DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

August 15, 2007

MEDICAID DRUG REBATE PROGRAM **Release No. 147**

For State Medicaid Directors

REVISED STATE INVOICE/UTILIZATION DATA RECORD FORMAT

State Release #146 mentioned that CMS was making some technical changes to the record format for the state invoice/utilization data that was previously included as an attachment to State Release #143. The updates to that record format are now complete and the revised version is attached to this release. As indicated in Release #146, the format has been updated to reflect new sizes and positions of the data fields. Also, in order to more closely align the record format with the state invoice form itself (i.e., CMS Form R-144), the field name "Rebate Amount Per Unit" has been changed to "Unit Rebate Amount." For your convenience, revised data definitions and updated instructions for states on submitting utilization data to CMS are attached to this release as well. Please update your systems accordingly in time for the fourth quarter 2007 implementation date for the new state invoice/utilization data format. The new format is being implemented on March 1, 2008, for the submission of fourth quarter 2007 data. State utilization data submitted in the new format prior to March 1, 2008, will be rejected. Furthermore, state utilization data submitted in the current format after March 1, 2008, will be rejected.

NEW CPI TO THREE DECIMAL PLACES WILL BE EFFECTIVE 3Q2007

In Release 78, CMS informed labelers that, beginning 2Q2007, the expanded CPI-U would be used for 2Q2007 innovator rebate calculations. This expected change to our MDR database did not occur as planned. CMS expects this change to occur with the 3Q2007 rebate calculations.

MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM (DRP)
NATIONAL MEETING, SEPTEMBER 10-14, 2007

Registration Due by August 27, 2007

We are pleased to announce that the next National DRP Meeting will be held September 10-14 in Baltimore, Maryland at the Brookshire Suites, 120 East Lombard Street.

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.

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 10.

Please use the format provided below when registering and 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 a.m. and p.m., 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 a.m. and Tuesday a.m. only.

Sample Registration Format

Name(s) of Attendee(s):
Manufacturer (Labeler Codes Required): To assist with the scheduling, manufacturers that register multiple representatives for purposes of holding separate meetings should provide the specific state/manufacturer breakdown.
State(s):
Phone:
Email:
Date of Arrival & Departure (a.m./p.m.):

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.

Meeting details, hotel registration and list of attendees are provided on our web page at: http://www.cms.hhs.gov/MedicaidDrugRebateDispR/05_DRPMeetings.asp#TopOfPage.

The list of attendees on our web page will be updated weekly. If there is a manufacturer/state that you wish to meet that has not yet registered, feel free to contact them directly to request their attendance or let us know, and we can extend an invitation.

As always, feel free to contact any of the Regional Office DRP Team members for any state

specific DRP issues. Any non-state specific DRP questions or issues concerning the April meeting may be emailed to drp@cms.hhs.gov.

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Dabur Oncology PLC 10518	10/01/2007	07/02/2007
Torrent Pharma, Inc. 13668	10/01/2007	07/02/2007
Allegis Pharmaceuticals LLC 28595	10/01/2007	07/05/2007
Validus Pharmaceuticals, Inc. 30698	10/01/2007	07/05/2007
Inspire Pharmaceuticals, Inc. 31357	10/01/2007	07/19/2007
Oxford Pharmaceutical Services 64803	10/01/2007	07/05/2007
Indevus Pharmaceuticals, Inc. 67979	10/01/2007	07/31/2007

REINSTATED LABELERS

Shire US, Inc. 59417	10/01/2007	06/22/2007

TERMINATED LABELERS

The following labeler codes are being terminated effective 10/01/2007:

Santen Incorporated, labeler code 65086
PediaMed Pharmaceuticals, Inc., labeler code 66346
Laser Pharmaceuticals, LLC., labeler code 68134

VOLUNTARILY TERMINATED LABELERS

The following labeler has requested voluntary termination effective 10/01/2007:

Alphagen Laboratories, Inc., labeler code 59743

OTHER ATTACHMENTS

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period May 1, 2006, is attached.

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

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

5 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

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
05-01-06	4.807		12-04-06	4.999		07-02-07	4.930
05-08-06	4.864		12-11-06	4.926		07-09-07	4.956
05-15-06	4.864		12-18-06	4.952		07-16-07	4.982
05-22-06	4.828		12-25-06	5.004		07-23-07	5.029
05-30-06	4.843		01-01-07	5.062		07-30-07	4.966
06-05-06	4.833		01-08-07	5.072		08-06-07	4.909
06-12-06	4.926		01-15-07	5.108		08-13-07	4.763
06-19-06	4.958		01-22-07	5.129			
06-26-06	5.036		01-29-07	5.145			
07-03-06	5.088		02-05-07	5.145			
07-10-06	5.056		02-12-07	5.160			
07-17-06	5.098		02-19-07	5.171			
07-24-06	5.108		02-26-07	5.185			
08-07-06	5.124		03-05-07	5.112			
08-14-06	5.114		03-12-07	5.112			
08-21-04	5.109		03-19-07	5.075			
08-28-06	5.093		03-25-07	5.070			
09-04-06	4.984		04-02-07	5.055			
09-11-06	4.947		04-09-07	5.023			
09-18-06	4.942		04-16-07	5.008			
09-25-06	4.895		04-23-07	4.976			
10-02-06	4.890		04-30-07	4.924			
10-09-06	4.978		05-07-07	4.898			
10-16-06	5.072		05-14-07	4.867			
10-23-06	5.124		05-21-07	4.914			
10-30-06	5.108		05-28-07	4.919			
11-06-06	5.088		06-04-07	4.846			
11-13-06	5.088		06-11-07	4.773			
11-20-06	5.071		06-18-07	4.617			
11-27-06	5.036		06-25-07	4.820			

MDRI Detailed Manufacturer Contact Information Date Range: ACTIVE AND FUTURE

Labeler Name: DABUR ONCOLOGY PLC **Effective Date:** 07/02/2007

NDC: 10518 **Transmission Option:** 2 **Termination Date:**

Legal Information

MICHELLE CASE
DABUR PHARMA US, INC
200 S. ANDREWS AVE
#7B
FT. LAUDERDALE, FL 33301
(954) 615-2225

Invoice Information

MICHELLE CASE
DABUR PHARMA US, INC
200 S. ANDREWS AVE
#7B
FT. LAUDERDALE, FL 33301
(954) 615-2225

Technical Information

MICHELLE CASE
DABUR PHARMA US, INC
200 S. ANDREWS AVE
SUITE #7B
FT. LAUDERDALE, FL 33301
(954) 615-2225

Labeler Name: TORRENT PHARMA, INC. **Effective Date:** 07/02/2007

NDC: 13668 **Transmission Option:** 2 **Termination Date:**

Legal Information

DAWN CHITTY
TORRENT PHARMA, INC.
5380 HOLIDAY TERRACE
SUITE 40
KALAMAZOO, MI 49009
(269) 544-2299

Invoice Information

RANDALL PERRY
TORRENT PHARMA, INC.
P.O. BOX 259
ACWORTH, GA 30101
(770) 975-7337

Technical Information

RANDALL PERRY
TORRENT PHARMA, INC.
P.O. BOX 259
ACWORTH, GA 30101
(770) 975-7337

Labeler Name: ALLEGIS PHARMACEUTICALS LLC **Effective Date:** 07/05/2007

NDC: 28595 **Transmission Option:** 2 **Termination Date:**

Legal Information

CHRIS HENDERSON
SIMMONS LAW GROUP, PA
240 TRACE COLONY PARK DRIVE
RIDGELAND, MS 39157
(601) 914-2884

Invoice Information

TRIP POLLES
ALLEGIS PHARMACEUTICALS
276 NISSAN PARKWAY
CANTON, MS 39046
(601) 859-0038

Technical Information

TRIP POLLES
ALLEGIS PHARMACEUTICALS
276 NISSAN PARKWAY
CANTON, MS 39046
(601) 859-0038

Labeler Name: VALIDUS PHARMACEUTICALS, INC. **Effective Date:** 07/05/2007

NDC: 30698 **Transmission Option:** 2 **Termination Date:**

Legal Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS, INC.
INC.
2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Invoice Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS, INC.

2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Technical Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS,

2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Labeler Name: INSPIRE PHARMACEUTICALS, INC. **Effective Date:** 07/19/2007

NDC: 31357 **Transmission Option:** 2 **Termination Date:**

Legal Information

RAYMOND W. HINES
INSPIRE PHARMACEUTICALS, INC.
INC.
4222 EMPEROR BOULEVARD
SUITE 200
DURHAM, NC 27703-8030
(919) 941-9777 x217

Invoice Information

TONYA M. BROWN
INSPIRE PHARMACEUTICALS, INC.

4222 EMPEROR BOULEVARD
SUITE 200
DURHAM, NC 27703-8030
(919) 941-9777 x715

Technical Information

TONYA M. BROWN
INSPIRE PHARMACEUTICALS,

4222 EMPEROR BOULEVARD
SUITE 200
DURHAM, NC 27703-8030
(919) 941-9777 x715

Labeler Name: SHIRE US, INC. **Effective Date:** 10/01/2007

NDC: 59417 **Transmission Option:** 2 **Termination Date:**

Legal Information

AARON BUDA
SHIRE US, INC.
725 CHESTERBROOK BLVD
WAYNE, PA 19087
(484) 595-8965

Invoice Information

PATRICIA SUMMERS
SHIRE US, INC.
725 CHESTERBROOK BLVD
WAYNE, PA 19087
(484) 595-8827

Technical Information

PATRICIA SUMMERS
SHIRE US, INC.
725 CHESTERBROOK BLVD
WAYNE, PA 19087
(484) 595-8827

Labeler Name: OXFORD PHARMACEUTICAL SERVICES **Effective Date:** 07/05/2007

NDC: 64803 **Transmission Option:** 2 **Termination Date:**

Legal Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS, INC.
INC.
2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Invoice Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS, INC.

2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Technical Information

JAMES HUNTER
VALIDUS PHARMACEUTICALS,

2001 ROUTE 46 EAST
SUITE 310
PARSIPPANY, NJ 07054
(973) 402-4938

Labeler Name: INDEVUS PHARMACEUTICALS, INC. **Effective Date:** 07/31/2007

NDC: 67979 **Transmission Option:** 2 **Termination Date:**

Legal Information

RICHARD NORTON
INDEVUS PHARMACEUTICALS, INC.
PHARMACEUTICALS, INC.
33 HAYDEN AVENUE
LEXINGTON, MA 02421-7971
(781) 402-3445

Invoice Information

LYNNE MARTON
INDEVUS PHARMACEUTICALS, INC.

349 BURNING TREE COURT
HALF MOON BAY, CA 94019
(650) 726-9544

Technical Information

LYNNE MARTON
INDEVUS

349 BURNING TREE COURT
HALF MOON BAY, CA 94019
(650) 726-9544

CMS RECORD SPECIFICATION
STATE INVOICE/MEDICAID DRUG REBATE DATA
UTILIZATION RECORD FORMAT
(Form CMS-F-144)
March 2008

Source: State Agencies
Target: CMS & Manufacturers

Field	Size	Position	Remarks
Record ID	4	1 – 4	Constant of "UTIL"
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 Reg. Name	10	23 – 32	Product name as appears on FDA listing form. (1st 10 characters)
Unit Rebate Amount	12	33 – 44	9(5).9(6)
* Units Reimbursed	15	45 – 59	9(11).999
* Rebate Amount Claimed	12	60 – 71	9(9).99
* Number of Prescriptions	8	72 – 79	9(8)
** M'Caid Amount Reimb.	13	80 – 92	9(10).99
** Non-M'Caid Amount Reimb.	13	93 - 105	9(10).99
*Total Amt Reimbursed	14	106 – 119	9(11).99
Correction Flag	1	120 – 120	0 = Original record 1 = Correction record

All fields with decimals now require actual decimal
* Changed field length size
** New Field

Effective: March 1, 2008

STATE INVOICE/UTILIZATION FIELD DEFINITIONS

Record ID: Constant "UTIL"

State Code: Two-character post office abbreviation for the state. Alphabetic, 2 digits.

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 zero-filled for 4-digit labeler codes.

Product Code:

Second segment of NDC. Alphanumeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.

Package Size Code:

Third segment of NDC. Alphanumeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.

Period Covered:

Calendar quarter and year covered by data submission. Numeric, 5-digit field, Q/YYYY

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: 4-digit calendar year covered.

Product FDA Reg. Name:

(Abbreviated) – First 10 characters of product name as it appears on the FDA listing form. Alphanumeric values, 10 digits.

Unit Rebate Amount:

The CMS calculated amount (per reported unit type) to be multiplied by Units Reimbursed by the state during the period covered. Numeric values, 12 digits: 5 whole numbers, 6 decimal places, and a decimal point.

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, 15 digits: 11 whole numbers, 3 decimal places and a decimal point.

Rebate Amount Claimed:

The rebate amount that 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, 12 digits: 9 whole numbers, 2 decimal places and a decimal point.

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, 8 digits, whole numbers only.

M'caid Amount Reimb:

Medicaid Amount Reimbursed – The total amount reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11-digit NDC) drug in the period covered. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

Non-M'caid Amount Reimb:

Non-Medicaid Amount Reimbursed – The amount reimbursed (by non-Medicaid entities) to pharmacies for the (11-digit NDC) drug in the period covered. The Non-Medicaid Amount Reimbursed includes any reimbursement amount for which the state is not eligible for Federal Matching Funds. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

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, 14 digits: 11 whole numbers, 2 decimal places and a decimal point.

Correction Flag:

Indictor as to whether this is the first submission (original record) or whether it is a correction to an existing record.
0 = Original record
1 = Correction

TOPIC **RELEASE #**

SENDING UTILIZATION DATA

To CMS:

States should report their utilization data to CMS using a 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: 120 characters, fixed block (FB),
  7440 characters per block.

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

NOTE: We CANNOT process round reel cartridges anymore.

Send the **cartridge** to:

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

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

States should send a separate confirmation letter indicating the data set name, volume serial number, and the date the cartridge was sent to CMS. **(A copy of this letter should also be enclosed with the cartridge.)**

Send the confirmation letter to:

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

TOPIC **RELEASE #**

SENDING UTILIZATION DATA

In an effort to eliminate errors that hinder CMS's processing of quarterly state utilization cartridges, a checklist was developed for state use and is provided on the following page. States should make every effort to comply with the checklist; if they do not, the CMS tape librarians will not be able to determine that the cartridges are drug rebate utilization tapes. All unrecognizable cartridges are erased by CMS tape library personnel. **THIS WILL CAUSE YOUR UTILIZATION DATA TO BE LOST AND RESUBMISSION OF YOUR DATA WILL BE REQUIRED.**

TOPIC **RELEASE #**

MEDICAID DRUG REBATE PROGRAM
STATE UTILIZATION CARTRIDGE SUBMISSION CHECKLIST

The CMS tape library receives a large quantity of cartridges from many outside sources. To ensure that your cartridge is received and processed correctly, please adhere to the following checklist:

____ Ensure the correct naming convention is used for the data set on the cartridge.

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

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

____ Generate a confirmation letter indicating the file name, volume serial number, and the date the cartridge was sent. Send this letter to the following address:

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

____ Enclose a copy of the confirmation letter with the cartridge.

___ Confirm that the cartridge is addressed as follows:

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

____ If re-using a CMS tape, REMOVE OR OBLITERATE ALL OF CMS'S EXTERNAL LABELS AND PLACE A NEW LABEL ON THE CARTRIDGE; otherwise, the cartridge will be returned to blank stock and utilization data will need to be resubmitted.