufacturer.

Additionally, under Section II.(i) of the NDRA, manufacturers must ensure that their contact information is up-to-date per the required fields on the official manufacturer contact form, OMB-approved CMS-367d (OMB Control Number 0938-0578). This is necessary in order to obtain and maintain access to the Medicaid Drug Programs (MDP) system used by the MDRP and to ensure timely reporting of Medicaid Drug Rebate Program (MDRP) data to CMS.

System access for your labeler code is managed by the technical contact, who is responsible for overseeing all other user access to your labeler code's data. Therefore, we strongly suggest that manufacturers are selective in designating an individual for this role.

CMS is aware that many manufacturers utilize third party consulting firms or other contractors to manage their participation in the MDRP. As you are aware, confidential and proprietary data are contained within the system, as are sensitive correspondence documents between CMS and states and manufacturers. Therefore, all CMS-367d submissions to update the manufacturer's contact information for a labeler code must either be submitted via email directly from the manufacturer or have written approval directly from the manufacturer before CMS can process the requested updates.

Additionally, we understand that manufacturers utilize third party consulting firms or other contractors to fulfill the technical contact role. We remind manufacturers that they should notify CMS immediately when the contract between these parties and the manufacturer is no longer in effect, so CMS can remove the 3rd party access to the confidential and proprietary data in the system. This applies to both active and terminated labeler codes of a manufacturer.

Division of Pharmacy (DP) Updated Resource Mailbox Information

Below, please find an updated listing of the Division of Pharmacy (DP) email resource mailboxes and their corresponding descriptions/specified subject(s):

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

- For inquiries regarding State DUR Reporting, DUR Annual Reports, Combatting Opioid Misuse and Abuse, Antipsychotic Medication Use in Children, State DUR Innovative Practices and DUR Guidance.

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

- The Medicaid Drug Rebate Program (MDRP) DRP is for states and/or manufacturers that are unable to mutually resolve MDRP disputes, and are seeking CMS assistance. **Note:** The DRP pertains only to Medicaid units in dispute, and not to rate changes or unpaid rebate amounts not officially disputed, as addressed on our DRP webpage on Medicaid.gov: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-dispute-resolution/index.html.

DrugRebateAgreement@cms.hhs.gov - National Drug Rebate Agreement (NDRA)

- Requests for a new NDRA or reinstatement of an NDRA
- Request for an NDRA voluntary termination

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

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

MDP@cms.hhs.gov (Formerly DDR@cms.hhs.gov) **- Medicaid Drug Programs (MDP) Access / System Administration**

- Inquiries pertaining to user access within MDP
- Inquiries about user management within MDP
- Inquiries regarding the status of your IDM role request to access MDP
- Submitting 367d (Manufacturer) and 368 (State) contact change forms for processing
- Annual IDM role certification questions
- **Note:** - For CMS Enterprise Portal login issues or issues pertaining to your CMS IDM User ID and IDM role, please contact the MDP IDM Help Desk.
    - The MDP IDM Help Desk is able to assist with everything IDM ID related, such as creating an IDM User ID, requesting or removing an IDM role, password resets, unlocking your IDM account, assisting with MFA devices and codes, assisting with identity (ID) Proofing, assisting with updating your IDM ID profile (email address

changes, name changes, etc.).

- **The MDP IDM Help Desk can be reached via email at: MDP-Helpdesk@softrams.com or via telephone at (833) 637-6370.**

MDROperations@cms.hhs.gov - Medicaid Drug Rebate Program (MDRP) Operations

- For inquiries pertaining to the reporting of Product information, Pricing information, and any pertinent operational questions regarding the MDRP and/or any issues with Medicaid Drug Programs (MDP) system.

MDRPChangeRequests@cms.hhs.gov - Manufacturer Product or Pricing Information Change Requests

- For Manufacturer inquiries pertaining to Medicaid Drug Rebate Program (MDRP) Product and /or Price Information Change Requests.
- Requests may include changes to Product and/or Pricing information reported and certified beyond 12 quarters (i.e., change(s) to Market Date, FDA Approval Date, COD Status, Drug Category, Base AMP and Monthly and/or Quarterly Pricing where permitted consistent with regulations at section 447.510(b)(1).
- Requests may include changes to Product and/or Pricing information where additional review is required by CMS.

MDRUtilization@cms.hhs.gov - State Drug Utilization Data (SDUD)

- For inquiries pertaining to the SDUD, including the SDUD posted on Medicaid.gov.
- For inquiries pertaining to the State and/or manufacturer Medicaid Drug Rebate Program (MDRP) Medicaid Drug Programs (MDP) File Formats and Data Definitions.

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

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

RPS@cms.hhs.gov - Survey of Retail Pharmacy Prices and National Average Drug Acquisition Cost (NADAC)

- For information and assistance with the monthly Survey of Retail Pharmacy Prices and the NADAC file.

RxDrugPolicy@cms.hhs.gov - Medicaid Prescription Drug Program Policy

- For manufacturers and states to request guidance and assistance related to policy matters within the MDRP (such as clarification on applicable statutes and regulations).
- For manufacturers to request guidance and assistance with unit type and units per package size (UPPS) reporting.
- Per Manufacturer Release No. 78, manufacturers should not submit reasonable assumptions to CMS. Should a manufacturer disregard this instruction and submit such assumptions, they will not be reviewed, and their receipt should not be considered as acquiescence by CMS to the submitted assumptions.

Sincerely,

/s/

Alissa Mooney DeBoy
Director
Disabled and Elderly Health Programs Group