DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

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.

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.

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

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.

STATE INVOICE

UTILIZATION DATA REPORTING REQUIREMENTS

Statute requires states to report quarterly drug utilization data to labelers participating in the drug rebate program **not later than 60 days** after each rebate period. States are also required to transmit a copy of this quarterly utilization data report to CMS. (Utilization adjustment data for prior rebate periods are discussed later in this section.)

The law requires the Secretary to establish the format for this data submittal. The Secretary delegated the establishment of the reporting format to CMS. In 1991, the former Health Care Financing Administration and State Medicaid agency representatives developed the State Invoice (form CMS-R-144) to report utilization data to labelers. OMB approved the invoice format and CMS mandates its use. This section contains form CMS-R-144, along with the electronic format and definition of each data element required.

For each covered outpatient drug dispensed **AND** PAID FOR BY THE STATE, the invoice specifically requires reporting the following for **EACH** NDC number listed by the state.

1. State Code
2. Period Covered
3. Labeler Code
4. Product Code
5. Package Size Code
6. Product FDA Registration Name
7. Rebate Amount Per Unit
8. Total Units Reimbursed
9. Total Rebate Amount Claimed
10. Number of Prescriptions
11. Medicaid Amount Reimbursed
12. Non-Medicaid Amount Reimbursed
13. Total Amount Reimbursed
14. Correction Record Flag

Please remember that the utilization data reported on the invoice MUST be based on the payment date NOT on the date dispensed.

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SENDING UTILIZATION DATA (Cont'd.)

States should report their utilization data to CMS using either a tape or cartridge with an IBM Standard Label. The characteristics of this media are:

- Data Set Name: RBTE.Qq.Yyyyy.xx
  Where q = quarter
  yyyy = year
  xx = State postal abbreviation

- Record Profile: 82 characters, fixed block (FB),
  9,266 characters per block.

NOTE: **If the standards outlined above are not met, THE TAPE WILL NOT BE PROCESSED.**

Send the **tape or cartridge** to:

Centers for Medicare & Medicaid Services
Office of Information Systems
Attention: Tape Library
North Building
7500 Security Boulevard
Baltimore, Maryland 21244

NOTE: When CMS completes its processing of state utilization tapes, the tapes/cartridges are not returned to the states. Likewise, states are not required to return quarterly tapes/cartridges to CMS.

MEDICAID DRUG REBATE PROGRAM
STATE UTILIZATION TAPE SUBMISSION CHECKLIST

The CMS tape library receives a large quantity of tapes from many outside sources. To ensure that your tape is received and processed correctly, please follow the checklist below.

___ Did you assure that the correct naming convention is used for the data set on the tape?

RBTE.Qq.Yyyyy.xx Where q = quarter
yyyy = year
xx = State postal abbreviation

DO NOT USE FOREIGN.OPCART.DRqyyyy.xx or FOREIGN.LOPREEL.Dqyyyy.xx

___ Is there an external label on the tape indicating that it is a drug rebate tape? (A label with a data set name containing RBTE.Qq.Yyyyy.xx is necessary.) If not already there, please include it now.

___ Did you generate a confirmation letter indicating the file name, volume serial number, and the date the tape was sent? If not, please do so now. This letter is sent to the following address:

Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Mail Stop S3-13-15
7500 Security Boulevard
Baltimore, Maryland 21244

___ Please enclose a copy of the confirmation letter with the tape/cartridge.

___ Please assure that the tape/cartridge is addressed as follows:

Centers for Medicare & Medicaid Services
Office of Information Systems
Attention: Tape Library
North Building
7500 Security Boulevard
Baltimore, Maryland 21244

___ If you re-used a CMS tape, YOU SHOULD REMOVE OR OBLITERATE ALL OF CMS'S EXTERNAL LABELS AND PLACE A NEW LABEL ON THE TAPE/CARTRIDGE; otherwise, the tape/cartridge will be returned to blank stock and your data will not get processed. This will require a resubmission of your data.

REPORTING UTILIZATION CHANGES

TO LABELERS

States should submit utilization changes to labelers for individual NDCs when there are changes to:

- the total units reimbursed.

CMS encourages states to send labelers utilization-related changes affecting:

- the number of prescriptions;
- the Medicaid amount reimbursed;
- the Non-Medicaid amount reimbursed; and/or
- the total reimbursement amount

Changes are reported with current quarter utilization data, **BUT NOT** on the same invoice pages as current quarter data. STATES SHOULD REPORT UTILIZATION CHANGES TO LABELERS USING A SEPARATE INVOICE PAGE FOR **EACH** QUARTER CHANGES OCCURRED. States sending invoice pages representing multiple quarters delay invoice processing.

Delayed invoice processing is also caused by states that use inconsistent utilization change reporting methods. States should initially notify labelers of the method used to report utilization changes. States may completely overlay previously reported data, or may report just the addition or subtraction to previously reported data. Whichever method is chosen, consistency from quarter to quarter is the primary factor. If the state's method of reporting utilization changes is revised, States may use the short form developed by CMS to notify labelers. This form is provided on the following page.

TO CMS

States should submit changes to the total units reimbursed, the number of prescriptions, the Medicaid amount reimbursed, the non-Medicaid amount reimbursed, or the total amount reimbursed. These utilization changes should be included on the data tape containing the current quarter utilization.

CMS uses the state correction records as a **replacement** for a record submitted in a prior quarter.

For each correction record sent to CMS, the state should ensure that:

1. The correction flag = "1"; and
2. QYYYY = the calendar quarter and 4-digit year being corrected. (This is never the current calendar quarter/year.)

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

Source: State Agencies
Target: CMS and Manufacturers

FIELD	SIZE	POSITION	REMARKS
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	1st 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.

STATE INVOICE (FORM CMS-R-144)
DATA DEFINITIONS

::::::

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

::::::

::::::

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.

Area Code 410

OPERATIONS

Operational Questions MDROPERATIONS@cms.hhs.gov

Samone Angel	786-1123	samone.angel@cms.hhs.gov
Cindy Bergin	786-1176	cindy.bergin@cms.hhs.gov
Tamara Bruce	786-1519	tamara.bruce@cms.hhs.gov
Chris Holmes	786-3328	christene.holmes@cms.hhs.gov
Karen Leshko	786-1291	karen.leshko@cms.hhs.gov

DIVISION OF PHARMACY (POLICY)

Joe Fine (Technical Director)	786-3325
Kim Howell	786-6762
Meagan Khau	786-1357
Madlyn Kruh	786-3239
Bernadette Leeds	786-9463
Christina Lyon	786-3332
Larry Reed (Technical Director)	786-3325
Yolanda Reese	786-9898
Gail Sexton	786-4583
Marge Watchorn	786-4361

SYSTEM MAINTENANCE

E-mail inquiries to: MDRtech@cms.hhs.gov

DISPUTE RESOLUTION PROGRAM

Sue Gaston	786-6918	susan.gaston@cms.hhs.gov
Tamara Bruce	786-1519	tamara.bruce@cms.hhs.gov
Diane Dunstan	303-844-7040	diane.dunstan@cms.hhs.gov

FAX

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

WEBSITE www.cms.hhs.gov/medicaiddrugrebateprogram

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

Date of Auction	Invest. Rate		Date of Auction	Invest. Rate		Date of Auction	Invest. Rate
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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