DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
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Center for Medicaid, CHIP, and Survey & Certification

January 6, 2011

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 157**

For State Technical Contacts

NEW MEDICAID DRUG REBATE FILE FORMATS EFFECTIVE FIRST QUARTER 2011

As previously notified, Section 2501 of the Affordable Care Act included changes to certain Medicaid drug rebate provisions, effective first quarter 2010. Several of these changes impact the Unit Rebate Amount (URA) calculation for drugs covered under the Medicaid Drug Rebate Program, including a new rebate percentage in the URA calculation for certain categories of drugs (e.g., innovator clotting factor drugs for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act and innovator drugs approved by the FDA for exclusively pediatric indications). The Affordable Care Act also required that amounts attributable to these increased rebates be remitted to the Federal government.

To facilitate this process, per the State Medicaid Director letter #10-019, CMS will be calculating a unit rebate offset amount (UROA) that will identify the offset amount per unit of a drug at the 9-digit national drug code (NDC) level on a quarterly basis for States. States will then apply the UROA to the number of units of each drug for which they receive payment from a manufacturer to determine a Quarterly Rebate Offset amount (QROA) per drug per manufacturer. The per drug QROAs will be totaled across all manufacturers to determine each State's total QROA, and this amount will then be reported by States on the Medicaid Quarterly Expenditure reports as the total offset amount each quarter.

To accommodate the new UROA field, we have created the attached new file format, which will be provided to the States either via electronic file transfer (EFT) or along with the quarterly State rebate tape as a separate file, in addition to being posted into DDR. We have also attached a copy of the rebate file format, which has been updated to include an indicator for both clotting factor and exclusively pediatric drugs. These new formats will be applied beginning with the first quarter 2011 State files that are provided to the States in May 2011; however, we are providing this information now so that States will have sufficient time to update their systems in anticipation of these changes. In addition, the new file formats will also be available in DDR along with the other quarterly rebate files.

UNAPPROVED NEW DRUGS--DELETIONS FROM MDR

The States were previously notified that the NDC listed below is a vaccine; therefore, the NDC does not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and is subsequently no longer eligible for inclusion in the rebate program.

NDC	Product Name
00052-0603	TICE BCG VACCINE USP (FOR INTRAVESICAL OR PERCUTANEOUS USE)

The States were previously notified that the FDA has determined that the following active single-ingredient oral colchicine NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. 75 Fed. Reg. 60768 (October 1, 2010). According to the FDA, these products do not have approved New Drug Applications; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program.

NDC	Product Name
00143-1201	COLCHICINE TABLET 0.6MG
00591-0944	COLCHICINE 0.6MG
00603-3052	COLCHICINE 0.6 MG TAB
51552-0991	COLCHICINE USP
64125-0104	COLCHICINE 0.6 MG TABLETS
68013-0001	COLCHICINE 0.6 MG

The States were previously notified that the FDA has determined that the following active Exocrine Pancreatic Insufficiency NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. 69 Fed. Reg. 23410 and 72 Fed. Reg. 60860 (April 28, 2004 and October 26, 2007). According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program.

NDC	Product Name
00045-0341	PANCREASE/MT (r) PANCRELIPASE CAPSULES
00045-0342	PANCREASE/MT (R) PANCRELIPASE CAPSULES
00045-0343	PANCREASE/MT (R) PANCRELIPASE CAPSULES
00045-0346	PANCREASE MT 20

As a reminder, while the products listed above are not eligible for Medicaid coverage under the Medicaid Drug Rebate Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan. In other words, notice of non-coverage of these

products as covered outpatient drugs does not necessarily exclude them from appropriate coverage elsewhere in the Medicaid program.

PRODUCT DELETIONS

NDC	Product Name
42546-0412	PRUCLAIR CREAM
42546-0130	PRUTECT CREAM

NEW REBATE AGREEMENTS

Labeler Name: Lantheus Medical Imaging, Inc.
Optional Effective Date: 10/06/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 11994

Labeler Name: Akorn Strides
Optional Effective Date: 11/10/2010
Mandatory Effective Date: 04/01/2011
Labeler Code: 23360

Labeler Name: Tris Pharma, Inc.
Optional Effective Date: 11/30/2010
Mandatory Effective Date: 04/01/2011
Labeler Code: 27808

Labeler Name: Somaxon Pharmaceuticals, Inc.
Optional Effective Date: 10/14/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 42847

Labeler Name: CNS Therapeutics Inc.
Optional Effective Date: 12/28/2010
Mandatory Effective Date: 04/01/2011
Labeler Code: 45945

Labeler Name: VIIV Healthcare
Optional Effective Date: 10/19/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 49702

Labeler Name: Kylemore Pharmaceuticals LLC
Optional Effective Date: 09/16/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 49769

Labeler Name: Nesher Pharmaceuticals, Inc.
Optional Effective Date: 11/09/2010
Mandatory Effective Date: 04/01/2011
Labeler Code: 51477

Labeler Name: Orphan Europe, SARL
Optional Effective Date: 12/15/2010
Mandatory Effective Date: 04/01/2011
Labeler Code: 52276

Labeler Name: Cangene Bio Pharma
Optional Effective Date: 08/18/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 53270

Labeler Name: Lehigh Valley Technologies, Inc.
Optional Effective Date: 10/07/2010
Mandatory Effective Date: 01/01/2011
Labeler Code: 64950

TERMINATED LABELERS

Effective 01/01/2011

Labeler Name	Labeler Code
Smith & Nephew, Inc.	50484
Family Pharmacy–Amerisource/Bergen	52735
Idec Pharmaceuticals – Biogen Idec	64406
Vatring Pharmaceuticals, Inc.	65199
Rx Elite Holdings, Inc. DBA RxElite	66794
Cura Pharmaceutical Co., Inc.	66860

Effective 04/01/2011

Labeler Name	Labeler Code
Rosemont Pharmaceuticals	13632
Oncology Therapeutics Network Joint Vent	15210
Sirion Therapeutics, Inc.	42826
American Red Cross	52769
Tri-Med Laboratories	55654
Advanced Vision Research	58790
Digestive Care, Inc.	59767
Synthon Pharmaceuticals, Inc.	63672
Cebert Pharmaceuticals, Inc.	64019
Avanir Pharmaceuticals, Inc.	64597

FDA VOLUNTARY MARKET WITHDRAWALS

MERIDIA (sibutramine), October 8, 2010
The States were previously notified that, due to the risk of serious cardiovascular events, the FDA issued a voluntary withdrawal notice (http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm228830.htm) for Meridia (sibutramine). As a result of this action, the following NDCs were terminated in the Medicaid Drug Rebate Program effective October 8, 2010:

00074-2456-12, MERIDIA-SIBUTRAMINE HCI MONOHYDRATE
00074-2457-12, MERIDIA-SIBUTRAMINE HCI MONOHYDRATE
00074-2458-12, MERIDIA-SIBUTRAMINE HCI MONOHYDRATE

DARVON/DARVOCET (Propoxyphene), November 11, 2010
The States were previously notified that, due to the risk of cardiac toxicity, the FDA issued a voluntary withdrawal notice (http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm**)** for Darvon/Darvocet (Propoxyphene). As a result of this action, the following NDCs were terminated in the Medicaid Drug Rebate Program effective November 19, 2010:

66479-0510-10 DARVON PULVULES 65MG
66479-0512-10 DARVON-N 100MG
66479-0513-10 DARVOCET-A500 100MG
66479-0514-10 DARVOCET-N 50MG
66479-0515-10 DARVOCET-N 100MG
66479-0515-50 DARVOCET-N 100MG

Please direct your drug rebate data questions to mdroperations@cms.hhs.gov and your drug policy questions to the Division of Pharmacy at RxDrugPolicy@cms.hhs.gov.

/s/
Elaine Olin
Acting Director
Data and Systems Group

Attachments

CMS Record Specification
Unit Rebate Offset Amount (UROA)
File Record Format
May 1, 2011

Source: CMS
Target: State Agencies

Field	Size	Position	Remarks
Record ID	4	1 - 4	Constant of “99@@”
Labeler Code	5	5 - 9	NDC #1
Product Code	4	10 - 13	NDC #2
Package Size Code	2	14 - 15	NDC #3
Period Data Represents	7	16 – 22	MMMYYYY
Unit Rebate Offset Amt.	11	23 - 33	99999V999999
Record Type Indicator	1	34 – 34	See Data Element Definitions

Logical Record Length = 53
Block Size = 9010
Cartridge Name = FOREIGN.OPCART.ROqyyyy.xx
q = 1 Digit Calendar Quarter (i.e., 1, 2, 3, or 4)
yyyy = 4 Digit Year (i.e., 2010, 2011, etc.)
xx = 2 Character State code (i.e., MD)
Example: FOREIGN.OPCART.RO42010.MD

UNIT REBATE OFFSET AMOUNT
FIELD DEFINITIONS

Records ID: Constant value of “99@@”

Labeler Code: First segment of National Drug Code (NDC1) that identifies the manufacturer, labeler, relabeler, packager, repackager 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 Data Represents:

Calendar months and year the data represents (MMMYYYY)

Valid values for MMM:

JFM = January, February, March
AMJ = April, May, June
JAS = July, August, September
OND= October, November, December

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

Unit Rebate Offset Amount per Unit:

The CMS calculated amount per unit type

Record Type Indicator: Current period record:

0 = initial or current UROA record

Prior Period Adjustment (PPA) record:

8 = value of the old UROA as previously sent (informational)
9 = new or replacement UROA value

REBATE FIELD DEFINITIONS

Record ID:	Constant value of “01@@”
Labeler Code:	First segment of National Drug Code (NDC1) that identifies the manufacturer, labeler, relabeler, packager, repackager 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. (YYYYQ). 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 it appears on the FDA listing form.
Drug Category:	Classification of drug. N= Non-innovator multiple source – Generic S= Single source – Brand name I = Innovator multiple source – Brand Name
DESI Indicator:	A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective [LTE]) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs Valid Values: 2 = Safe and effective or non-DESI drug 3 = Drug under review (no NOOH issued) 4 = LTE/IRS drug for SOME indications 5 = LTE/IRS drug for ALL indications 6 = LTE/IRS drug withdrawn from market

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: The CMS calculated amount per unit type to be claimed as a rebate by the state.

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 distributed by labeler.

Drug 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 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 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

Record Type Indicator: Current period record:
0 = initial URA record
Prior Period Adjustment (PPA) record:
2 = value of the old URA previously sent (informational)
3 = new or replacement URA value

CMS Record Specification
MEDICAID DRUG REBATE
Rebate File Record Format
May 1, 2011

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
Product Name	10	21 - 30	See Data Element Definitions
Drug Category	1	31 - 31	See Data Element Definitions
DESI Indicator	1	32 - 32	See Data Element Definitions
TEC	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	11	48 - 58	99999V999999
FDA Approval Date	8	59 - 66	MMDDYYYY
Date Entered Market	8	67 - 74	MMDDYYYY
Termination Date	8	75 - 82	MMDDYYYY
Drug Type Indicator	1	83 - 83	See Data Element Definitions
Clotting Factor Indicator	1	84 - 84	Y or N
Pediatric Indicator	1	85 – 85	Y or N
Record Type Indicator	1	86 – 86	See Data Element Definitions

Logical Record Length = 86
Block Size = 9030
Cartridge Name = FOREIGN.OPCART.DRqyyyy.xx
q = 1 Digit Quarter (i.e., 1, 2, 3, or 4)
yyyy = 4 Digit Year (i.e., 1999, 2000, etc.)
xx = 2 Character State code (i.e., MD)
Example: FOREIGN.OPCART.DR41998.MD

REBATE FIELD DEFINITIONS

Records ID:	Constant value of “01@@”
Labeler Name:	Corporate name of entity identified by the labeler code.
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Thera. EQ. CD: 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.
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TAB	=	Tablet
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