DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

March 7, 2007

MEDICAID DRUG REBATE PROGRAM **Release No. 145**

For State Medicaid Directors

MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING - APRIL 16-20, 2007

Registration Due by March 30, 2007

We are pleased to announce that the next National DRP Meeting will be held April 16-20 in Baltimore, Maryland at the Tremont Plaza Suite Hotel, 222 St. Paul Place.

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, April 16.

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 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.

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 (AM/PM):

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 you wish to meet with a manufacturer/state who has not yet registered, feel free to contact them directly to request their attendance or let us know and we can extend an invitation.

Note: DRP meeting contingent on CMS budget.

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.

CHANGES TO THE ADJUSTMENT/DISPUTE CODES REPORTED ON THE RECONCILATION OF STATE INVOICE (ROSI) AND THE PRIOR QUARTER ADJUSTMENT STATEMENT (PQAS)

When labelers complete the ROSI (form CMS-304) or the PQAS (form CMS-304a) they must enter the appropriate code(s) to explain any adjustments and/or disputes, as necessary. A list of acceptable adjustment/dispute codes is attached to this release.

We have recently made changes to these codes in response to requests from states and labelers and in an effort to assist in the resolution of Medicaid drug rebate disputes. Specifically, the codes have been revised to be more comprehensive and should now accommodate any adjustment or dispute. Please note that only the codes listed on the attached should be used to explain adjustments and/or disputes and that some codes may be appropriate for either situation. Some codes provide for supporting documentation; however, supporting documentation can always be submitted, even for those instances where it is not specifically mentioned.

EXTENDED DEADLINE FOR IMPLEMENTING CHANGES TO CMS FORM R-144

State Release #143 discussed some changes that were recently made to the CMS Form R-144 (the state invoice); however, that release did not specify a deadline by which these changes needed to be implemented and integrated into existing state systems. A previous fax to states on September 8, 2006 indicated that the revised CMS Form R-144 should be used for rebate invoicing beginning with the invoice for the first quarter of 2007 (which is the invoice states will send to manufacturers in late May 2007). However, as a result of other significant systems changes necessitated by the Deficit Reduction Act (DRA) of 2005, we are extending this implementation deadline to give all parties additional time to make the systems modifications related to the revised invoice. **Therefore, the revised CMS Form R-144 must now be used beginning with the invoice for the fourth quarter of 2007 (which is the quarterly invoice states will send to manufacturers in late February 2008).** If states are able to update their systems with the invoice changes before the fourth quarter 2007 invoicing period, they have the option to do so; however, states will not be required to use the revised CMS Form R-144 until the fourth quarter 2007 invoicing period.

In addition, the previous state fax indicated that the new state utilization data fields (i.e., the Medicaid Amount Reimbursed data field and the Non-Medicaid Amount Reimbursed data field) should be included with state utilization data submissions beginning with the first quarter of 2007 submission (which is the utilization data states will submit to CMS in June 2007). However, because the deadline for implementing the invoice changes has been extended, the deadline for implementing the abovementioned changes to the utilization data has been extended as well. **As a result, the revised utilization data format must now be used beginning with each state's fourth quarter 2007 utilization data submission to CMS (which is the quarterly utilization data states will submit to CMS in March 2008). Please note that all quarterly utilization data submissions sent to CMS prior to the fourth quarter 2007 utilization data submission should be transmitted in the previous format. CMS's system will not accept the new format until early 2008 to accommodate the new implementation deadline.**

Any questions regarding this information should be directed to mdroperations@cms.hhs.gov.

RE-ACTIVATED NDCs IN MDR

State Releases #137 and #138 previously stated that several Sodium Chloride products were being deleted from the Medicaid Drug Rebate (MDR) system because they did not meet the definition of a covered outpatient drug as defined in Section 1927(k)(2) of the Social Security Act (the Act). However, in further discussing these products with the Food and Drug Administration (FDA), we have determined that some of the previously deleted Sodium Chloride products are approved as prescription drugs under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act and, therefore, do meet the definition of a covered outpatient drug as defined in the Act. As a result, the following NDCs have been re-activated in the MDR system and will appear on the state rebate tape as active drug products that are eligible for rebates beginning with the fourth quarter of 2006:

00074-1812
00074-1918
00409-1918
00517-2802
00517-2810

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The following product was reported by the labeler as DESI Code 2; however, the FDA has informed us that the class of drugs to which this product belongs (i.e., combination guaifenesin, chlorpheniramine, hydrocodone, pseudoephedrine) has been determined to be DESI code 5 (DESI 6514, May 25, 1982):

68047-0190 Drotuss

The following product was reported by the labeler as DESI Code 2; however, the FDA has informed us that the class of drugs to which this product belongs (i.e. combination guaifenesin, pyrilamine, phenylephrine) has been determined to be DESI code 5 (DESI 6514, May 25, 1982):

65162-0530 A-Tan 12X Suspension

The following products were reported by the labelers as DESI Code 2 however, the FDA has informed us that the class of drugs to which these products belong (i.e., combination trypsin, balsam peru, castor oil) has been determined to be DESI code 6 (DESI 10110, February 12, 1972 (37 FR 3202)):

51991-0124 Trypsin Complex Ointment
13279-0104 Allanderm-T Ointment

The following product was reported by the labeler as DESI Code 5; however, the FDA has informed us that the drug is DESI Code 6 (DESI 11853, December 24, 2002 (67 CFR 78476)):

00182-1396 Trimethobenzamide Hydrochloride

Please be aware that these drugs will no longer be eligible for Federal financial participation. The first quarter 2007 CMS tape to states will reflect the abovementioned DESI Code changes.

The following products were reported by the labelers as DESI Code 5; however, the FDA has informed us that the drugs are DESI Code 2:

68462-0193 Codeine 30MG
68462-0194 Codeine 60MG
00603-1636 Quintex HC SF DF AF

Please be aware that these drugs will be eligible for Federal financial participation.
The first quarter 2007 CMS tape to states will reflect these DESI Code changes.

NON-DRUG DELETIONS FROM MDR

As part of our continuing effort to remove non-drug items from the Medicaid Drug Rebate (MDR) system, the following products will be deleted from the MDR master file of covered outpatient drugs effective July 01, 2007:

00135-0025 GERITOL TONIC
00135-0026 GERITOL COMPLETE TABLETS
00135-0027 GERITOL EXTEND CAPLETS

00182-0418 OYST-CAL D TABLETS
00182-1576 OYST-CAL 500
00182-4439 OYST-CAL D 500 TABLETS

00281-4285 CHROMAGEN

00472-1469 FERROUS SULFATE DROPS

00536-4103 OYSCO D/CALCIUM SUPPLEMENT TABS
00536-4106 OYSCO 500 TABS
00536-7817 OYSCO 500 + D

16103-0360 OYSTER SHELL CALCIUM
16103-0361 OYSTER SHELL CALCIUM + VITAMIN D

24385-0644 OYSTER SHELL CALCIUM
24385-0912 OYSTER SHELL CALCIUM, 250 MG

49348-0061 OYSTER SHELL CALCIUM 250 MG. W/VIT D
49348-0264 OYSTER SHELL CALCIUM 500 MG. W/VIT D
49348-0323 OYSTER SHELL CALC+D
49348-0330 OYSTER SHELL+D
49348-0708 STRONG STRIPS BANDAGES
49348-0758 BANDAGES BUTTERFLY CLOSURES

52569-0232 OYSTER SHELL CALCIUM

51645-0760 FERROUS SULFATE 325MG TABLETS FC (GREEN)
51645-0761 FERROUS SULFATE 325MG TABLETS FC (RED)

52569-0468 FERROUS SULFATE 325 MG

60258-0127 OYSTER CALCIUM 500MG +D TABLETS

62107-0049 OYSTER SHELL CALCIUM 500MG

62107-0073 OYSTER SHELL CALCIUM 250MG PLUS VITAMIN D

62107-0075 OYSTER SHELL CALCIUM 500MG PLUS VITAMIN D

63739-0041 CALCIUM (AS OYSTER SHELL) W/VITAMIN D TAB 250MG

63739-0291 CALCIUM (AS OYSTER SHELL) W/VIT. D 500MG/200IU

64011-0129 CHROMAGEN

64011-0198 CHROMAGEN CAPLET

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.

OPERATIONS TRAINING GUIDE IS NOW OBSOLETE

As you know, the Deficit Reduction Act of 2005 (DRA) made significant changes to the Medicaid Drug Program, including changes to data reporting requirements. These program modifications have rendered the current Operational Training Guide obsolete; therefore, this guide should no longer be used as a reference material. As a result, CMS is in the process of finishing two new data guides, one for states and one for labelers. We hope to make the respective guides available to State Technical Contacts (TCs) and Labeler TCs in the near future.

State TCs will be emailed the State Data Guide. Labelers who have access to Drug Data Reporting for Medicaid (DDR) will be able to download the Labeler Data Guide from DDR. Future inquiries should only be based on the information contained in the new data guides, because the information in the existing training guide is no longer relevant.

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Graceway Pharmaceuticals, LLC 13453	04/01/2007	01/10/2007
Triax Pharmaceuticals, LLC 14290	07/01/2007	02/01/2007
Summit Pharmaceuticals DBA Enemeez, Inc. 17433	04/01/2007	12/13/2006
Mallinckrodt Brand Pharmaceuticals, Inc. 23635	07/01/2007	02/05/2007

SJ Pharmaceuticals, LLC		
24839	04/01/2007	01/24/2007
Fresenius Medical Care North America		
49230	04/01/2007	01/22/2007
Cumberland Pharmaceuticals, Inc.		
66220	07/01/2007	02/01/2007

Contact information for new labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler code is being terminated effective 04/01/2007:

Iopharm Laboratories, Inc. (Labeler Code 61646)

The following labeler codes are being terminated effective 07/01/2007:

JMI-Daniels Pharmaceuticals, Inc. (Labeler Code 00689)
The Liposome Company, Inc. (Labeler Code 61799)

VOLUNTARILY TERMINATED LABELERS

The following labelers have requested voluntary termination effective 04/01/2007:

Emrex/EconoMed Pharmaceuticals, Inc. (Labeler Code 38130)
Seneca Pharmaceuticals, Inc. (Labeler Code 47028)
Harvest Pharmaceuticals, Inc. (Labeler Code 67754)

The following labelers have requested voluntary termination effective 07/01/2007:

3M Pharmaceuticals (Labeler Code 17518)
Myogen, Inc. (Labeler Code 20694)
3M Pharmaceuticals (Labeler Code 55298)
GlaxoSmithKline (Labeler Code 00766)
GlaxoSmithKline (Labeler Code 45800)
GlaxoSmithKline (Labeler Code 49692)
GlaxoSmithKline (Labeler Code 53100)
Richmond Pharmaceuticals, Inc. (Labeler Code 54738)

OTHER ATTACHMENTS

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period October 3, 2005, 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

3 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

Adjustment and/or Dispute Codes for Reconciliation of State Invoice and/or Prior Quarter Adjustment Statement

A. Rebate per unit (RPU) amount has been revised by labeler and reported to CMS, as required.

B. Labeler has calculated RPU and/or rebate where none was reported by State.

C. Units invoiced adjusted through mutual agreement between labeler/State.

D. Labeler/State Unit Type and/or Units Per Package Size (UPPS) value discrepancy (e.g., unit type and/or UPPS reported on invoice does not match CMS tape).

E. Labeler/State decimal discrepancy or rounding problems (e.g., State invoice does not reflect decimal value on CMS tape).

F. *Package size discrepancy (e.g., could include correction to package size by labeler).

G. *Transferred NDC to another labeler code or company. (Labeler code is ultimately responsible for rebate payment.)

H. Utilization change from the State.

I. RPU amount adjusted through correspondence between labeler/State. USE THIS CODE ONLY when the State has reported a RPU not based on the CMS tape and code A is not applicable.

J. No State reimbursement reflected on claims level detail.

K. *****J-Code to NDC crosswalk requires validation data (e.g., crosswalk to products with multiple NDCs and/or package sizes).

L. Generic Substitution.

M. Duplicate claim.

N. *****Discontinued/terminated NDC for which the shelf life expired more than one year from the dispense date. (Documentation should support dispensed date.)

O. Invalid/miscoded NDC.

P. *State units invoiced exceed unit sales. (Documentation should include supporting methodology and data source.)

Q. Utilization/quantity is inconsistent with the number of prescriptions.

R. *****Utilization/quantity is inconsistent with pharmacy reimbursement levels, including Third Party Payments. (This dispute code must be used in conjunction with another code or other supporting documentation.)

S. *****Utilization/quantity is inconsistent with State historical trends or current State program information. (Documentation should include trend/program information.)

T. Utilization/quantity is inconsistent with lowest dispensable package size.

U. *****Product not rebate eligible (e.g., product was not reported to CMS because the product is not a covered outpatient drug, product is for a non-Medicaid State-only program, an HMO non-fee-for-service program, etc…).

V. *****No record of sales directly to State or State history of purchase from out-of-State provider (e.g., border pharmacies, mail order pharmacies, etc.).

W. Closed out. All disputes resolved.

X. *****PHS entity not extracted from State data. (Documentation should include PHS provider number.)

***Supporting Documentation REQUIRED.**
Note: Some adjustment/dispute codes are specifically noted to require supporting documentation; however, supporting documentation can always be submitted, even for those instances where it is not specifically mentioned on this document.

MDRI Detailed Manufacturer Contact Information Date Range: 12/13/2006 to 07/01/2007

Labeler Name: GRACEWAY PHARMACEUTICALS, LLC **Effective Date:** 01/10/2007

NDC: 13453 **Transmission Option:** 2 **Termination Date:**

Legal Information
JOHN BELLAMY
GRACEWAY PHARMACEUTICALS, LLC
340 EDGEMONT AVENUE
SUITE 500
BRISTOL, TN 37620
(423) 274-2100 x2120

Invoice Information
NICOLE YOUNG
GRACEWAY PHARMACEUTICALS, LLC
2 WEST LIBERTY BLVD.
SUITE 203
MALVERN, PA 19355
(484) 321-5600 x21023

Technical Information
STEPHANIE KUPSKI
GRACEWAY PHARMACEUTICALS, LLC
2 WEST LIBERTY BLVD
SUITE 203
MALVERN, PA 19355
(484) 321-5600 x21004

Labeler Name: TRIAX PHARMACEUTICALS, LLC **Effective Date:** 02/01/2007

NDC: 14290 **Transmission Option:** 1 **Termination Date:**

Legal Information
MARK JORDAN
TRIAX PHARMACEUTICALS, LLC
20 COMMERCE DRIVE
SUITE 232
CRANFORD, NJ 07016
(908) 372-1211

Invoice Information
CHARLES TATE
TRIAX PHARMACEUTICALS, LLC
20 COMMERCE DRIVE
SUITE 232
CRANFORD, NJ 07016
(908) 372-1204

Technical Information
CHARLES TATE
TRIAX PHARMACEUTICALS, LLC
20 COMMERCE DRIVE
SUITE 232
CRANFORD, NJ 07016
(908) 372-1204

Labeler Name: SUMMIT PHARMACEUTICALS DBA ENEMEEZ, INC. **Effective Date:** 12/13/2006

NDC: 17433 **Transmission Option:** 2 **Termination Date:**

Legal Information
JIM PRITCHARD
SUMMIT PHARMACEUTICALS DBA
ENEMEEZ, INC.
2515 E. ROSE GARDEN LN
SUITE 1
PHOENIX, AZ 85050
(602) 276-3434

Invoice Information
JEAN CAMPBELL
SUMMIT PHARMACEUTICALS DBA
ENEMEEZ, INC.
2515 E. ROSE GARDEN LN
SUITE 1
PHOENIX, AZ 85050
(602) 276-3434

Technical Information
JEAN CAMPBELL
SUMMIT PHARMACEUTICALS DBA
ENEMEEZ, INC.
2515 E. ROSE GARDEN LANE
SUITE 1
PHOENIX, AZ 85050
(602) 276-3434

MDRI Detailed Manufacturer Contact Information Date Range: 12/13/2006 to 07/01/2007

Labeler Name: MALLINCKRODT BRAND PHARMACEUTICALS, INC. **Effective Date:** 02/05/2007

NDC: 23635 **Transmission Option:** 1 **Termination Date:**

Legal Information
BRIAN ELSBERND
MALLINCKRODT BRAND
PHARMACEUTICALS
675 MCDONNELL BLVD.
10-4-S
ST. LOUIS, MO 63042
(314) 654-3168

Invoice Information
VENITA DAVIS
MALLINCKRODT BRAND
PHARMACEUTICALS
675 MCDONNELL
10-4-S
ST. LOUIS, MO 63042
(314) 654-6226

Technical Information
BRIAN ELSBERND
MALLINCKRODT BRAND
PHARMACEUTICALS
675 MCDONNELL BOULEVARD
10-4-S
ST. LOUIS, MO 63042
(314) 654-3168

Labeler Name: SJ PHARMACEUTICALS, LLC **Effective Date:** 01/24/2007

NDC: 24839 **Transmission Option:** 2 **Termination Date:**

Legal Information
TERRI JACKSON-WADE
SJ PHARMACEUTICALS, LLC
4587 DAMASCUS ROAD
MEMPHIS, TN 38118
(901) 369-9418 x395

Invoice Information
TERRI JACKSON-WADE
SJ PHARMACEUTICALS, LLC
4587 DAMASCUS ROAD
MEMPHIS, TN 38118
(901) 369-9418 x395

Technical Information
TERRI JACKSON-WADE
SJ PHARMACEUTICALS, LLC
4587 DAMASCUS ROAD
MEMPHIS, TN 38118
(901) 369-9418 x395

Labeler Name: FRESENIUS MEDICAL CARE NORTH AMERICA **Effective Date:** 01/22/2007

NDC: 49230 **Transmission Option:** 2 **Termination Date:**

Legal Information
MITCHELL KRINSKY
FRESENIUS MEDICAL CARE NORTH
AMERICA
920 WINTER STREET
WALTHAM, MA 02451-1457
(781) 699-9187

Invoice Information
ANGELA PORTER
FRESENIUS MEDICAL CARE NORTH
AMERICA
920 WINTER STREET
WALTHAM, MA 02451-1457
(781) 699-9000 x4195

Technical Information
J. BRIAN GRADY
FRESENIUS MEDICAL CARE NORTH
AMERICA
920 WINTER STREET
WALTHAM, MA 02451-1457
(781) 699-4541 x4541

MDRI Detailed Manufacturer Contact Information Date Range: 12/13/2006 to 07/01/2007

Labeler Name: CUMBERLAND PHARMACEUTICALS, INC. **Effective Date:** 02/01/2007

NDC: 66220 **Transmission Option:** 1 **Termination Date:**

Legal Information

JIM HERMAN
CUMBERLAND PHARMACEUTICALS, INC.
2525 WEST END AVENUE
SUITE 950
NASHVILLE, TN 37203
(615) 255-0068 x214

Invoice Information

AMELIA WATKINS
CUMBERLAND PHARMACEUTICALS, INC.
2525 WEST END AVENUE
SUITE 950
NASHVILLE, TN 37203
(615) 255-0068 x212

Technical Information

AMELIA WATKINS
CUMBERLAND PHARMACEUTICALS, INC.
2525 WEST END AVENUE
SUITE 950
NASHVILLE, TN 37203
(615) 255-0068 x212

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
10-03-05	3.606		05-01-06	4.807		12-04-06	4.999
10-11-05	3.714		05-08-06	4.864		12-11-06	4.926
10-17-05	3.875		05-15-06	4.864		12-18-06	4.952
10-24-05	3.942		05-22-06	4.828		12-25-06	5.004
10-31-05	3.983		05-30-06	4.843		01-01-07	5.062
11-07-05	3.963		06-05-06	4.833		01-08-07	5.072
11-14-05	4.004		06-12-06	4.926		01-15-07	5.108
11-21-05	4.034		06-19-06	4.958		01-22-07	5.129
11-28-05	3.994		06-26-06	5.036		01-29-07	5.145
12-05-05	4.025		07-03-06	5.088		02-05-07	5.145
12-12-05	3.911		07-10-06	5.056		02-12-07	5.160
12-19-05	3.988		07-17-06	5.098		02-19-07	5.171
12-26-05	3.999		07-24-06	5.108		02-26-07	5.185
01-02-06	4.169		08-07-06	5.124			
01-09-06	4.252		08-14-06	5.114			
01-17-06	4.377		08-21-04	5.109			
01-23-06	4.397		08-28-06	5.093			
01-30-06	4.485		09-04-06	4.984			
02-06-06	4.485		09-11-06	4.947			
02-13-06	4.553		09-18-06	4.942			
02-21-06	4.563		09-25-06	4.895			
02-27-06	4.625		10-02-06	4.890			
03-06-06	4.615		10-09-06	4.978			
03-13-06	4.625		10-16-06	5.072			
03-20-06	4.662		10-23-06	5.124			
03-27-06	4.610		10-30-06	5.108			
04-03-06	4.651		11-06-06	5.088			
04-10-06	4.688		11-13-06	5.088			
04-17-06	4.719		11-20-06	5.071			
04-24-06	4.755		11-27-06	5.036			