## MEDICAID DRUG REBATE PROGRAM

# MDP QUARTERLY AMP FILE FORMAT Effective: July 1, 2021

**Target: States** 

	Field Name (.TXT) Header Row (.CSV)	Size	Position	Remarks
1	Labeler Code	5	1 - 5	NDC 1
2	Product Code	4	6 - 9	NDC 2
3	Package Size	2	10 - 11	NDC 3
4	Period Covered	5	12 - 16	QYYYY
5	Average Manufacturer Price	15	17 - 31	99999999.999999 or NR
6	Covered Outpatient Drug Status	2	32 - 33	XX
7	Unit Type	3	34 - 36	XXX
8	Therapeutic Equivalence Code	2	37 - 38	XX
9	Units Per Package Size	11	39 - 49	9999999.999
10	FDA Product Name	63	50 - 112	FDA Product Name
11	Labeler Name	40	113 - 152	Company associated with NDC 1

#### MEDICAID DRUG REBATE PROGRAM

## MDP QUARTERLY AMP FILE DATA DEFINITIONS

Effective: July 1, 2021

**Labeler Code:** The first segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

**Product Code:** Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

**Package Size:** Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

**Period Covered:** The calendar quarter and year that the Average Manufacturer Price (AMP) represents. Numeric 5-digit field; format: QYYYY.

#### Valid Values for Q:

- 1 = January 1 March 31
- 2 = April 1 June 30
- 3 = July 1 September 30
- 4 = October 1 December 31

<u>Valid Values for YYYY</u>: 4-digit calendar year equal to 1991 or later.

Average Manufacturer Price (AMP): The AMP per unit per product code only for the month/year covered, based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. Numeric values; 15-digit field: 8 whole numbers, the decimal point ('.') and 6 decimal places; right-justified; zero-padded for AMP values with fewer than 15 digits. If no AMP has been reported, this alphanumeric field will reflect a value of "NR".

**Covered Outpatient Drug (COD) Status:** A category that identifies how a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values; 2-digit field.

### Valid Values:

- 01 = Abbreviated New Drug Application (ANDA)
- 02 = Biological License Application (BLA)
- 03 = New Drug Application (NDA)
- 04 = NDA Authorized Generic
- 05 = 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- 06 = DESI 6\* LTE/IRS drug withdrawn from market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)

**Unit Type:** One of the 10 unit types by which a drug may be dispensed. 3-character field; left-justified; blank-filled for Unit Type values with fewer than 3 characters.

#### Valid Values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

SUP = Suppository

GM = Gram

ML = Milliliter

TAB = Tablet

TDP = Transdermal patch

EA = Each

MCI = Millicurie

UCI = Microcurie

**Therapeutic Equivalence Code (TEC):** FDA-assigned Therapeutic Equivalence Codes as found in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*. Alpha-numeric values; 2-digit field.

### Valid Values:

- AA = Products in Conventional Dosage Forms Not Presenting Bioequivalence Problems
- AB = Products Meeting Necessary Bioequivalence Requirements assigned an FDA TEC of AB, or AB1 through AB9
- AN = Solutions and Powders for Aerosolization
- AO = Injectable Oil Solutions
- AP = Injectable Aqueous Solutions and, in Certain Instances, Intravenous Non-Aqueous
- AT = Topical Products
- BC = Extended-Release Dosage Forms (Capsules, Injectables, and Tablets)
- BD = Active Ingredients and Dosage Form With Documented Bioequivalence Problems
- BE = Delayed-Release Oral Dosage Forms
- BN = Products in Aerosol-Nebulizer Drug Delivery Systems
- BP = Active Ingredients and Dosage Forms with Potential Bioequivalence Problems
- BR = Suppositories or Enemas That Deliver Drugs for Systemic Absorption

<sup>\*</sup>NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.

BS = Products Having Drug Standard Deficiencies

BT = Topical Products with Bioequivalence Issues

BX = Drug Products for Which the Data Are Insufficient To Determine Therapeutic Equivalence

NR = Not Rated

**Units Per Package Size (UPPS):** the total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values; 11-digit field: 7 whole numbers, the decimal point ('.') and 3 decimal places; right-justified; zero-padded for UPPS values with fewer than 11 digits.

**FDA Product Name:** Drug name as it appears on FDA SPL listing. Alpha-numeric values; 63-character field; left-justified; blank-filled for FDA Product Names fewer than 63 characters.

**Labeler Name:** Name of labeler as it appears on the signed rebate agreement. Alpha-numeric values; first 40 letters of labeler name; left-justified; blank-filled.