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. 77**

Bulletin

For
Participating Drug Manufacturers

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.

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. Labelers are required to accurately reflect the correct DESI code for the NDCs submitted to CMS in accordance with the terms of the national rebate agreement, including reporting changes to the DESI status of any NDC.

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. Labelers are reminded to comply with the terms of the national rebate agreement by submitting NDCs to CMS for only those products that meet the definition of a covered outpatient drug.

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.

OTHER ATTACHMENT

A copy of the current listing of the 91-day Treasury bill auction rates beginning with the period October 3, 2005, is attached.

Please direct any drug rebate data questions to MDROperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

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.

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			

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