



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244 -1850

September 9, 2009

**MEDICAID DRUG REBATE PROGRAM**

**Release No. 152**



## **For State Medicaid Directors**



### **UPCOMING FILE FORMAT CHANGE TO THE QUARTERLY STATE REBATE TAPE**

The Labeler Contact File portion of the quarterly state rebate tape does not currently reflect email addresses for each manufacturer's Invoice, Legal and Technical Contacts. In order to provide states with direct access to this information, the format of the Labeler Contact File is being modified to include these email addresses. This new format will be applied beginning with the fourth quarter 2009 state tape that will be mailed to the states in February 2010; however, we are providing this information now so that states will have sufficient time to update their systems in anticipation of these changes. Please note that the second and third quarter 2009 state tapes (mailed to the states in August 2009 and November 2009, respectively) will continue to reflect the old format. A copy of the updated Labeler Contact File format is attached to this release.

Please also note that the new email fields will be included on the labeler contact information file at [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/10\\_DrugComContactInfo.asp](http://www.cms.hhs.gov/MedicaidDrugRebateProgram/10_DrugComContactInfo.asp) beginning with the 2Q2009 (August 2009) posting.

(Contact: [mdoperations@cms.hhs.gov](mailto:mdoperations@cms.hhs.gov))

## **UNAPPROVED OTCs--DELETIONS FROM MDR**

Labeler 00225 has informed CMS that the following are unapproved OTC products and they 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). As a result, they are no longer eligible for rebate under the Medicaid Drug Rebate Program and are no longer qualified for State coverage under the rebate program, effective immediately.

NDC	Product Name
00225-0526	AYR GEL SWABS
00225-0528	AYR GEL NO DRIP
00225-0655	AYR VAPOR INHALER
00225-0680	SNORE
00225-0700	AYR RINSE KIT (SODIUM CHLORIDE)
00225-0705	AYR RINSE KIT REFILLS (SODIUM CHLORIDE)
00225-0710	AYR NETI POT (SODIUM CHLORIDE)

(Contact: [DRARxPolicy@cms.hhs.gov](mailto:DRARxPolicy@cms.hhs.gov))

## **TREATMENT OF TRICARE RETAIL PHARMACY BENEFIT PLAN TRANSACTIONS**

The Medicaid Drug Rebate Program specifically excludes Department of Defense (DoD) and Depot prices from the Best Price (BP) and Average Manufacturer Price (AMP) calculations.

On March 17, 2009, the Department of Defense (DoD) issued the regulation entitled, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals. This final rule implements section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA) which states that with respect to any prescription filled on or after the date of enactment of the NDAA, the TRICARE Retail Pharmacy Program shall be treated as an element of the DoD for purposes of procurement of drugs by federal agencies under Section 8126 of title 38, United States Code (U.S.C.).

The Medicaid Drug Rebate Program, as established and implemented by relevant statute, regulation, and the Medicaid Rebate Agreement, excludes DoD prices from AMP and BP calculations. For purpose of the rebate program, we have determined that TRICARE Retail Pharmacy Program prices should be treated as prices to DoD.

Accordingly, since prices to DoD are excluded from AMP and BP calculations under the Federal Medicaid statute and regulations, sales and prices of drugs, including associated rebates, discounts, and other price concessions, provided to the TRICARE Retail Pharmacy Program should be excluded from the calculation of AMP and BP. This guidance applies only to pharmaceuticals paid by DoD to eligible recipients consistent with the requirements of the TRICARE Retail Pharmacy Program.

If you have further questions please contact David Moscovic at [david.moscovic@cms.hhs.gov](mailto:david.moscovic@cms.hhs.gov) or 410-786-4693.

## **PREVENTIVE DISPUTE RESOLUTION MEASURES FOR STATE INVOICING**

It has been brought to our attention that there are some states that are still not providing the Non-Medicaid Reimbursement amounts on the quarterly invoices (CMS-R-144) as instructed by CMS, especially on the medical utilization primarily for the dual eligible patients for which there is the Medicare reimbursement amount.

The lack of this vital information does not allow manufacturers to evaluate the data, and requires them to review and validate claims level data on a line by line basis, which is very time consuming. In many instances, the reimbursement data provides manufacturers with the information needed to validate the units and determine whether the conversion from HCPCS/J-Code billing units to Medicaid billing units has been performed correctly. Without this information, many claims line items must be reviewed each quarter which may cause delays in invoice rebate payments.

(Contact: [DRP@cms.hhs.gov](mailto:DRP@cms.hhs.gov))

## **NEW REBATE AGREEMENTS**

The following are new labelers to the Medicaid Drug Rebate Program.

Labeler Name: AKRIMAX PHARMACEUTICALS LLC  
Optional Effective Date: 04/22/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 24090

Labeler Name: LE VISTA INC.  
Optional Effective Date: 04/15/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 42212

Labeler Name: PRUGEN, INC.  
Optional Effective Date: 07/03/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 42546

Labeler Name: VANDA PHARMACEUTICALS, INC.  
Optional Effective Date: 07/30/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 43068

Labeler Name: COUNTY LINE PHARMACEUTICALS, LLC  
Optional Effective Date: 07/27/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 43199

Labeler Name: GAVIS PHARMACEUTICALS, LLC  
Optional Effective Date: 06/09/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 43386

Labeler Name: SOLCO HEALTHCARE US, LLC  
Optional Effective Date: 05/12/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 43547

Labeler Name: CONVATEC INC.  
Optional Effective Date: 04/22/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 43553

Labeler Name: MACOVEN PHARMACEUTICALS, LLC  
Optional Effective Date: 05/30/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 44183

Labeler Name: WG CRITICAL CARE, LLC  
Optional Effective Date: 04/28/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 44567

Labeler Name: AMAG PHARMACEUTICALS, INC.  
Optional Effective Date: 07/23/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 59338

Labeler Name: CSL BEHRING GMBH  
Optional Effective Date: 06/12/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 63833

Labeler Name: ALKERMES, INC.  
Optional Effective Date: 04/30/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 65757

Labeler Name: MULTI-PAK PACKAGING  
Optional Effective Date: 04/30/2009  
Mandatory Effective Date: 07/01/2009  
Labeler Code: 66789

Labeler Name: OCTAPHARMA PHARMAZEUTIKAGM  
Optional Effective Date: 06/30/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 67467

Labeler Name: OCTAPHARMA A.B.  
Optional Effective Date: 06/30/2009  
Mandatory Effective Date: 10/01/2009  
Labeler Code: 68209

Contact information for new labelers can be found on the MDR program website.

**TERMINATED LABELERS**

**Effective 10/01/2009:**

<u>Labeler Name</u>	<u>Labeler Code</u>
Neurosci, Inc.	14565
Auriga Laboratories, Core Pharma	14629
Armstrong Pharmaceuticals	17270
Centurion Labs, LLC	23359
Stesso Pharmaceuticals	33753
Ocusoft Inc.	54799
Amkas Laboratories, Inc.	61073
Sirius Laboratories, Inc.	65880
Teamm Pharmaceuticals, Inc.	67336

**VOLUNTARILY TERMINATED LABELERS**

**Effective 10/01/2009:**

<u>Labeler Name</u>	<u>Labeler Code</u>
Triax Pharmaceuticals, LLC	14290
Deston Therapeutics, LLC	16881
Provident Pharmaceutical, Inc.	20091
Patrin Pharma.	39328
Santarus, Inc.	68012

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Please direct your drug rebate data questions to [mdoperations@cms.hhs.gov](mailto:mdoperations@cms.hhs.gov) and your drug policy questions to the Division of Pharmacy at [DRARxPolicy@cms.hhs.gov](mailto:DRARxPolicy@cms.hhs.gov).

/s/

Edward C. Gendron  
Director  
Finance, Systems and Budget Group

Attachment:

cc: Regional Administrators

**CMS LABELER CONTACT FILE  
RECORD FORMAT  
Effective: February 2010**

Source: CMS

Target: State Agencies

Field	Size	Position	Remarks
Labeler Code	5	1 - 5	NDC #1
Labeler Name	39	6 - 44	Manufacturer Name
Optional Eff. Date	8	45 - 52	MMDDYYYY
Termination Date	8	53 - 60	MMDDYYYY
Legal Contact Name	39	61 - 99	Name of Legal Contact
Legal Corporation	39	100 - 138	Corporation Name
Legal Address #1	39	139 - 177	Legal Address Line 1
Legal Address #2	39	178 - 216	Legal Address Line 2
Legal Address #3	39	217 - 255	Legal Address Line 3
Legal City	27	256 - 282	
Legal State	2	283 - 284	
Legal Zip	9	285 - 293	X(9)
Legal Phone	14	294 - 307	X(14) Area Code, Number, Extension
Legal Email	40	308 - 347	Legal Contact Email Address
Invoice Contact	39	348 - 386	Name of Invoice Contact
Invoice Corp.	39	387 - 425	Corporation Name
Invoice Address 1	39	426 - 464	Invoice Address Line 1
Invoice Address 2	39	464 - 503	Invoice Address Line 2
Invoice Address 3	39	504 - 542	Invoice Address Line 3
Invoice City	27	543 - 569	
Invoice State	2	570 - 571	
Invoice Zip	9	572 - 580	X(9)
Invoice Phone	14	581 - 594	X(14) Area Code, Number, Extension
Invoice Email	40	595 - 634	Invoice Contact Email Address
Technical Name	39	635 - 673	Name of Technical Contact
Technical Corp.	39	674 - 712	Corporation Name
Technical Address 1	39	713 - 751	Technical Address Line 1
Technical Address 2	39	752 - 790	Technical Address Line 2
Technical Address 3	39	791 - 829	Technical Address Line 3
Technical City	27	830 - 856	
Technical State	2	857 - 858	
Technical Zip	9	859 - 867	X(9)
Technical Phone	14	868 - 881	X(14)
Technical Email	40	882 - 921	Technical Contact Email Address
Active Indicator	1	922 - 922	0=Old, 1=Currently Active
Carriage Return	1	923 - 923	
Line Feed	1	924 - 924	

\*Logical Record Length = 924

\*Labeler Contact file is second physical file on rebate tape.