Medicaid Drug Rebate Program (MDRP)

National Drug Rebate Agreement (NDRA) Reference Guide

Updated: February 24, 2023

***Disclaimer**: This Medicaid Drug Rebate Program (MDRP) Data Guide is intended for the use of state and manufacturer staff involved in the operational processes of the MDRP. This Data Guide is intended to provide information and guidance on data reporting and processes; it is not intended as a revision or modification of the requirements set forth in section 1927 of the Social Security Act (the Act), the National Drug Rebate Agreement (NDRA), program releases, or any regulations. In the event that any part of this guide conflicts with any of the foregoing, the Act, NDRA, program releases, and regulations take precedence.*

All references to drugs, National Drug Codes, and products in this Data Guide refer to Covered Outpatient Drugs (CODs) as defined in section 1927 of the Act and the NDRA.

Requesting a New Rebate Agreement

Requests for new NDRAs are processed through our Medicaid Drug Programs (MDP) application. If you do not already have access to MDP, you will need to obtain access. Instructions can be found on the Medicaid Drug Programs (MDP) System Access webpage.

In order for a drug to be covered under Medicaid, the manufacturer of the drug must have an active NDRA. Those manufacturers are required to report all their drugs that satisfy the definition of a Covered Outpatient Drug (COD) to CMS, regardless of labeler code. Therefore, in order to comply with section 1927 of the Social Security Act ('the Act') and the terms of the NDRA, manufacturers must ensure that they have an active NDRA in place for all of their associated labeler codes if those labeler codes distribute CODs. When a participating manufacturer requests an NDRA for an additional labeler code that has CODs, that NDRA request will be subject to verification of their proposed COD list. For additional information, please refer to Federal Register 83 FR 12770.

Additionally, manufacturers entering into an NDRA must meet the requirements of section 1927(a)(1) of the Act, requiring compliance with sections 1927(a)(5) and 1927(a)(6). Those sections require that a manufacturer enter into an agreement with the Secretary of Health and Human Services that satisfies section 340B of the Public Health Service Act, and complies with section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs. Please note that an NDRA will not be issued by CMS unless these agreements are already in place.

To request an NDRA, a manufacturer must have access to the Medicaid Drug Programs (MDP) system. Instructions for requesting access may be found here: https://www.medicaid.gov/medicaid/prescription-drugs/downloads/medicaid-drug-prog-mdp-system.pdf

In preparation for making a request for an NDRA, a manufacturer should compile the following information:

I. Labeler Information:

1) **Labeler Code (NDC 1)**: The FDA assigned labeler code for the manufacturer requesting the new NDRA. If your FDA assigned labeler code is 4 digits, add a leading zero.
2) **Labeler Name**: Name of the labeler as reported to the FDA and as it appears in the NDC/NHRIC Labeler Codes Directory.
3) **Associated Labeler Codes**: Confirm whether the manufacturer has any associated labeler codes that have CODs. If there are associated labeler codes, you will be required to enter those labeler code(s) and name(s) as reported to the FDA. If an associated labeler code that distributes CODs does not currently have an active NDRA, you will need to request an NDRA for that labeler code or reinstatement of that labeler code, if applicable.
4) All prospective manufacturers must agree that they meet the requirements of 1927(a)(5) & 1927(a)(6) when submitting their request for an NDRA. Please note that a new NDRA will not be issued until an active 340b agreement is in place for your labeler code. For more information, visit the Health Resources & Services Administration (HRSA), Office of Pharmacy Affairs website: https://340bopais.hrsa.gov/ManufacturerSearch/000103378.

II. Drug Information:

A complete list of the NDCs that satisfy the definition of COD. This includes all 11-digit presentations, on either outer package or inner package. This includes all NDCs that should be reported with a COD Status of '05' or '06' (see section 'f' below). CMS utilizes the FDA's NSDE and data available on Drugs@FDA to be able to determine if a manufacturer's drugs are reported correctly to CMS. If there are NDCs listed with the FDA that your company determines do not satisfy the definition of COD, these products nonetheless need to be included on your list. For each NDC that has been determined not to satisfy the definition of COD, you must include the appropriate rationale for the NDC with your submission.

The following information is required. The information may be submitted online or via file transfer (.TXT or .CSV). For all ***Drug Product*** fields (e.g., COD Status, Application Number, FDA Approval Date, Market Date, etc.) the values must be the same for every package size that represents a 9-digit NDC.

1) **Product Code (NDC2)**: 4-digit second segment of the NDC. If your product code contains only 3 digits, add a leading zero.
2) **Package Code (NDC3)**: 2-digit third segment of the NDC. If your package code contains only 1 digit, add a leading zero.
3) **FDA Drug Name**: The drug's Proprietary Name as it appears on FDA's SPL listing (NSDE file), for each 11-digit NDC.
4) **FDA Approval Date**: The FDA Approval Date is the date on which the drug's NDA, ANDA, or BLA is approved by the FDA. If a drug's approval date is prior to 9/30/1990 (i.e., the start of the MDR program), report 9/30/1990 as the FDA Approval Date since dates earlier than the start of the MDR program are not applicable. If a drug has received FDA approval, the FDA Approval Date can be found at Drugs@FDA or the Orange Book. If the drug is unapproved, use the default date of 9/30/1990 as the FDA Approval Date.
5) **Drug Category:** Indicates whether the drug is a single source (S), innovator multiple source (I), or non-innovator multiple source (N). Please refer to Section 1927(k)(7)(A) of the Act and 42 CFR 447.502 for statutory and regulatory definitions in order to determine the correct value.

   Drug Category must correspond to the COD Status (see 'f' below). For example, generally:

   - Drugs with a COD Status of '01-ANDA' are reported as N
   - Drugs with a COD Status of '02-BLA' are reported as S
   - Drugs with a COD Status of '03-NDA' are reported as either S or I, as applicable
   - Drugs with a COD Status of '05-13' are reported as N
6) **Covered Outpatient Drug (COD) Status**: The COD Status is an indicator that identifies how a drug meets the statutory definition of a covered outpatient drug in accordance with section 1927 of the Social Security Act. The following list identifies all COD Status values:

- 01 - Abbreviated New Drug Application (ANDA)
- 02 - Biological License Application (BLA)
- 03 - New Drug Application (NDA)
- 04 - NDA Authorized Generic
- 05 - DESI 5* (Drug Efficacy Study Implementation) – FDA's DESI review determined that the drug is "Less than effective for all of its labeled indications", or the drug is "identical, related or similar" to such drug ('LTE/IRS')
- 06 - DESI 6* – LTE/IRS drug withdrawn from market
- 07 - Prescription Prenatal Vitamin or Fluoride
- 08 - Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Prenatal Vitamin or Fluoride)
- 09 - OTC Monograph Tentative
- 10 - OTC Monograph Final
- 11 - Unapproved Drug – Drug Shortage
- 12 - Unapproved Drug – Per 1927(k)(2)(A)(ii)
- 13 - Unapproved Drug – Per 1927(k)(2)(A)(iii)

*NDCs with a COD Status of 05 or 06 (DESI) are not eligible for coverage or rebates under the Medicaid Drug Rebate Program. However, drug and pricing data are required and Unit Rebate Amounts (URA) are calculated.

7) **FDA Application Number/OTC Monograph Number, if applicable**: FDA Application Number (for COD status 1-4) or OTC Monograph Part number (for COD status 9-10), as appropriate.

   For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the application number (assigned by the FDA for approval to market a drug or biological in the United States) under which the NDC is currently marketed. This field, if populated, must contain 7 digits, with leading zeroes added if necessary.

   For drugs, with a COD Status of either OTC Monograph Final or Tentative, the first four characters are a constant of 'PART', followed by a 3-digit numeric value (between 311 - 399) identifies the FDA's regulatory citation for the OTC Monograph.

   This data element does not apply to drugs with a COD Status of 5, 6, 7, 8, 11, 12, or 13.

   Note: if the OTC Monograph Number begins with "M", contact MDROperations@cms.hhs.gov for assistance.

8) **Market Date**: For S, I, and N drugs marketed under an FDA-approved application (e.g. ANDA, BLA, NDA), the earliest date the drug was marketed under the application number under any labeler code. For drugs marketed without an FDA-approved application (e.g., OTC monograph, unapproved drug), the earliest date the drug was marketed under **any labeler code**. For all drugs (i.e., those marketed with or without an FDA-approved application) that were purchased or otherwise acquired from another labeler, the Market Date should be equal to the Market Date of the original drug. Thus, the Market Date of a drug is frequently not the date on which a labeler began marketing the drug, but may be a much earlier date.

   The Market Date cannot be a future date.

9) **Purchased Product Date (PPD)**: If the market date is not the date that your company began marketing the drug under the NDC, then you will need to report a PPD. Therefore,

the PPD should never be the same date as the market date. The PPD is the date that your company first markets the drug under this NDC (this date can result, if an drug from one company is purchased by another company, the re-designation of an drug from one of a company's labeler codes to another of that same company's labeler codes, or a cross-licensing arrangement). This is an optional field.

The Purchase Product Date (PPD) cannot be a future date.

10) **Drug Type:** Identifies a drug as prescription (Rx) or over-the-counter (OTC). The drug type must be the same for every package size of a 9-digit NDC.

11) **Unit Type**: One of 10 unit types describing a drug. The unit type must be the same for every package size of a 9-digit NDC.

Valid Values:

AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
EA = Each
GM = Gram
MCI = Millicurie
UCI = Microcurie
ML = Milliliter
SUP = Suppository
TAB = Tablet
TDP = Transdermal Patch

For more information on this topic, please search the Manufacturer Releases on Medicaid.gov.

12) **Unit per Package Size (UPPS)**: UPPS are the total number of units in the smallest dispensable amount (not necessarily the total quantity in the package) for the 11-digit NDC.

For more information on this topic, please search the Manufacturer Releases on Medicaid.gov for "Units Per Package Size" or "UPPS".

13) **Termination Date**: The date the drug was withdrawn from the market or the drug's last lot expiration date.

III. Submitting Drug Information:

Drug data may be entered either via direct file upload (.TXT or .CSV) or manual on-line entry

.TXT File: .TXT (text) refers to a file format that allows only plain text content with very little formatting (e.g., no bold or italic types). Such files can be viewed and edited in simple text editors.

.CSV File: .CSV (Comma Separated Value) refers to a file where commas are commonly used to separate the data fields in the file. A CSV file is typically used to store and exchange large amounts of tabular data between two different applications. CSV files are plain text files and can contain numbers and letters only. Data in CSV files is structured in a table format. Spreadsheet software (e.g. Microsoft Excel) is most commonly used to open and edit them.

IV. Contact Information:

The rebate agreement requires that a manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues. Addresses for mail services that are used to forward mail outside the U.S. or U.S. Territories are not permitted. If the contact information provided does not comply with this requirement, a final rebate agreement will not be executed.

1) **Technical Contact**: Primary point-of-contact (POC) for all aspects of the Labeler's participation in the MDRP and also responsible for managing Designee access to the Labeler's data in the system. **NOTE**: The Technical Contact's email address cannot be a generic email or a resource mailbox and must be the TC's direct email address. Additionally, if an individual is designated as the TC for more than one labeler code, they must use the same email address for all labeler codes. This email address must also be the same email address associated with the TC's CMS User ID.
2) **Invoice Contact**: Individual responsible for processing/managing state invoices.
3) **Legal Contact**: Individual to contact for legal issues concerning the NDRA and/or the Labeler's participation in the MDRP.

Please review Manufacturer Release 115 for additional information regarding the submission of CMS 367d forms and how they relate to MDP system access.

V. Attestation of drug availability

Labelers are required to submit documentation (e.g., wholesaler verification) via email to drugrebateagreement@cms.hhs.gov or provide a written attestation that the product(s) are currently available for sale.

VI. Signatory Information:

The rebate agreement can be signed electronically using an e-signature or alternatively, it can be printed, signed and uploaded to the MDP system.

Enter the following Rebate Agreement Signatory information:

- Title
- Full Name
- Mailing Address
- Phone Number
- Email Address (example@mail.com format required)

Requesting Reinstatement to MDRP:

Requests for an NDRA reinstatement are processed through our Medicaid Drug Programs (MDP) application. If you do not already have access to MDP, you will need to obtain access. Instructions can be found on the Medicaid Drug Programs (MDP) System Access webpage.

I. Labeler Information:

1) **Labeler Code (NDC 1)**: The FDA assigned labeler code for the manufacturer requesting the new NDRA. If your FDA assigned labeler code is 4 digits, add a leading zero.

2) **Labeler Name**: Name of the labeler as reported to the FDA and as it appears in the NDC/NHRIC Labeler Codes Directory.

3) **Associated Labeler Codes**: Confirm whether the manufacturer has any associated labeler codes that have CODs. If there are associated labeler codes, you will be required to enter those labeler code(s) and name(s) as reported to the FDA. If an associated labeler code that distributes CODs does not currently have an active NDRA, you will need to request an NDRA for that labeler code or reinstatement of that labeler code, if applicable.

4) All prospective manufacturers must agree that they meet the requirements of 1927(a)(5) & 1927(a)(6) when submitting their request for an NDRA. Please note that a new NDRA will not be issued until an active 340b agreement is in place for your labeler code. For more information, visit the Health Resources & Services Administration (HRSA), Office of Pharmacy Affairs website: https://340bopais.hrsa.gov/ManufacturerSearch/000103378.

II. Reinstatement Steps:

The following are the steps that need to be taken prior to a labeler being reinstated into the MDRP:

1) Determine if you need to submit a revised CMS Form 367d to update contact information, and if applicable. If so, the current Manufacturer Contact Form (CMS-367d) is located on Medicaid.gov at: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-mdrp-file-formats-data-definitions-and-medicaid-drug-programs-mdp-email-communications/index.html. Please note that the CMS-367d must be filled out in its entirety, and should be submitted to MDP@cms.hhs.gov for processing.

2) Determine if the drugs that are currently in MDP under this labeler code are still active and if not, report a termination date for those drugs. Termination dates should be reported for drugs that are no longer on the market. If a terminated NDC does not have a 'Stop Marketing Date' on FDA's NSDE, you should update the SPL information with FDA.

3) If there are drugs in MDP that remain active, you need to review all drug information, correct or request correction of any incorrect information, and report any missing data, if applicable.

4) If an NDC that appears in MDP has been re-used for a different drug and the drug data in MDP does not represent the drug currently labeled with the NDC, contact MDROperations@cms.hhs.gov to request that you be able to re-use the NDC. If you determine that an NDC currently in MDP is not a COD, contact rxdrugpolicy@cms.hhs.gov and ask that the NDC be removed from MDP. You must provide your rationale as to why the drug does not satisfy the definition of COD. If any of the drug product data that appears in MDP is incorrect, contact MDRPChangeRequests@cms.hhs.gov with information including the NDC and the fields that need to be corrected and we will advise of next steps.

5) If the drugs are missing any quarterly and/or monthly pricing, it will have to be submitted prior to reinstatement. However, pricing cannot be submitted until any missing product data fields are entered and certified in MDP. You will be required to provide accurate Unit Rebate Amounts (URAs) to CMS for any quarterly pricing that was not reported and/or certified prior to termination from the MDRP, so that states are able to calculate the amount of any unpaid rebates and/or interest, if applicable.

6) If there are unreported NDCs which were available for sale during the time period your labeler code was previously a participating manufacturer in the MDRP, all product and applicable pricing data must be submitted and certified in MDP.

7) When the above steps have been completed, notify us at DrugRebateAgreement@cms.hhs.gov to officially request reinstatement. We will then contact all the State Medicaid Agencies and let them know that your labeler code is seeking reinstatement. We will ask the States for the amount of any rebates that are past due, including interest. We will forward that information to you for payment. When debts are paid, you must obtain a statement of confirmation from the State and forward that statement to us.

   Please note that any NDRAs that were Terminated for Cause, will additionally need to ensure that all their cited violations have been remediated

8) When CMS has confirmed that these steps have been completed and there are no outstanding issues, the new NDRA will be issued. The Mandatory Effective Date (MED) of the reinstatement will be effective as of the first day of the calendar quarter that begins more than 60 days after the date the reinstatement is entered into. The Optional Effective Date (OED) will be the date that the labeler signs and returns the new rebate agreement.