DEPARTMENT OF HEALTH & HUMAN SERVICES

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Center for Medicaid , CHIP, and Survey & Certification

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MEDICAID DRUG REBATE PROGRAM **Release No. 155**

For State Medicaid Directors

AFFORDABLE CARE ACT OPERATIONAL GUIDANCE & FIRST QUARTER 2010 REBATE INFORMATION

In an effort to expedite this guidance, we previously provided interim guidance via email on May 24, 2010; however, we have since received questions requesting clarification on some of the provisions. Therefore, we have updated the language on the new rebate calculation for Single Source (S)/ Innovator Multiple Source (I) line extension drugs in an oral solid dosage form and on the limit of the rebate amount for S/I drugs under this section. We will continue to provide additional guidance as soon as it becomes available.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, together called the Affordable Care Act (ACA). Section 2501 of ACA, as amended by section 1206 of HCERA, include changes to certain Medicaid Drug Rebate (MDR) provisions, effective first quarter 2010. Several of these changes impact the Unit Rebate Amount (URA) calculation for all drugs covered under the MDR Program. Specifically, these sections increase the rebate percentages for S, I, and Non-Innovator (N) drugs and establish new requirements for calculating rebates for reformulated S/I drugs in oral solid dosage form. Additional details about these revised calculations may be found below.

In accordance with the national rebate agreement, labelers are responsible for calculating URAs. However, CMS usually provides States with calculated URAs for use on rebate invoices so that States can verify these URAs with any labeler-adjusted URAs that States may receive. CMS was not able to calculate a URA using the new rebate percentages or requirements for reformulated drugs in time for first quarter 2010 rebate processing. Therefore, until CMS' MDR systems (i.e.,

Drug Data Reporting for Medicaid (DDR) and MDR) are modified to reflect the URA changes implemented by ACA, CMS does not expect to be calculating these URAs.

In order to facilitate the data exchange between CMS and States, CMS did not send updated URAs to States on the first quarter 2010 tapes, along with the usual labeler contact and drug product data files. As a result, State invoices will not contain updated URAs, and labelers remain responsible for calculating these amounts. These uncalculated URAs will also be reflected in DDR beginning with the URAs for the first quarter of 2010 until system modifications are made. (Please note that this does not affect any prior period adjustments (PPAs) which are based on percentages in effect prior to ACA.) Therefore, labelers should update and submit their URAs to States using the OMB-approved Reconciliation of State Invoice (ROSI) form (Form CMS-304) that reflects the ACA amendments beginning with the first quarter 2010 drug rebate reporting period. A copy of the ROSI can be found in the MDR Data Guide for Labelers which is posted on the DDR website.

The URA calculation changes are summarized below:

Changes to the Basic URA Calculation

--Innovator (S/I Drug Category) drugs are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 23.1 percent.

--Innovator (S/I Drug Category) clotting factor drugs for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent. A list of these NDCs will be posted and updated in DDR in the near future for State and labeler use.

--Innovator (S/I Drug Category) drugs approved by the Food and Drug Administration (FDA) for exclusively pediatric indications are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent.

--Non-innovator (N Drug Category) drugs are subject to an increase in the minimum rebate percentage used to calculate rebates. To calculate the Basic URA of these products, the product's AMP is now multiplied by 13 percent.

New Rebate Calculation for S/I Line Extension (i.e., New Formulations) Drugs in Oral Solid Dosage Forms

For a drug that is a line extension (new formulation) of an S/I drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:

- the AMP for the line extension drug,
- the highest additional rebate for any strength of the original S/I drug, and

- the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).

Limit on Rebate Amount for S/I Drugs

--The total rebate obligation for all innovator drugs (S/I Drug Category) is capped at 100% of AMP.

Labelers are responsible for calculating rebates and URAs in accordance with the statute. CMS is currently working on systems updates and will promptly notify labelers and States when the changes are in place. At that time, States will receive PPAs retroactive, if applicable, to the first quarter 2010.

(Contact: mdroperations@cms.hhs.gov)

LIST OF PEDIATRIC AND CLOTTING FACTOR DRUGS AVAILABLE SOON IN DDR

The Affordable Care Act (ACA) establishes several new rebate calculations for those National Drug Codes (NDCs) covered under the Medicaid Drug Rebate Program, effective January 1, 2010. Under section 2501 of the ACA, most single source and innovator multiple source drugs are subject to a minimum rebate of 23.1 percent. Section 2501(a)(1)(B) of the ACA added a new section 1927(c)(1)(B)(iii) to the Social Security Act (the Act) to require a new minimum rebate of 17.1 percent of the average manufacturer price (AMP), effective January 1, 2010 for a drug approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.

We plan to interpret this provision in accordance with Federal regulations published by the FDA regarding pediatric labeling requirements for prescription drugs, and plan to interpret in light of the FDA labeling and as the indications for pediatric use on the labeling. In accordance with regulations at 21 CFR 201.57, and 21 CFR 201.80, the FDA defines pediatric use for drugs use as for pediatric populations and pediatric patients. The FDA defines pediatric populations and pediatric patients as the pediatric age group from birth to 16 years. Accordingly, we plan to apply the 17.1 percent minimum rebate to those single source or innovator multiple source drugs approved by the FDA exclusively for pediatric indications meeting this FDA definition. Drugs that are not approved, or labeled, exclusively with indications for pediatric use will not qualify for the minimum rebate provisions in section 1927(c)(1)(B)(iii of the Act.

Until CMS's systems can be updated to include an identifier for these drugs and others specified in ACA, we have compiled an initial draft list of those pediatric drugs we have been able to identify that we believe to meet the above-mentioned definition. This list will be posted on the Bulletin Page in the Drug Data Reporting for Medicaid (DDR) application for State and labeler use. Additionally, this list will be posted on the Policy & Reimbursement's Spotlight web page at http://www.cms.gov/Reimbursement/02_Spotlight.asp. If you have concerns or are aware of other drugs that meet the pediatric definition specified above, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov and specify the drug(s) for which you have concerns or that you believe meet this definition as well as supporting documentation, including the FDA labeling, so that CMS can review this and, if appropriate, update the list accordingly.

Additionally, the ACA added a new section 1927(c)(1)(B)(iii) establishing a minimum rebate of 17.1 percent for clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. We expect that when products are included on the list, the minimum rebate of 17.1 percent of AMP will be used as a basis for rebate calculation. CMS has obtained this data from Medicare Part B and will post the list of clotting factor NDCs on the Bulletin Page in DDR for State and labeler use. This list will also be posted on the Policy & Reimbursement's Spotlight web page. If you have any questions or corrections to this list, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov so that we can review this submission and, if appropriate, update the list accordingly.

CMS will issue additional guidance regarding changes to the Medicaid Drug Rebate Program as it becomes available.

REMOVAL OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS AS COVERED OUTPATIENT DRUGS

We are providing policy clarification regarding the inclusion of APIs and excipients in the drug rebate program. An API is a bulk drug substance, which is defined by the FDA as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. 21 C.F.R. § 207.3(a)(4). APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the MDR program. In addition, excipient products used in compounds (*e.g.*, aquaphor, petrolatum, etc.) are non-drug products and, as a result, should not be reported to the MDR program. However, FFP may be available for these products if the State plan allows for their coverage as incident to another service category (*e.g.* Home Health, Nursing, Other Practitioner).

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. We are notifying manufacturers that the NDCs do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. As with all deletions, we will notify the States regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage. Please note that this is not a definitive list. If additional API and/or excipient NDCs are identified, please notify MDROperations@cms.hhs.gov to have them removed from the MDR Program.

The State Medicaid agency should also review their State plan to assure that to the extent that it wishes to continue coverage of these products, the plan allows for such coverage. Where the plan does not allow for such coverage, a State plan amendment should be submitted.

If you have any questions, please contact Joseph Fine at 410-786-2128.

BANKRUPTCY FILING BY LABELER CODE 11042 – MIDDLEBROOK PHARMACEUTICAL, INC.

We have recently become aware that labeler code 11042 (Middlebrook Pharmaceutical, Inc.) filed a Chapter 11 Voluntary Petition in the U.S. Bankruptcy Court for the District of Delaware.

When labelers file for bankruptcy, states are expected to protect Medicaid interests related to any rebate payments owed from the affected labelers. To that end, we strongly encourage states to file a proof of claim for any outstanding rebate payments in the bankruptcy proceedings of the abovementioned labelers.

In addition, we are in the process of determining whether this labeler code should be terminated from the Drug Rebate Program as a result of the bankruptcy filing. If a determination is made that the labeler should be terminated, we will notify you of the termination via an email notification.

(Contact: mdroperations@cms.hhs.gov)

UNAPPROVED NEW DRUGS--DELETIONS FROM MDR

The States were previously notified that the FDA has determined that the following active 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. 73 Fed. Reg. 54831 (September 23, 2008). 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. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

NDC	Product Name
13279-0100	PAPAIN UREA OINTMENT
13279-0101	ALLANFIL 405 OINTMENT
13279-0102	ALLANZYME SPRAY
13279-0103	ALLANFIL SPRAY
51552-0584	PAPAIN POWDER PURIFIED
58177-0804	ETHEZYME PAPAIN UREA DEBRIDING OINTMENT
58177-0816	ETHEZYME 830 PAPAIN-UREA DEBRIDING OINTMENT
58980-0711	KOVIA OINTMENT
58980-0722	KOVIA 6.5 OINTMENT
58980-0765	ZIOX OINTMENT
58980-0776	ZIOX 405 OINTMENT

As a reminder, while these products are not eligible for Medicaid coverage under the MDR 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.

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. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

NDC	Product Name
00032-1205	CREON5CAPSULES
00032-1210	CREON10CAPSULES
00032-1220	CREON20CAPSULES
00091-4175	KUTRASE CAPSULES RX
10267-2737	PANCRELIPASE 8,000 TABLETS
39822-9045	PANCRELIPASE 4,500
39822-9100	PANCRELIPASE 10,000
39822-9160	PANCRELIPASE 16,000
39822-9200	PANCRELIPASE 20,000
58177-0028	PANGESTYME MT 16 CAPSULES
58177-0029	PANGESTYME CN 10 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0030	PANGESTYME CN 20 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0031	PANGESTYME EC CAPSULES
58177-0048	PANGESTYME UL 12 CAPSULES
58177-0049	PANGESTYME UL 18 CAPSULES
58177-0050	PANGESTYME UL 20 CAPSULES
58177-0416	PLARETASE
58914-0002	ULTRASE MT 12
58914-0004	ULTRASE MT 20
58914-0018	ULTRASE MT18
58914-0045	ULTRASE MS 4
58914-0111	VIOKASE
58914-0115	VIOKASE 8OZ POWDER
58914-0116	VIOKASE 16000
59767-0001	PANCRECARB MS-8
59767-0002	PANCRECARB MS-4
59767-0003	PANCRECARB MS-16

As a reminder, while these products are not eligible for Medicaid coverage under the MDR 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.

The States were previously notified that FDA has determined that the following active NDCs are unapproved new drugs within the meaning of section 301(a) and (d) and Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d) and 355(a) and the drugs are

misbranded in violation of Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1), subject to enforcement action, and cannot be marketed without appropriate FDA approval. 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. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

As a reminder, while these products are not eligible for Medicaid coverage under the MDR 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.

NDC	Product Name
00603-1314	HYOSCYAMINE SULFATE DROPS (15 ML)
00603-1315	HYOSCYAMINE SULFATE LIQUID (16 OZ)
00603-5141	PHENAZOPYRIDINE HC1 (O.1G) TABLETS
00603-5142	PHENAZOPYRIDINE HC1 (O.2G) TABLETS

(Contact: mdroperations@cms.hhs.gov)

NOTIFICATION OF CHANGES IN DESI CODE

The states were previously notified that the following products were reported by the labeler with a DESI code of 2 (i.e., rebate- eligible); however, the FDA has determined that the drugs are subject to a Federal Register notice dated April 20, 1999 (64 FR 19374) which proposed to withdraw approval of certain New Drug Applications and Abbreviated New Drug Applications for controlled-release nitroglycerin tablets and capsules. Therefore, the appropriate DESI code for each of these products is a code of 5 (i.e., less-than-effective/IRS drug for all indications). As a result, these drugs are no longer eligible for coverage under the MDR Program.

00603-4782	NITROGLYCERIN CAP
49483-0221	NITRO-TIME 2.5MG
49483-0222	NITRO-TIME 6.5MG
49483-0223	NITRO-TIME 9MG
58809-0615	CARBATAB-12

(Contact: mdroperations@cms.hhs.gov)

NEW REBATE AGREEMENTS

Labeler Name:	Baxter Healthcare Corporation
Optional Effective Date:	04/01/2010
Mandatory Effective Date:	04/01/2010
Labeler Code:	00941

Labeler Name:	Actavis Pharma Manufacturing Private Limited
Optional Effective Date:	04/27/2010

Mandatory Effective Date: 07/01/2010
Labeler Code: 14550

Labeler Name: Topco Associates LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 36800

Labeler Name: Allaire Pharmaceuticals, LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 43351

Labeler Name: Amerisource Bergen Drug Corporation
Optional Effective Date: 07/05/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 46122

Labeler Name: Alvogen Inc.
Optional Effective Date: 01/29/2010
Mandatory Effective Date: 04/01/2010
Labeler Code: 47781

Labeler Name: Dyax Corp.
Optional Effective Date: 01/28/2010
Mandatory Effective Date: 04/01/2010
Labeler Code: 47783

Labeler Name: Neurogesx, Inc.
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 49685

Labeler Name: Nautilus Neurosciences, Inc.
Optional Effective Date: 06/08/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 50192

Labeler Name: Leo Pharma Inc.
Optional Effective Date: 02/23/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50222

Labeler Name: QLT Ophthalmics Inc.
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50236

Labeler Name: Avpak
Optional Effective Date: 04/30/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50268

Labeler Name: Wallace Pharmaceuticals
Optional Effective Date: 07/20/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 51525

Labeler Name: Amedra Pharmaceuticals, LLC
Optional Effective Date: 07/20/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 52054

Labeler Name: Gensavis, LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 52304

Labeler Name: Physician Therapeutics LLC
Optional Effective Date: 04/13/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 68405

TERMINATED LABELERS

Effective 04/01/2010

Labeler Name	Labeler Code
Skin Medica	67402

Effective 07/01/2010

Labeler Name	Labeler Code
Microbix Biosystems, Inc.	24430
Le Vista Inc.	42212
Sage Pharmaceuticals, Inc.	59243
Dabur Pharma US, Inc.	10518

Effective 10/01/2010

Labeler Name	Labeler Code
Beta Dermaceuticals, Inc.	53062

VOLUNTARILY TERMINATED LABELERS

Effective 07/01/2010

Labeler Name	Labeler Code
Blaine Company	00165
Targacept	17205
Topix Pharmaceuticals, Inc.	58211

Effective 10/01/2010

Labeler Name	Labeler Code
Novavax, Inc. (formerly Fielding)	00421

PRODUCT DELETIONS

00904-0985	SYRVITE SYRUP
00145-1504	ZEASORB POWDER
00145-1057	OILATUM CLEANSING BAR
37205-0110	MAGNESIUM CITRATE
37205-0113	DAIRY DIGEST SUPP
37205-0114	DAIRY DIGEST SUPPLEMENT ULTRA
37205-0301	NATURAL VEGETABLE POWDER LAXATIVE
37205-0303	NATURAL VEGETABLE POWDER ORANGE
37205-0347	NATURAL VEGETABLE POWDER LAXATIVE
37205-0362	CITRATE OF MAG LO SODIUM
37205-0366	NATURAL VEGETABLE POWDER SUG-FREE
37205-0480	FIBER SUPPLEMENT 12.3OZ SF
37205-0606	CRANBERRY TAB 50
45802-0357	IMPROVED SALINE MIST 45ML
49614-0134	MAGNESIUM CITRATE LEMON
49614-0135	MAGNESIUM CITRATE CHERRY
49614-0227	FIBER SUPPLEMENT 12.3OZ SF
49614-0345	FIBER LAX 13OZ ORANGE ORIGINAL
49614-0347	FIBER LAX 10OZ ORANGE SMOOTH
49614-0350	FIBER CAPLETS 625MG 90
49614-0366	FIBER LAX 10OX SF ORG SMOOTH
49614-0388	DAIRY DIGESTIVE 32
63717-0099	ICAR-C TABLETS
63717-0102	ICAR PEDIATRIC SUSPENSION
63717-0103	ICAR PEDIATRIC CHEWABLE TABLET

As a reminder, while these products are not eligible for Medicaid coverage under the MDR 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.

UPCOMING MODIFICATIONS TO THE STATE UTILIZATION DISCREPANCY ERROR AND ALERT REPORT

In an effort to improve both the quality and the processing of the state utilization data, we will soon be changing some of the error and alert edits included on the utilization discrepancy report. In addition, the format of the discrepancy report is being changed to consolidate it and to make it more straightforward for states. Please note that these changes will NOT require the States to make any change to the current file structure used to submit utilization data to CMS/MDR. The revised list of discrepancy report error and alert messages is attached, along with an example of the new format for the report and some additional utilization data process information that will be implemented.

(Contact: mdroperations@cms.hhs.gov)

CHANGE TO THE DISPUTE RESOLUTION PROGRAM

CMS is in the process of replacing the Central Office Dispute Resolution Program (DRP) Team Lead, who recently retired. Therefore, as DRP issues arise for which a State and/or labeler would like to request CMS's assistance, please follow the established practice of contacting the appropriate Regional Office DRP Coordinator. The contacts may be found on the web at: www.cms.gov/MedicaidDrugRebateDispR/Downloads/rodrpcoordinators.pdf

The Denver Regional Office's DRP/Drug Coordinator continues to serve as the Lead RO for DRP issues and should be copied on all dispute-related communications to other Regional Office DRP Coordinators.

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 .

Rick Friedman /s/ for

Penny R. Thompson
Acting Director
Data and Systems Group

Attachments

cc:
Regional Administrators