



August 23, 2006

**MEDICAID DRUG REBATE PROGRAM****RELEASE #143**

## For State Medicaid Directors



### **CHANGES TO CMS FORM R-144 (STATE INVOICE)**

States are required to submit a quarterly invoice of utilization data to drug manufacturers that have national rebate agreements with CMS. CMS Form R-144, which is the invoice form used by the states to submit this utilization information to manufacturers, has been revised to include two new columns: the Medicaid Amount Reimbursed column and the Non-Medicaid Amount Reimbursed column. Previously, only one column related to reimbursement was present on the invoice; however, that column did not allow states to differentiate between instances in which both the state and a third party payer each reimbursed a portion of the same claim, and instances in which the state reimbursed the entire claim. As a result, manufacturers would sometimes dispute the units reimbursed that a state submitted on the invoice because the number of units reimbursed did not correspond to the reimbursement amount included on the form. Therefore, the aforementioned new columns have been added to the invoice to more clearly identify what portion of each Medicaid prescription claim was paid by the State Medicaid Agency and what portion, if any, was paid by another third party. With this revision, CMS anticipates a reduction in the number of Medicaid disputes. Pages F26 and M12 of the Operational Training Guide have been updated to reflect the addition of the two new reimbursement columns and are attached to this release. In addition, pages F16, F23, F25, F27 and F30 of the Operational Training Guide have been revised to reflect this change.

### **MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING SEPTEMBER 11-15, 2006**

We are pleased to announce that the next National DRP Meeting will be held September 11-15 in Baltimore, Maryland at the Tremont Plaza Suite Hotel, 222 St. Paul Place. This meeting is a continuation of the highly successful DRP meetings held in Baltimore in recent years.

While this meeting is open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. As in the past, prior planning is absolutely imperative to the success of these meetings; therefore, we are requesting that you register PROMPTLY by sending an email to the DRP email address at: [drp@cms.hhs.gov](mailto:drp@cms.hhs.gov).

When registering, please be sure to include the following information: the name, email address and phone number of each individual attending and the manufacturer (including labeler code) or state that you are representing. Also indicate whether you will be attending the entire week or for just part of the week. Partial week attendees should specify on which days they will be attending. In addition, for each day you are participating, please indicate whether you will be attending both morning and afternoon sessions. For example, someone who is attending both sessions on all days of the conference will indicate that he or she is attending Monday-Friday AM and PM, whereas someone who is only attending the morning sessions on Monday and Tuesday of the conference week will specifically indicate that he or she is attending Monday AM and Tuesday AM only.

Whenever possible, priority scheduling will be afforded those who register earliest. We will ensure that adequate DRP staff is available to conduct the meetings based on your timely responses.

If possible, states should plan on arriving in Baltimore in time to attend a "state-only" meeting with the DRP Team the morning of Monday, September 11. Meeting details and hotel registration information is provided on our web page at [http://www.cms.hhs.gov/MedicaidDrugRebateDispR/05\\_DRPMeetings.asp#TopOfPage](http://www.cms.hhs.gov/MedicaidDrugRebateDispR/05_DRPMeetings.asp#TopOfPage).

### **NON-DRUG DELETIONS FROM MDR**

As part of our continuing effort to remove non-drug items from the from the Medicaid Drug Rebate (MDR) system, the following products will be deleted from the MDR Master file of covered outpatient drugs effective 10/1/06:

00121-0530-05	FERROUS SULFATE LIQUID
00182-1201-40	FERROUS SULFATE ELIXIR
00182-4028-01	FERROUS SULFATE TABLETS
00182-4028-10	FERROUS SULFATE TABLETS
00182-4028-89	FERROUS SULFATE TABLETS
00182-4029-01	FERROUS SULFATE TABLETS
00182-4030-10	FERROUS SULFATE TABLETS
00182-4082-01	FERROUS GLUCONATE TABLETS
00182-4476-29	SLOW FE
00245-0061-01	FERROUS GLUCONATE
00245-0108-01	FERROUS SULFATE ENTERIC COATED TABLETS
00245-0108-10	FERROUS SULFATE ENTERIC COATED TABLETS
00472-1465-16	FERROUS SULFATE ELIXIR
00472-1465-28	FERROUS SULFATE ELIXIR
00472-1465-95	FERROUS SULFATE DROPS
00536-0650-85	FERROUS SULFATE ELIXIR A
00536-3478-07	FERROUS SULFATE

00536-3478-08	FERROUS SULFATE
00574-0508-01	FERROUS GLUCONATE
00574-0508-10	FERROUS GLUCONATE
00574-0508-11	FERROUS GLUCONATE
00574-0608-01	FERROUS GLUCONATE E.C.
00574-0608-10	FERROUS GLUCONATE E.C.
00574-0608-11	FERROUS GLUCONATE E.C.
00603-0179-29	FERROUS SULFATE
00603-0179-32	FERROUS SULFATE
00603-0762-47	FERROUS SULFATE DROPS
00603-0763-58	FERROUS SULFATE ELIX
00677-0069-01	FERROUS GLUCONATE
00677-0070-01	FERROUS SULFATE
00677-0070-10	FERROUS SULFATE
00677-0071-01	FERROUS SULFATE
00677-0071-10	FERROUS SULFATE
00677 -0527-33	FERROUS SULFATE
00677 -0990-06	MULTI FERROUS FOLIC
17714-0024-01	FERROUS SULFATE TABLET
17714-0024-10	FERROUS SULFATE TABLET
24385-0137-78	IRON TABS, FERROUS SULFATE
24385-0528-65	FERROUS SULFATE SLOW
24385-0630-50	FERROUS SULFATE SOLUTION DROPS
24385-0875-78	FERROUS SULFATE IRON TABS
49348-0454-80	FERROUS SULFATE DROPS
49348-0455-10	FERROUS SULFATE-IRON SUPPLEMENT
49483-0008-04	FERROUS SULFATE
49483-0027-04	FERROUS SULFATE
50383-0630-50	FERROUS SULFATE SOLUTION DROPS
50383-0778-16	FERROUS SULFATE ELXIR
51552-0310-06	FERROUS SULFATE GRAN
51552-0586-06	FERROUS SULFATE DRIED PWD
51552-1084-06	FERROUS GLUCONATE DIHYDRATE
51552-1084-07	FERROUS GLUCONATE DIHYDRATE
52569-0466-21	FERROUS SULFATE BLISTER PACK
52735-0019-01	VIT FERROUS SULFATE
52735-0360-08	FP FERROUS SULFATE SLOW
54738-0091-01	FERROUS SULFATE TABS
54738-0091-03	FERROUS SULFATE TABS
54738-0091-13	FERROUS SULFATE TABS
54838-0001-80	FERROUS SULFATE ELIXIR
54838-0002-50	FERROUS SULFATE DROPS
59743-0801-10	FERROUS SULFATE TABLETS
60258-0182-01	FERROUS FUMERATE
60432-0057-50	FERROUS SULFATE DROPS
60432-0066-16	FERROUS SULFATE ELXIR
62107-0044-01	FERROUSUL
63739-0102-01	FERROUS SULFATE
63739-0102-03	FERROUS SULFATE

63739-0259-01 FERROUS SULFATE  
 63739-0259-03 FERROUS SULFATE  
 63868-0682-01 FERROUS SULFATE

The abovementioned products were not approved as prescription drugs by the Food and Drug Administration (FDA) under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act and therefore, do not meet the definition of covered outpatient drugs as defined in Section 1927(k)(2) of the Social Security Act.

**NEW LABELERS**

	Mandatory Coverage	Optional Coverage
Misemer Pharmaceutical, Inc. (Labeler Code 00276)	10/01/2006	07/10/2006
Bristol-Myers Squibb and Gilead Sciences, LLC (Labeler Code 15584)	07/01/2006	07/01/2006
Focus Laboratories, Inc. (Labeler Code 15821)	10/01/2006	07/03/2006
Pharbest Pharmaceuticals, Inc. (Labeler Code 16103)	10/01/2006	07/31/2006
A. Aarons, Inc. (Labeler Code 18754)	10/01/2006	07/03/2006
Myogen, Inc. (Labeler Code 20694)	10/01/2006	07/26/2006
Tower Laboratories Ltd. (Labeler Code 50201)	10/01/2006	07/06/2006
CorePharma, LLC (Labeler Code 64720)	10/01/2006	07/25/2006
Teva Neuroscience, Inc. (Labeler Code 68546)	10/01/2006	07/27/2006
KVD Pharma, Inc. (Labeler Code 68716)	10/01/2006	07/31/2006

**REINSTATED LABELERS**

Respa Pharmaceuticals, Inc. (Labeler Code 60575)	10/01/2006	N/A
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Contact information for new and reinstated labelers is attached for your convenience.

**TERMINATED LABELERS**

The following labeler codes are being terminated effective 07/01/2006:

Novopharm USA, Inc.                      Labeler Code 55953

**PERSONNEL/STAFF CHANGES**

After 30 years of service, Sue Williams retired from CMS effective June 30, 2006.

Effective immediately, Samone Angel has joined the drug rebate Operations staff.

Page O2 of the Operational Training Guide has been revised to reflect these changes and is attached to this release.

**UPDATES TO THE OPERATIONAL TRAINING GUIDE**

Pages F20 and F22 have been revised to reflect an addition to the address for sending the state utilization tapes.

Pages F28 and F29 of the Operational Training Guide have been updated to reflect minor changes in the data definitions for the state invoice.

Page G10 of the Operational Training Guide has been updated to reflect the new “400/400” Edit Report.

**OTHER ATTACHMENT**

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period March 7, 2005, is attached.

Please remember to direct your drug rebate questions to MDROperations@cms.hhs.gov

/s/

Edward C. Gendron  
Director  
Finance, Systems and Budget Group

Attachments

cc:  
All State Drug Rebate Technical Contacts  
All Regional Administrators.

**MEDICAID DRUG REBATE PROGRAM  
RECORD FORMAT  
STATE INVOICE/UTILIZATION RECORD  
(FORM CMS-R-144)**

Source: State Agencies  
Target: CMS and Manufacturers

<b>FIELD</b>	<b>SIZE</b>	<b>POSITION</b>	<b>REMARKS</b>
Record ID	4	1 - 4	Constant of "01"
State Code	2	5 - 6	P.O. Abbreviation
Labeler Code	5	7 - 11	NDC #1
Product Code	4	12 - 15	NDC #2
Package Size Code	2	16 - 17	NDC #3
Period Covered	5	18 - 22	QYYYY
Product FDA Registration Name	10	23 - 32	1 <sup>st</sup> 10 positions only
**Rebate Amount Per Unit	9	33 - 41	9(5)v9(4)
** Units Reimbursed	14	42 - 55	9(11)v999
** Rebate Amount Claimed	11	56 - 66	9(9)v99
**Number of Prescriptions	7	67 - 73	9(7)
*** M'Caid Amount Reimb.	12	74 - 85	9(10)v99
*** Non-M'Caid Amount Reimb.	12	86-97	9(10)v99
**Total Amount Reimbursed	13	98-110	9(11)v99
Correction Flag	1	111-111	See Data Element Definitions
Filler *	19	112-130	For future expansion

- \* This "filler" is required when states send utilization data to CMS.
  - \*\* Changed field length size
  - \*\*\* New fields
- NOTE:** Data elements designated as **ALPHANUMERIC** on the following pages may include numbers, letters, etc. Those designated as **ALPHABETIC** contain letters only.

**MEDICAID DRUG REBATE PROGRAM  
STATE INVOICE (FORM CMS-R-144)  
DATA DEFINITIONS**

.....  
DATA ELEMENT NAME: State Code - Two-character abbreviation for state.  
Alphabetic, 2 digits.

.....  
DATA ELEMENT NAME: Labeler Code - First segment of National Drug  
Code (NDC) that identifies the manufacturer,  
labeler, relabeler, packager, repackager or  
distributor of the drug. Numeric values only, 5  
digit field, right justified, and 0-filled for 4 digit  
labeler codes.

.....  
DATA ELEMENT NAME: Product Code - Second segment of NDC.  
Alphanumeric values, 4 digit field, right justified,  
0-filled for 3 digit product codes.

.....  
DATA ELEMENT NAME: Package Size Code - Third segment of NDC.  
Alphanumeric values, 2 digit field, right  
justified, 0-filled for 1 digit package size code.

.....  
DATA ELEMENT NAME: Period Covered - Calendar quarter and year  
covered by data submission. Numeric, 5 digit  
field, 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.

.....

**MEDICAID DRUG REBATE PROGRAM  
STATE INVOICE (FORM CMS-R-144)  
DATA DEFINITIONS**

.....  
DATA ELEMENT NAME: Product FDA Registration Name (abbreviated)  
- First 10 characters of product name as it appears  
on FDA registration form. Alphanumeric values,  
10 digits.

.....  
DATA ELEMENT NAME: Rebate Amount Per Unit - The CMS calculated  
amount (per reported unit type) to be multiplied  
by Units Reimbursed by the state during the  
period covered. Numeric values, 9 digits: 5 whole  
numbers and 4 decimals (assumed).

.....  
DATA ELEMENT NAME: Units Reimbursed - The number of units (based  
on Unit Type) of the drug (11 digit NDC level)  
reimbursed by the state during the period covered.  
Numeric values, 14 digits: 11 whole numbers and  
3 decimals (assumed).

.....  
DATA ELEMENT NAME: Rebate Amount Claimed - The rebate amount the  
state agency claims it is owed by the labeler for  
the period covered for this (11 digit NDC) drug.  
It is calculated by multiplying the units  
reimbursed by the rebate amount per unit.  
Numeric values, 11 digits: 9 whole numbers and 2  
decimal places (assumed).

.....



**MEDICAID DRUG REBATE PROGRAM  
STATE INVOICE (FORM CMS-R-144)  
DATA DEFINITIONS**

.....  
DATA ELEMENT NAME:     Number of Prescriptions - The number of prescriptions reimbursed (by the Medicaid program ONLY) to pharmacies for the (11 digit NDC) drug during the period covered. Numeric values, 7 digits, whole numbers only.

.....  
DATA ELEMENT NAME:     Medicaid Amount Reimbursed - The amount reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11 digit NDC) drug in the period covered. Numeric values, 12 digits: 10 whole numbers and 2 decimals (assumed).

.....  
DATA ELEMENT NAME:     Non-Medicaid Amount Reimbursed - The amount reimbursed (by NON- Medicaid entities) to pharmacies for the (11 digit NDC) drug in the period covered. Numeric values, 12 digits: 10 whole numbers and 2 decimals (assumed).

.....  
DATA ELEMENT NAME:     Total Amount Reimbursed - The total amount reimbursed by **BOTH** Medicaid and Non-Medicaid entities to pharmacies for the (11 digit NDC) drug in the period covered (above two fields added together). This total is not reduced or affected by Medicaid rebates paid to the state. This amount represents both the Federal and State reimbursement and is inclusive of dispensing fees. Numeric values, 13 digits: 11 whole numbers and 2 decimals (assumed).

.....  
DATA ELEMENT NAME:     Correction Flag - Indicates that this record is a correction. Numeric values, 1 digit.  
Valid Values:            0 = original record  
                              1 = correction record

.....

For ALL CPI-U creep calculations beginning with 93-4, the (NEW) values are used. The labeler in this example entered the program in the 4th qtr of 1995 and supplied Baseline data and 95-4 AMP/BP prices on this NDC but did not supply pricing data for the 3rd quarter of 1992. When this report is generated it will show that the AMP from 92-3 is missing and that URAs for this NDC CANNOT be generated by CMS until it is supplied. (Section H of this guide contains a complete discussion of the URA calculation.)

Also, from time to time, a labeler finds that an NDC that should have been coded as “S” or “I” was incorrectly submitted as an “N”, or vice versa. The system will ***not*** allow these changes to be made, so labelers must work with CMS drug rebate operations staff to initiate these changes. Before any change is made, CMS will require documentation from the labeler.

**Report 3** is the “400/400 REPORT.” This report contains a list of NDCs for which no URAs were calculated for the current quarter as a result of possible pricing errors. Specifically, each NDC on the 400/400 Report was submitted to CMS with current quarter pricing that caused the URA to calculate more than 400% higher or more than 400% lower than the previous quarter. States do not receive current quarter URAs for any of the NDCs included on this report.

In addition to the NDC, this report contains historical product/pricing information that allows manufacturers to evaluate each URA and make corrections where necessary. If, after reviewing the 400/400 Report, it is determined that the pricing is correct, there is no need to notify CMS. Instead, the manufacturer should use the calculated URA found in the last column of the report (entitled “This Quarter Rebate”) to compute the total rebate owed to the states for each NDC. After the next quarter’s data is processed, CMS will report these URAs to the states as Prior Period Adjustments. If, however, a review of the 400/400 Report confirms that the AMP and/or BP is incorrect, the manufacturer should calculate the current quarter’s URA based on the correct pricing and use that (corrected) URA when submitting rebates to the states. In addition, the pricing corrections should be submitted to CMS with the next quarterly data submission.

**NOTE:** The following pages show examples of notices sent to labelers as a result of CMS’s various edit reports.



**G10**

## **CMS DRUG REBATE PROGRAM**

Area Code 410

### **OPERATIONS**

Operational Questions

**MDROPERATIONS@cms.hhs.gov**

Samone Angel  
Cindy Bergin  
Tamara Bruce  
Chris Holmes  
Karen Leshko

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786-1176     cindy.bergin@cms.hhs.gov  
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786-3328     christene.holmes@cms.hhs.gov  
786-1291     karen.leshko@cms.hhs.gov

### **DIVISION OF PHARMACY (POLICY)**

Joe Fine (Technical Director)  
Kim Howell  
Meagan Khau  
Madlyn Kruh  
Bernadette Leeds  
Christina Lyon  
Larry Reed (Technical Director)  
Yolanda Reese  
Gail Sexton  
Marge Watchorn

786-3325  
786-6762  
786-1357  
786-3239  
786-9463  
786-3332  
786-3325  
786-9898  
786-4583  
786-4361

### **SYSTEM MAINTENANCE**

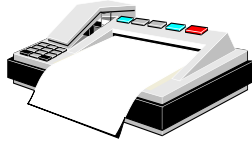
E-mail inquiries to: [MDRtech@cms.hhs.gov](mailto:MDRtech@cms.hhs.gov)

### **DISPUTE RESOLUTION PROGRAM**

Sue Gaston  
Tamara Bruce  
Diane Dunstan

786-6918     susan.gaston@cms.hhs.gov  
786-1519     tamara.bruce@cms.hhs.gov  
303-844-7040     diane.dunstan@cms.hhs.gov

**FAX**



786-0390 – Operations  
786-5882 or 786-9004 - Policy

**WEBSITE** [www.cms.hhs.gov/medicaiddrugrebateprogram](http://www.cms.hhs.gov/medicaiddrugrebateprogram)

Rev. 8/06

**02**

**WEEKLY U.S. T-BILL INVESTMENT RATE**  
weekly 91-day treasury bill auction rates

<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>
03-07-05	2.767	10-03-05	3.606	05-01-06	4.807
03-14-05	2.792	10-11-05	3.714	05-08-06	4.864
03-21-05	2.859	10-17-05	3.875	05-15-06	4.864
03-28-05	2.839	10-24-05	3.942	05-22-06	4.828
04-04-05	2.792	10-31-05	3.983	05-30-06	4.843
04-11-05	2.767	11-07-05	3.963	06-05-06	4.833
04-18-05	2.864	11-14-05	4.004	06-12-06	4.926
04-25-05	2.941	11-21-05	4.034	06-19-06	4.958
05-02-05	2.931	11-28-05	3.994	06-26-06	5.036
05-09-05	2.911	12-05-05	4.025	07-03-06	5.088
05-16-05	2.859	12-12-05	3.911	07-10-06	5.056
05-23-05	2.957	12-19-05	3.988	07-17-06	5.098
05-31-05	2.998	12-26-05	3.999	07-24-06	5.108
06-06-05	3.029	01-02-06	4.169	08-07-06	5.124
06-13-05	3.039	01-09-06	4.252	08-14-06	5.114
06-20-05	3.029	01-17-06	4.377	08-21-04	5.109
06-27-05	3.147	01-23-06	4.397		
07-05-05	3.214	01-30-06	4.485		
07-11-05	3.204	02-06-06	4.485		
07-18-05	3.292	02-13-06	4.553		
07-25-05	3.420	02-21-06	4.563		
08-01-05	3.477	02-27-06	4.625		
08-08-05	3.539	03-06-06	4.615		
08-15-05	3.549	03-13-06	4.625		
08-22-05	3.539	03-20-06	4.662		
08-29-05	3.575	03-27-06	4.610		
09-06-05	3.513	04-03-06	4.651		
09-12-05	3.529	04-10-06	4.688		
09-19-05	3.575	04-17-06	4.719		
09-26-05	3.518	04-24-06	4.755		



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