



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 RECONCILIATION 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	08-21-06	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		

TOPICAL INDEX – DRUG LABELER RELEASES 1 - 77

TOPIC	RELEASE #
340B Program	46, 51
50% Rebate Cap - Technical Amendment Passed	07
400/400 Edit Reports	75
Adding New Package Sizes to Existing Products	09
Additional Rebate Calculation Revision	10
Address Change (Express Mail)	70
Adjustment Code for CMS-304 & CMS-304a	21, 77
Adjustments that Cause Rebate Corrections	26
Administrative Fees' Effect on AMP & BP	14
Anthrax/Delay of 3/2001 Data	53
Average Manufacturer Price (AMP)	
BP/Upps Clarification	03
Additional Guidance - AMP calculation	29, 31
Calculation Methodology Revision	14, 61
For Terminated Drugs	07
Hemophilic Drugs Clarification	11
Multiple Package Size	43
AMP/BP, Calculating for Different Quarters	07
AMP/BP Calculations-Pharmacy Benefit Managers (PBMs)	28-29
Backup Drug Rebate Library	73
Baseline Change Resulting from OBRA of 1993	13, 15
Batch Edit Report Summary Sheet E-mailed	65
Best Price (BP)	
340B Covered Entities	51
Calculation (VHCA)	06
DSH Covered Entities	11
Effect of Sales to HMOs, etc.	47, 68
Exclusions	07
MPDIMA of 2003	63
TennCare	11, 38
Versus Average Manufacturers Price	15
Buying Innovator Products for Resale	26
Buying/Selling Products	70
Closure During Federal Furloughs	21
CMS R-144 (State Invoice) – Changes	75
Common Data Errors	02
Contact Information/Ownership Changes	04, 06, 17, 21, 33, 63
CPI-U Values	22, 48
Data Definition Update	04, 10
Data Edit Reports	
Batch Edit Reports/Maintaining Backup Files	73
Revised Cover Letters	73
Data File Update	02
Data Requests	59
Deficit Reduction Act of 2005 (DRA)	76
Depot Prices	03
Depot Prices-TRRx	69
DESI -	

TOPICAL INDEX – DRUG LABELER RELEASES 1 - 77

TOPIC	RELEASE #
Codes	09
Field Changes	15
Indicator Change	03-04
Program Overview	04
Discounts/Price Arrangements	02
Diskette Program/Data File (New)	5, 53
Diskette Users	07, 33, 38, 53
WINDOWS Version Only	25, 27
Dispute Resolution Issues	24, 26, 31, 39
E-Mail Address	62
Meetings	59, 63, 65, 67, 70, 72, 77
Transfer of Function	58
Web Site	59
Workgroup Survey Results	13
Drug Category Change	23
Drug Data Reporting for Medicaid (DDR)	76
Drug Product Deletions/Reporting Requirements	04, 30, 45
Drug Product Information Changes	03, 30, 45
Duplicate Payment Prevention (VHCA)	06
E-Mail Address for Operational Questions	72
E-Mail Address for Technical Questions	60
Failure of Manufacturers to Notify States of	
Disputes or Pay Rebates	24
FDA Approval Date	09, 73
FDA Date Submission for OTC Drugs	10
FDA/MDRI Data Match	51, 52, 54, 55
Hands-On Training	22, 23
Heparin/Saline Flush Syringes & Other Non-Drug Products	66
HIPPA – Prescription Numbers	59
Hotline	11, 18
Improper Rebate Withholding/Interest Implications	54
Individual Co-Payments or Insurance Payments	06
Information Sharing	21
Inner/Outer NDC Numbers (reporting)	71
Innovator Products, Buying for Resale	38
Interest Calculation under Section V(b)	07, 40, 46
Interest:	
Failure to Pay	26, 40
When PPAs are Submitted	58
Internet:	
Home Page	38, 50, 56, 72
Prescription Reimbursement Information	59
Pharmacy Plus Demonstrations	59
Invoice/Remittance Advice Report Survey	10
Invoicing for State Pharmacy Assistance Programs	57
Labeler Codes - Addition Procedures	13
Late Data Submissions	04, 09, 53

TOPICAL INDEX – DRUG LABELER RELEASES 1 - 77

TOPIC	RELEASE #
Mailing Pricing Data\Other Correspondence to CMS	06, 17, 21, 36
Market Date	09, 73
MDR Technical E-mail Address	60, 69
Minimum Rebate Percentage & Rebate Cap (VHCA)	06, 07
Multiple Package Sizes	57
New Diskette Program/Data File	05
New Package Size Reporting	51
OIG Review	57
Omnibus Budget Reconciliation Act of 1993	09
Parenteral/Enteral Products	02
Partial Rebate Payments	19
Personnel Changes	60, 65, 71
Pharmacy Benefit Managers (PBMs)	28, 30
Pharmacy Plus Demonstrations Webpage	59
Policy E-Mail Address	53, 56
Powder-Filled Vials, Ampules, & Syringes	11
Prescription Reimbursement Information Website	59
Prior Authorization	19
Prior Period Adjustment Processing	19
Prior Quarter Adjustment Statement (PQAS) Approval	22
Prior Quarter Adjustment Statement Form Use	27, 32, 62
Proposed Discount Equal Access Legislation	16
Public Health Service Drug Pricing Program	13
Publication of Drug Rebate Regulations CMS-2175-FC	61
Quarterly Pricing Data	
Notification of Receipt	63
Requirements	02-03, 07, 08, 12, 38
Revisions/Updates (diskette and telecommunication)	69
Questions and Answers	26
Rebate Agreement: Optional Effective Dates	46
Rebate Percentages for 1994	12
Rebates for Drugs Purchased Through the FSS	53
Rebates on OTC Drug Product	06
Rebate/Reimbursement Issues	25, 31, 54
Recalculation Requests	76
Reconciliation of State Invoice (ROSI) Approval	22, 26
Reconciliation of State Invoice Form Use	27, 32, 62
Recordkeeping Regulations	63
Regulation (CMS-2175-F)	67
Regulation (CMS-2238-P)	76
Regulations, Publication of Proposed	19
Re-Introducing a Product to the Market	73
Remittance Advice Report (RAR)	07, 15-16, 20
Remittance Advice Report Implementation Workgroup	17-18
Reporting NDCs for Generic Products	04
Re-Use of NDCs	51, 73
Selling Products to Another Labeler	43, 48
Separate Rebate Agreements with States	11, 48, 53

TOPICAL INDEX – DRUG LABELER RELEASES 1 - 77

TOPIC	RELEASE #
Shelf Life	03, 31
Staff Relocation	16, 35, 36, 37
State Issues	
Hearing Process	13
Rebate Payments	03
Remittance Advice Contacts	09
State Pharmacy Assistance Programs-Revised Criteria	59, 68, 73
State/R.O. Drug Rebate Contact Persons	06, 08, 17, 46
T-bill Rates	37, 39, 65
Technical Contacts	62
Tennessee Behavioral Health Pharmacy Benefit	38
Termination Appeal Process	11
Termination Dates	31, 48
Termination From Program	19
Therapeutic Equivalency Code	25-26
Tolerance Threshold for Interest	15
Training Guide	65, 66, 67, 69, 70 71, 73, 77
Unique Medicaid Factors & Rebate Disputes	14
Unit-Dose Packaging	04
Unit Rebate Amount Discrepancy Report	37
Unit Rebate Calculation (URA) Modification	02
New CMS Edits	13
Recalculations	24, 38
Recalculations for Incorrect URAs for 1Q98	35, 36
Rounding Method Change	46, 47, 48, 51
Discrepancy Report	34
Unit Type	
Convert to NCPDP 7 plus add AEACH@(EA)	13
Conversion Date Change	09
EACH	73
Specification Changes	06, 08
Updated Version of Diskette Program/Sterling Reporting	67
Utilization Adjustments	22
VA Appropriations Act	03
Vermont Rebate Invoices	23
Veterans Health Care Act of 1992 (VHCA)	06
Virus Transmission Via Diskette	16, 18
Vitamins	30
Y2K	32, 33, 34