DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

December 28, 2011

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 159**

For State Technical Contacts

USE OF STATE UTILIZATION DATA FOR CALCULATION OF ANNUAL BRANDED PRESCRIPTION DRUG FEE

State utilization data is now being used as part of the methodology for establishing an annual fee on branded prescription drug manufacturers that was established by Section 9008 of the Affordable Care Act. In general, the government drug programs specified in Section 9008 (e.g., Medicaid, Medicare Part B and Medicare Part D) are required to report drug sales information to the Department of Treasury each year so that the fees can be accurately calculated. For purposes of the Medicaid data, CMS does not want to impose a new reporting requirement on the States as part of this process; therefore, the State utilization data that is currently reported under Section 1927(b)(2)(A) of the Act is being provided to the Department of Treasury as one element of Medicaid's drug sales information. Therefore, timely and complete State utilization data reporting is essential to this process. We will be reviewing your State's utilization file submissions for all quarters of 2010 to ensure that CMS has received the data, and that the State has responded to any utilization emails or reports that it has received from CMS. Please review the utilization data that has been submitted for 2010 to determine whether any additional submissions or corrections are necessary. If so, please send the additional data immediately via your State's current drug rebate utilization data transmission process (i.e., Electronic File Transfer or electronic cartridge).

Please contact MDROperations@cms.hhs.gov if there are any questions.

BANKRUPTCY FILINGS BY DRUG LABELERS

Graceway Pharmaceuticals, LLC (Labeler codes 29336, 13453, 00089 and 15456), filed a bankruptcy petition under Chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court on September 29, 2011 (http://www.gracewaypharma.com/news/0099-information-vendors-regarding-graceways-recently-announced-bankruptcy). Labelers that have filed for bankruptcy may voluntarily terminate from the program or be terminated from the program by CMS if necessary pursuant to section 1927(b)(4)(B). However, filing for bankruptcy does not result in automatic termination from the program. If a labeler is terminated from the program following a filing for bankruptcy, as with all terminations, we will notify States of the terminated labeler by

email. In general, when labelers file for bankruptcy, States are expected to protect Medicaid's interest related to any rebate payments owed from the affected labelers.

Please contact MDROperations@cms.hhs.gov if there are any questions.

COVERAGE OF OVER THE COUNTER (OTC) PRENATAL VITAMINS UNDER THE MEDICAID DRUG REBATE PROGRAM

Please be advised that non-prescription (OTC) prenatal vitamins do not appear to meet the definition of a covered outpatient drug as set forth in section 1927(k)(4) of the Social Security Act; therefore, they do not appear to be eligible for coverage under the Medicaid Drug Rebate Program (MDRP). We have recently become aware of some non-prescription (OTC) products labeled as prenatal vitamins that labelers have included in their reporting to us, and some States have reported utilization for these products.

We are currently in the process of identifying these products for deletion from the MDRP, and, as with all product deletions, we will notify the States regarding the removal of these products. In the meantime, you may wish to review your Medicaid Drug Rebate database to determine whether non-prescription (OTC) prenatal vitamins are currently being utilized in your State. Please note that should a product no longer be eligible for inclusion in Medicaid Drug Rebate Program, we will notify you of the NDC number. These products may be eligible for Medicaid coverage or FFP as part of home health services or EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved State plan. As a reminder, prescription prenatal vitamins continue to meet the definition of a covered outpatient drug and are rebate-eligible.

To assist us in removing these products from the MDRP, please identify and forward to CMS any NDCs in your MDR database that are labeled as OTC prenatal vitamins and that appear in our Drug Data Reporting for Medicaid (DDR) system as active drugs. Please forward the NDCs to our email box MDRoperations@cms.hhs.gov for our review.

MARKET WITHDRAWALS

As previously notified, the following NDCs were terminated 10/25/2011 due to a market withdrawal. Additional information regarding the withdrawal can be found on the FDA website at http://www.fda.gov/Drugs/DrugSafety/ucm277114.htm.

NDC	Product Name
00002-7559-01	XIGRIS
00002-7561-01	XIGRIS

DEVICE DELETIONS FROM THE MEDICAID DRUG REBATE PROGRAM

The States were previously notified that the following device products do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act (the Act). The

Food and Drug Administration (FDA) has informed us that these products received FDA clearance under the 510(k) premarket notification submission process used for certain devices under the Federal Food, Drug and Cosmetic Act. As a result, they are not covered outpatient drugs as defined in section 1927(k)(2) of the Act and are, therefore, no longer eligible for inclusion in MDRP or eligible for FFP as covered outpatient drugs. The device products that are no longer rebate eligible are as follows:

NDC	Product Name
00095-0070-14	TROPAZONE LOTION
00095-0071-12	TROPAZONE CR (TROPAZONE CREAM)

NEW DRUG DETERMINATION—DELETIONS FROM MDR

On May 4, 2011, CMS provided you with a list of cough, cold and allergy NDCs that were no longer eligible for coverage under the Medicaid Drug Rebate Program. In addition to the products included in that initial notification, the FDA has also determined that the following NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act in accordance with the document published in the Federal Register titled, "Drugs for Human Use: Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough or Allergy; Enforcement Action Dates" (76 Fed. Reg. 11794 (March 3, 2011)). Therefore, we have determined that the NDCs listed below 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.

The labelers of these products are responsible for paying rebates on these NDCs for any State utilization that occurred prior to the date of this notice. In addition, States should be aware that the fourth quarter 2011 rebate file will be the last quarterly rebate file that will include these NDCs in order to facilitate rebate billing for such utilization.

CMS is continuing to work with the FDA to identify other NDCs that do not qualify as covered outpatient drugs. Should you have any questions or concerns regarding additional NDCs that you believe are subject to the FDA's Federal Register Notice on unapproved oral, cough, cold and allergy drug products, please send a list of those NDCs to our email resource box at MDROperations@cms.hhs.gov.

NDC	Product Name
00642-0647	TUSSO-ZMR CAP
00642-0649	TUSSO-ZR SYRUP
23589-0002	HISTEX LIQUID
23589-0004	ACCUHIST DROPS
50383-0856	TANNATE 12D SUSPENSION
51991-0286	MINTUSS DR SYRUP
51991-0493	TRIPLEX DM LIQUID
51991-0537	QUARTUSS DM DROPS
51991-0597	GUIATEX PE SYRUP
64543-0085	NEW RESCON JR TABLETS
64543-0090	NEW RESCON MX
66992-0136	VAZOL-D LIQUID
66993-0534	R-TANNA TABLETS

66993-0537	R-TANNA S PEDIATRIC SUSP 5/4.5MG
68032-0211	RE DRYLEX SYRUP

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The states were previously notified of the FDA's determination of the changes in DESI code status for the following.

The labeler reported a DESI code of 2 (i.e., rebate- eligible) for the following NDC; however, the FDA has determined that the NDC is less than effective/IRS drug for all indications, DESI code 5:

NDC	**Product Name**
43199-0021	HYDROCORTISONE ACETATE SUPPOSITORY 25 MG

The labelers reported the following NDCs with a DESI code of 5 (i.e., less than effective/IRS drug for all indications); however, the FDA has determined that the NDCs are safe and effective, DESI code 2:

NDC	**Product Name**
00574-0159	OPIUM TINCTURE, USP (DEODORIZED)
62559-0153	OPIUM TINCTURE, USP (DEODORIZED)

PRODUCT DELETIONS

As previously notified on 7/25/11, the NDCs listed below are over-the-counter dietary supplements; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k)(2) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. The labelers of these products are responsible for paying rebates on these NDCs for any State utilization that occurred prior to the date of this notice.

Please note that while these products are not eligible for coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved State plan.

NDC	**Product Name**
24478-0103	MYKIDZ IRON 10
27808-0022	MYKIDZ IRON 10

NEW REBATE AGREEMENTS

Labeler Name: CREEKWOOD PHARMACEUTICAL, INC.
Optional Effective Date: 07/12/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 15310

Labeler Name: GE HEALTHCARE, INC.
Optional Effective Date: 07/05/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 00407

Labeler Name: AMERICAN ANTIBIOTICS, INC.
Optional Effective Date: 09/14/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 15749

Labeler Name: BAXTER HEALTHCARE CORPORATION
Optional Effective Date: 08/12/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 43066

Labeler Name: INCYTE CORPORATION
Optional Effective Date: 12/08/2011
Mandatory Effective Date: 04/01/2012
Labeler Code: 50881

Labeler Name: SEATTLE GENETICS, INC.
Optional Effective Date: 09/26/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 51144

Labeler Name: ACTIENT PHARMACEUTICALS
Optional Effective Date: 10/07/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 52244

Labeler Name: GENSOURCE RX
Optional Effective Date: 08/18/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 52343

Labeler Name: ALMATICA INC.
Optional Effective Date: 08/09/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 52427

Labeler Name: PURETEK CORPORATION
Optional Effective Date: 07/18/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 59088

Labeler Name: ORCHIDPHARMA, INC
Optional Effective Date: 10/24/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 59834

Labeler Name: MCKESSON CORP.
Optional Effective Date: 12/15/2011
Mandatory Effective Date: 04/01/2012
Labeler Code: 62011

Labeler Name: BELCHER PHARMACEUTICALS, LLC
Optional Effective Date: 09/14/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 62250

Labeler Name: WINDER LABORATORIES, LLC
Optional Effective Date: 10/05/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 75826

Labeler Name: HORIZON PHARMA, INC.
Optional Effective Date: 09/06/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 75987

Labeler Name: ECLAT PHARMACEUTICALS, LLC
Optional Effective Date: 10/05/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 76014

Labeler Name: TALEC PHARMA
Optional Effective Date: 09/01/2011
Mandatory Effective Date: 01/01/2012
Labeler Code: 76181

Labeler Name: RITEDOSE PHARMACEUTICALS, LLC
Optional Effective Date: 12/14/2011
Mandatory Effective Date: 04/01/2012
Labeler Code: 76204

Labeler Name: EXELAN PHARMACEUTICALS, INC
Optional Effective Date: 12/02/2011
Mandatory Effective Date: 04/01/2012
Labeler Code: 76282

TERMINATED LABELERS

Labeler Code	Labeler Name	Effective Date
00496	FERNDALE LABORATORIES INC.	10/01/2011
00525	PAMLAB, LLC	01/01/2012

14508	SUN PHARMACEUTICAL INDUSTRIES, INC.	10/01/2011
23110	PROBACTIVE BIOTECH, INC.	10/01/2011
23589	TIBER LABORATORIES	01/01/2012
43378	CODADOSE INCORPORATED	01/01/2012
52604	JONES PHARMA, INCORPORATED	10/01/2011
55515	WATSON PHARMA, INC.	10/01/2011
60267	HOPE PHARMACEUTICALS	10/01/2011
61451	AMERIFIT PHARMA, INC.	10/01/2011
66500	NOVAVAX, INC.	10/01/2011
66591	AAI PHARMA	10/01/2011
66814	WORLD GEN, LLC	10/01/2011
67871	QOL MEDICAL	10/01/2011
68032	RIVER'S EDGE PHARMACEUTICALS	01/01/2012

Please direct your drug rebate data questions to MDROperations@cms.hhs.gov and your drug policy questions to RxDrugPolicy@cms.hhs.gov.

/s/

Barbara Coulter Edwards
Director
Disabled & Elderly Health Programs Group