Medicaid Drug Rebate Program (MDRP)

National Drug Rebate Agreement (NDRA)

Reference Guide

Updated: December 22, 2020

Requesting a New Rebate Agreement

Manufacturers that wish to participate in the MDRP are required to report all their CODs to CMS, regardless of labeler code. Therefore, in an effort to prevent selective reporting of NDCs, manufacturers must ensure that all associated labeler codes with CODs enter into a rebate agreement in order to comply with the terms of the NDRA. When a participating manufacturer requests an agreement for a newly acquired 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 in section 1927(a)(1) of the Act, requiring compliance with sections 1927(a)(5) and 1927(a)(6). Those sections require that a manufacturer enters into an agreement with the Public Health Service that satisfies section 340B of the Public Health Service Act, and, enters into a master agreement with the Secretary of Veterans Affairs.

1. **Required Labeler Information:**
   a) **Labeler Code**: Enter the labeler code for the new NDRA.
   b) **Labeler Name**: Name of the labeler as reported to the FDA's NDC/NHRIC Labeler Codes Directory (https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes).
   c) **Associated Labeler Codes**: Confirm if you do or do not have any associated labeler codes that have covered outpatient drugs (CODs). If you do have associated labeler codes, you will be required to also enter their labeler code and name as reported to the FDA. Note: If an associated labeler code that has CODs does not currently have an active NDRA, you will need to request a separate NDRA.
2. **Required Product Information:**

   Requestors are required to submit a complete list of every NDC (11-digit/package size level, including both NDCs on the outer package, as well as on any inner packages) that meet the definition of a COD, which also includes all NDCs that should be reported with a COD Status of "05" or "06". If there are NDCs listed with the FDA that your company determines do not meet the definition of a COD, you will need to provide a rationale for each NDC or report "stop marketing" dates to FDA if the NDC is no longer marketed.

   The following required information may be submitted on-line or via file transfer (.TXT or .CSV).

   a) **Product Code**: 4-digit second segment of the NDC

b) **Package Size**: 2-digit third segment of the NDC

c) **FDA Product Name**: The Drug Name as it appears on FDA SPL listing FDA's NSDE file, for each 11-digit NDC.

d) **FDA Approval Date**: For CODs for which the FDA does not require approval (COD Status 5-13), use 09/30/1990 or, if the drug was first marketed after 09/30/1990 (COD Status 1-4), the actual date first marketed.

e) **Drug Category:** Drug Category: For S, I and N drugs marketed under an FDA-approved application (e.g. ANDA, BLA, NDA, NDA Authorized Generic), the earliest date the drug was first marketed under the application number by any labeler. For drugs marketed without an FDA-approved application (e.g., OTC monograph, unapproved drug), the earliest date the drug was first marketed by any labeler. 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 product.

f) **Covered Outpatient Drug (COD) Status**: This value should be the same for every package size of a 9-digit NDC. The COD Status is an indicator that identifies how a drug meets the statutory definition of a covered outpatient drug in accordance with section 1927of 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 - (Drug Efficacy Study Implementation) DESI 5* – LTE/IRS drug for all indications
06 - DESI 6* – LTE/IRS drug withdrawn from market
07 - Prescription Pre-Natal Vitamin or Fluoride
08 - Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal 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 05/06 (DESI 5/6) are not eligible for coverage or rebates under the Medicaid Drug Rebate Program. However, pricing is required and Unit Rebate Amounts (URA) are calculated.

g) **FDA Application Number/OTC Monograph Number**: 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.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product (e.g., "315"). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product, or three zeros if a Monograph Number is not available.

h) **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 first marketed under the application number by any labeler. For drugs marketed without an FDA-approved application (e.g., OTC monograph, unapproved drug), the earliest date the drug was first marketed by any labeler. 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 product. 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. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system, since dates earlier than the start of the Medicaid Drug Rebate Program have no bearing on the program.

i) **Purchased Product Date (PPD)**: The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.).

j) **Drug Type:** Identifies each 11-digit NDC as prescription (Rx) or over-the-counter (OTC).

k) **Unit Type**: One of 8 unit types by which a drug may be dispensed. The unit type should be the same for every package size of a 9-digit NDC and should be reported as one of the following values:

Valid Values:
AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
EA = Each
GM = Gram
ML = Milliliter
SUP = Suppository
TAB = Tablet
TDP = Transdermal Patch

l) **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 for "units per package size" or "UPPS".

m) **Termination Date**: The date a drug is withdrawn from the market or the drug's last lot expiration date.

3. **Submitting Product Information:**

   Product 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.

4. **Contact Information:**

   Manufacturers participating in the MDRP are required to have Technical, Invoice, and Legal Contacts with mailing addresses in the United States (U.S.) or U.S. Territories. Mailing addresses that are forwarding services outside of the U.S. or U.S. Territories are not permitted. Please note that the final part of the rebate agreement request process will require that official contact information be submitted. If the contact information provided at that time does not comply with this requirement, a final rebate agreement may not be issued.

   - **Technical Contact**: Primary point-of-contact (POC) regarding 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.
   - **Invoice Contact**: Individual responsible for processing/managing state invoices.
   - **Legal Contact**: Individual to contact for legal issues concerning the NDRA and/or the Labeler's participation in the MDRP.

5. **Signatory Information:**

   The last step in the rebate agreement process is signing the agreement. Users can do so electronically with an e-signature or print a copy of the rebate to sign and upload to the MDP system.

   Enter the following Rebate Agreement Signatory information:

   - First Name
   - Last Name
   - Corporation Name
   - Phone Number
   - Address (example@mail.com format required)
   - Email address

Requesting a NDRA Reinstatement:

- You will need access to Drug Data Reporting System (DDR) system. Check to determine if you will need to submit a completed CMS Form 367d to update contact information, if applicable. If you do not have access to DDR, you will need to obtain it. Instructions for obtaining access to DDR can be found at: https://www.medicaid.gov/medicaid/prescription-drugs/downloads/medicaid-drug-rebate-program/eidm-instructions-for-ddr-users.pdf.

- Once you have DDR access, determine if the drugs that are currently in DDR under this labeler code will remain or if termination dates need to be submitted. Termination dates are for products that are no longer on the market and have a "discontinued" date listed on the FDA's website. If there are products in DDR that will remain, you need to review all product information and update any missing data fields, if applicable.

- If the products have any missing quarterly and or monthly pricing, it will have to be submitted prior to reinstatement. However, it cannot be updated until any missing data fields are entered and certified in DDR. Your labeler will be required to provide accurate Unit Rebate Amounts (URAs) to CMS for any quarterly pricing that was not 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.

- If there are unreported NDCs which were available for sale at any time 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 DDR.

- When the above steps have been completed, notify us at this email address. We will then contact all the State Medicaid Agencies and let them know that your labeler is seeking reinstatement. We will ask the States what rebates are past due, including interest. We will forward that information to you for payment. When debts are paid, we ask you to obtain a statement of confirmation from the State and forward that statement to us