**Code Book for “Product Data for Newly Reported Drugs in the Medicaid Drug Rebate Program”**

**Source:** U.S. Department of Health & Human Services

**Publisher:** Centers for Medicare & Medicaid Services

**Study Description:**  The data in this set contains newly reported, active covered outpatient drugs which were reported by participating drug manufacturers since the last quarterly update of the Drug Products in the Medicaid Drug Rebate Program (MDRP) database.

The database was put into one comma separated values file with a total of 22 different values to puck information from, these are the values and their descriptions:

* **NDC 1:** ID Code
* **NDC 2:** ID Code
* **NDC 3:** ID Code
* **Labeler Name**: Name of the company that packages and manufactures the drugs.
* **Labeler Status**: Used to see if the company is still active or not.
* **FDA Name**: The name with which the public knows each drug, including its type (tablets, diluent, etc) and the amount.
* **COD Status**: Category that identifies whether or not a product meets the statutory definition of a covered outpatient drug in accordance with the Social Security Act (sections 1927(k)(2) to 1927(k)(4))
* **FDA Application number**: Seven-digit application number that is assigned by the FDA for approval to market a generic or new drug in the US.
* **Drug-category**: Indicates whether the drug is single source, innovator multiple source, or non-innovator multiple source.
* **Drug Type:** Identifies drugs as prescription (Rx=1) or Over-the-Counter (OTC=2)
* **Line Extension**: Identifies whether or not a product is a line extension drug as defined in Section 1927(c)(2)(C) of the Social Security Act, including whether the drug is excluded from the statutory definition of a line extension on the basis of being an abuse-deterrent formulation (ADF).
* **FDA Approval Date:** NDC or monograph approval date.
* **Market Date:** For S, I, and N drugs marketed under an FDA-approved application (e.g. BLA, NDA, ANDA), 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), if a drug was 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 Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.
* **Unit Type**: One of the 8 unit types by which a drug can be dispensed.

Valid Values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

SUP = Suppository

GM = Gram

ML = Milliliter

TAB = Tablet

TDP = Transdermal patch

EA = EACH

* **Unit per Package Size**: Total number of units, smallest dispensable container or entity for the product defined by the full NDC.
* **Therapeutic Equivalent Code (TEC):** The classification as contained in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made. This 2-digit code begins with either an “A” (therapeutically equivalent to other products), a “B” (not therapeutically equivalent to any other product), or contains “NR” (not rated) rating. Products are considered equivalent if they contain the same active ingredients, are of the same dosage form and are identical in strength.
* **5i Indicator:** Term to identify drugs that are inhaled, infused, instilled, implanted, or injected, or value of previously reported Termination Date and/or Reactivation Date period.
* **Purchased Product Date:** Date product was purchased.
* **Coverage Effective date:** How long can the product stay effective.
* **Drug Termination Date**: Date on which the reported Termination Date was certified by the labeler in DDR (N/A)
* **Drug Reactivation Date:**