QUARTERLY DRUG REBATE FILE
Quarterly URA File Format and Data Definitions
August 2016

Source: CMS
Target: State Agencies

Field	Size	Position	Remarks
Record ID	4	1 - 4	Constant of "01@@"
Labeler Code	5	5 - 9	NDC #1
Product Code	4	10 - 13	NDC #2
Package Size Code	2	14 - 15	NDC #3
Period Covered	5	16 - 20	QYYYY
Prd. FDA Reg. Name	10	21 - 30	See Data Element Definitions
Drug Category	1	31 - 31	See Data Element Definitions
Filler	1	32 - 32	Spaces
FDA Thera. EQ. CD.	2	33 – 34	See Data Element Definitions
Unit Type	3	35 – 37	See Data Element Definitions
Units Per Pkg Size	10	38 – 47	9999999V999
Rebate Amt. Per Unit (a.k.a. URA)	11	48 – 58	99999V999999
URA Type	1	59-59	See Data Element Definitions
FDA Approval Date	8	60 – 67	MMDDYYYY
Date Entered Market	8	68 – 75	MMDDYYYY
Termination Date	8	76 – 83	MMDDYYYY
Date Termination Date Reported	8	84 - 91	MMDDYYYY
Drug Type Indicator	1	92 – 92	See Data Element Definitions
Clotting Factor Indicator	1	93 – 93	Y or N
Pediatric Indicator	1	94 – 94	Y or N
COD Status	2	95 – 96	See Data Element Definitions
FDA Application No./OTC Monograph No.	7	97 – 103	See Data Element Definitions
Reactivation Date	8	104 – 111	MMDDYYYY
Line Extension Drug Indicator	1	112 - 112	See Data Element Definitions
Record Type Indicator	1	113 – 113	See Data Element Definitions

Logical Record Length = 113

URA FILE DATA DEFINITIONS

Record ID:
Constant value of "01@@"

Labeler Code:
First segment of National Drug Code (NDC1) that identifies the manufacturer, labeler, re-labeler, packager, re-packager or distributor of the drug

Product Code:
Second segment of National Drug Code (NDC2)

Package Size Code:
Third segment of National Drug Code (NDC3)

Period Covered:
Calendar year and quarter covered by data submission (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

Valid values for YYYY: Four-digit calendar year covered.

Product Name:
Product name as approved by and/or listed with the FDA.

Drug Category:
Classification of drug
N = Non-innovator multiple source – Generic
S = Single source – Brand name
I = Innovator multiple source – Brand Name

Therapeutic Equivalency 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.
http://www.fda.gov/cder/ob/default.htm

Unit Type:
Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit.

Valid Values:
AHF = refers only to injectable Anti-Hemophilic Factor units
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal patch
EA = EACH (Refers to drugs not identifiable by any other unit type)

Units Per Package Size:
Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC.

Rebate Amount Per Unit (a.k.a. URA):
The CMS calculated amount per unit type to be claimed as a rebate by the state.

URA Type:
The methodology that CMS used to calculate the URA. For any drug that is not a Line Extension, the URA type will be the Standard methodology, and for Line Extension drugs the URA type will be the greater of the Standard or Alternative methodology. NOTE: If a zero URA appears on the quarterly file (i.e., along with a "1" rebate indicator), the URA Type field will be blank.

Valid Values:
S = Standard
A = Alternative

FDA Approval Date:
Date of FDA Approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer.

Date Entered Market:
If marketed prior to 10-01-1990, first date of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed.

Termination Date:
Date drug was withdrawn from market or shelf life of last lot sold if no longer manufactured/distributed by labeler.

Date Termination Date Reported:
Date on which the reported Termination Date was certified by the labeler in DDR.

D**rug Type Indicator:**
Indicator to show whether this drug product can be acquired only by prescription or can be acquired Over-the-Counter (OTC).

Valid values:
1 = Rx
2 = OTC

Clotting Factor Indicator:
In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug as a clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act.

Valid values:
Y = Yes
N = No

Pediatric Indictor:
In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug approved by the FDA exclusively for pediatric indications for patients in the FDA-defined pediatric age group (i.e., birth to 16 years).

Valid values:
Y = Yes
N = No

COD Status:
A category that identifies whether or not 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.

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)

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

FDA Application No./OTC Monograph No.:
For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the seven-digit application number that is assigned by the FDA for approval to market a generic drug or new drug in the United States.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. 7 alphanumeric characters. 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., "225"). 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 3 zeroes if a Monograph Number is not available.

For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field should be zero-filled.

Reactivation Date: The date on which a terminated product is re-introduced to the market.

Line Extension Drug Indicator:
Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act. NOTE: If a Line Extension Drug Indicator has not been reported for an NDC, this field will be blank on the quarterly file.

Valid Values:
Y = Yes
N = No

Record Type Indicator:

0 Indicator = initial, valid URA for an NDC and a particular quarter/year
1 Indicator = zero URA (due to missing quarterly pricing, 400/400 edit, systems edits, etc.)
2 Indicator = value of previously calculated URA
3 Indicator = value of replacement URA (always appears along with a corresponding 2 Indicator record)
4 Indicator = value of each initial Termination Date and value of each initial Reactivation Date in a Termination/Reactivation Date set. (Each NDC can have more than one set of Termination/Reactivation Dates.)
5 Indicator = value of previously reported Termination Date and/or Reactivation Date period
6 Indicator = value of replacement Termination Date and/or Reactivation Date period (always appears along with a corresponding 5 Indicator record)
7 Indicator = URA for this quarter/year is no longer valid due to a product change by the labeler (e.g., Term. Date change, Market Date change, etc.)
8 Indicator = URA for this quarter/year was previously invalid, but is now valid again due to another product data change by the labeler (e.g., Term. Date change, Market Date change, etc.)