

August 5, 2005

**MEDICAID DRUG REBATE PROGRAM**

**RELEASE #138**

## **For State Medicaid Directors**

### **NON-DRUG DELETIONS FROM MDR**

In accordance with previously released state faxes and as part of our continuing effort to remove non-drug items from the Medicaid Drug Rebate (MDR) system, the following products were deleted from the MDR Master file of covered outpatient drugs effective July 1, 2005. The products are as follows:

00338-8017-77 Sodium Chloride 0.9% Syringe  
00338-8019-70 Sodium Chloride 0.9% Syringe  
00338-8020-72 Sodium Chloride 0.9% Syringe  
00338-8021-79 Sodium Chloride 0.9% Syringe  
00338-8302-69 Sodium Chloride 0.9% Syringe  
00338-8303-70 Sodium Chloride 0.9% Syringe  
00338-8303-72 Sodium Chloride 0.9% Syringe  
00074-1812-22 Sodium Chloride 0.9% Syr P/F  
00074-1918-32 Sodium Chloride 0.9% Syringe  
00074-1918-33 Sodium Chloride 0.9% Syringe  
00074-1918-35 Sodium Chloride 0.9% Syringe  
00074-5365-05 Sodium Chloride 0.9% Flush  
00074-5365-10 Sodium Chloride 0.9% Flush  
00409-1918-33 Sodium Chloride 0.9% Syringe

The abovementioned products were not approved as prescription drugs by the Food and Drug Administration 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. The manufacturers of these products will honor any utilization on these items through the second quarter of 2005 and will pay rebates as appropriate on that utilization.

**DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING -  
SEPTEMBER 19-23, 2005-----Registration Due by September 2, 2005**

We are pleased to announce that the next National DRP Meeting will be held September 19-23 in Baltimore, Maryland. This meeting is a continuation of the highly successful DRP meetings held in Baltimore in recent years. While the last several National DRP meetings have been located at the Tremont Suite Hotel, September's meeting will be held at the Tremont Park Hotel, located at 8 East Pleasant Street.

This meeting is open to all states and manufacturers; however, 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 completing and submitting the electronic registration form on our web page at <http://www.cms.hhs.gov/medicaid/drugs/drpmgtgs.asp>. Whenever possible, priority scheduling will be afforded those who register earliest. In addition, your timely responses will help to ensure that an adequate number of DRP staff is available to conduct the meetings.

If possible, states should plan on arriving in time to attend a "state-only" meeting with the CMS DRP Team the morning of Monday, September 19th. Additional meeting details and hotel registration information is provided on the abovementioned DRP web page.

As always, feel free to contact any of the RO DRP Team members for state-specific DRP issues. Any other DRP questions or issues concerning the September meeting may be emailed to [DRP@cms.hhs.gov](mailto:DRP@cms.hhs.gov).

**UPDATES TO THE OPERATIONAL TRAINING GUIDE**

Attached are revised pages to the operational training guide. Page O2 is revised to delete a policy staff member. Page O3 has a revision which reflects the new mailstop for express mail delivery to the drug rebate program (not to be used for utilization tapes). A revised page O5 reflects a name and contact information for region V and other phone number changes. Please share this information with the appropriate staff and replace these pages in your guide.

## **NEW LABELERS**

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Acorda Therapeutics, Inc. (Labeler code 10144)	October 1, 2005	May 27, 2005
Intendis, Inc. (Labeler code 10922)	October 1, 2005	August 01, 2005
NitroMed Inc. (Labeler code 12948)	October 1, 2005	August 01, 2005
Aurobindo Pharma USA, Inc. (Labeler code 13107)	July 1, 2005	June 2, 2005
Allan Pharmaceutical LLC (Labeler code 13279)	October 1, 2005	June 1, 2005
Talecris Biotherapeutics, Inc. (Labeler code 13533)	October 1, 2005	July 21, 2005
DepoMed, Inc. (Labeler code 13913)	October 1, 2005	July 27, 2005
Amylin Pharmaceuticals, Inc (Labeler code 66780)	October 1, 2005	May 24, 2005
Oncology Therapeutics Network Joint Venture, L.P. (Labeler code 67817)	October 1, 2005	July 05, 2005
Zyodus Pharmaceuticals (USA) Inc. (Labeler code 68382)	October 1, 2005	July 07, 2005
American Pharmaceutical Partners, Inc. (Labeler code 68817)	July 1, 2005	July 1, 2005
JDS Pharmaceuticals LLC (Labeler code 68968)	October 1, 2005	July 27, 2005

## **REINSTATED LABELER**

Ranbaxy Laboratories Inc. (Labeler code 10631) has signed a new rebate agreement with a mandatory coverage effective date of 10/01/2005. There is no optional coverage date for this reinstated labeler.

Contact information for new/reinstated labelers is attached for your convenience.

**TERMINATED LABELERS**

The following labeler codes were voluntarily terminated effective July 1, 2005:

Dex Gen Pharmaceuticals, Inc. (labeler code 65430); and  
Able Laboratories, Inc. (labeler code 53265).

The above terminations were previously faxed to the State technical contacts.

The following labeler codes are being voluntarily terminated effective October 1, 2005:

Lifecycle Ventures, Inc (labeler code 65939); and  
Praecis Pharmaceuticals, Inc. (labeler code 68158).

The following labeler codes are being terminated effective October 1, 2005:

Novartis Consumer Health, Inc. (labeler code 00043);  
Marlex Pharmaceuticals, Inc. (labeler code 10135);  
Gil Pharmaceutical Corp. (labeler code 58552);  
Iyata Pharmaceuticals, Inc. (labeler code 59291); and  
Shire US, Inc. (labeler code 59441).

**OTHER ATTACHMENT**

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period January 12, 2004, is attached.

Please remember to direct your drug rebate questions to a staff member listed in section “O” of the Medicaid Drug Rebate Operational Training Guide.

/s/

Edward C. Gendron  
Director  
Finance, Systems and Budget Group

5 Attachments

cc:  
All State Drug Rebate Technical Contacts  
All Regional Administrators

# CMS DRUG REBATE PROGRAM



## Area Code 410

### OPERATIONS

Cindy Bergin	786-1176	cynthia.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
Vince Powell (Technical Director)	786-3314	vincent.powell@cms.hhs.gov
Sue Williams	786-3334	susan.williams@cms.hhs.gov

### POLICY

Kim Howell	786-6762
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](mailto: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

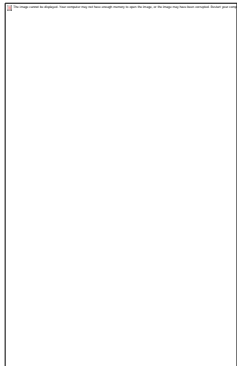


### FAX

786-0390 – Operations  
786-8534 - Policy

WEBSITE [www.cms.hhs.gov/medicaid/drugs/drughmpg.asp](http://www.cms.hhs.gov/medicaid/drugs/drughmpg.asp)

# CMS MEDICAID DRUG REBATE MAILING ADDRESSES



**Regular Mail**  
CMS, CMSO

Drug Rebate  
Program

P.O. Box  
26686

Baltimore,  
Maryland  
21207



**xpress  
Mail**  
CMS,  
CMSO

Drug Rebate Program

Mail Stop S3-19-16  
7500 Security Boulevard  
Baltimore, Maryland 21244

**NOTE:** PLEASE DO NOT USE the express mail address to send general correspondence to CMS. The use of this mail stop for general correspondence will delay its delivery to the appropriate individual.

Rev. 8/05

**03**

## Regional Office Drug Rebate Dispute Resolution Program Coordinators

Analysts	E-mail	Phone #	States
<b>Region I – Boston</b> Ray Porter	<a href="mailto:raymond.porter@cms.hhs.gov">raymond.porter@cms.hhs.gov</a>	(617) 565-1260	Connecticut, New Hampshire, Maine, Massachusetts, Rhode Island, Vermont
<b>Region II – N.Y.</b> Robert Cochrane	<a href="mailto:robert.cochrane@cms.hhs.gov">robert.cochrane@cms.hhs.gov</a>	(212) 616-2420	New York, New Jersey
<b>Region III-Phil.</b> Jennifer Quinn	<a href="mailto:jennifer.quinn@cms.hhs.gov">jennifer.quinn@cms.hhs.gov</a>	(215) 861-4174	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
<b>Region IV - Atlanta</b> Jessie Spillers Elaine Elmore	<a href="mailto:jessie.spillers@cms.hhs.gov">jessie.spillers@cms.hhs.gov</a> <a href="mailto:elaine.elmore@cms.hhs.gov">elaine.elmore@cms.hhs.gov</a>	(404) 562-7418 (404) 562-7408	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
<b>Region V - Chicago</b> Claudia Simonson	<a href="mailto:claudia.simonson@cms.hhs.gov">claudia.simonson@cms.hhs.gov</a>	(312) 353-2115	Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
<b>Region VI - Dallas</b> Mike Jones	<a href="mailto:michael.jones@cms.hhs.gov">michael.jones@cms.hhs.gov</a>	(214) 767-6279	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
<b>Region VII - Kansas City</b> Frank Campbell	<a href="mailto:frank.campbell@cms.hhs.gov">frank.campbell@cms.hhs.gov</a>	(816) 426-6455	Iowa, Kansas, Missouri, Nebraska
<b>Region VIII – Denver</b> *Diane Dunstan	<a href="mailto:diane.dunstan@cms.hhs.gov">diane.dunstan@cms.hhs.gov</a>	(303) 844-7040	Colorado, Montana, North Dakota, South Dakota, Wyoming
<b>Region IX – San Francisco</b> Michael Sullivan	<a href="mailto:michael.sullivan@cms.hhs.gov">michael.sullivan@cms.hhs.gov</a>	(415) 744-3589	Arizona, California, Hawaii, Nevada
<b>Region X - Seattle</b> Maria Garza	<a href="mailto:maria.garza@cms.hhs.gov">maria.garza@cms.hhs.gov</a>	(206) 615-2542	Alaska, Idaho, Oregon, Washington



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

<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>
01-12-04	0.887	08-09-04	1.497	03-07-05	2.767
01-20-04	0.891	08-16-04	1.498	03-14-05	2.792
01-26-04	0.907	08-23-04	1.541	03-21-05	2.859
02-02-04	0.939	08-30-04	1.607	03-28-05	2.839
02-09-04	0.939	09-06-04	1.663	04-04-05	2.792
02-17-04	0.931	09-13-04	1.671	04-11-05	2.767
02-23-04	0.947	09-20-04	1.716	04-18-05	2.864
03-01-04	0.957	09-27-04	1.741	04-25-05	2.941
03-08-04	0.945	10-04-04	1.716	05-02-05	2.931
03-15-04	0.961	10-12-04	1.711	05-09-05	2.911
03-22-04	0.945	10-18-04	1.803	05-16-05	2.859
03-29-04	0.961	10-25-04	1.890	05-23-05	2.957
04-05-04	0.945	11-01-04	1.987	05-31-05	2.998
04-12-04	0.929	11-08-04	2.084	06-06-05	3.029
04-19-04	0.949	11-15-04	2.115	06-13-05	3.039
04-26-04	0.985	11-22-04	2.197	06-20-05	3.029
05-03-04	1.001	11-29-04	2.380	06-27-05	3.147
05-10-04	1.078	12-06-04	2.253	07-05-05	3.214
05-17-04	1.058	12-13-04	2.243	07-11-05	3.204
05-24-04	1.066	12-20-04	2.223	07-18-05	3.292
05-31-04	1.150	12-27-04	2.269	07-25-05	3.420
06-07-04	1.251	01-03-05	2.320	08-01-05	3.477
06-14-04	1.413	01-10-05	2.376		
06-21-04	1.336	01-18-05	2.407		
06-28-04	1.381	01-24-05	2.366		
07-05-04	1.344	01-31-05	2.525		
07-12-04	1.336	02-07-05	2.530		
07-19-04	1.352	02-14-05	2.592		
07-26-04	1.449	02-22-05	2.669		
08-02-04	1.490	02-28-05	2.772		

## TOPICAL INDEX - STATE MEDICAID RELEASES 1 - 138

TOPIC	RELEASE #
1A Drug Listing	11
Additional Copies of Releases to SMDs	40
Adjustment Code for Forms CMS-304 & CMS-304a	57
Allscrips Pharmaceuticals, Inc.	65, 68, 69
AMP Recalculations	107, 109, 110, 112
Bankruptcy - Drug Labelers	19, 61, 68
Best Price	
Effect of Sales to HMOs, etc.	137
To DSH Covered Entities	36
Under MPDIMA of 2003	128
Betaseron - Coverage & Reimbursement	38, 40
Bulk Transfer/Buy-Out of Major Pharm. Assets	54, 55
Calphron	76, 79
Caverject Coverage	55
Closure During Federal Furloughs	57
Compendia	70
Confidential Information Release	17
Constant Disputes by Drug Labelers	23
Contact Information	65, 92
CPI-U Information	09, 102
Dataset Name Changes on Quarterly Rebate Tapes	41
Depot Prices-TRRx	137
DESI Code Change	137
Dipyridamole Issue	26
Dispute Resolution:	
Definition	19
E-Mail Address	128
Issues	55, 65, 71, 86, 108
Meetings	117, 123, 129, 132, 136, 138
Process Stages	45
Transfer of Function	121
Web Site	122
Workgroup Survey Results	42
Dispute Resolutions	59
Drug Category Change	61, 76
Drug Efficacy Study & Implementation (DESI):	
Change Effective Date	20
Change Schedule	18
Effective Date Revisions	23, 24
DRUGDEX, a new compendium	70
Drug Emporium, Inc. Effective Date	65
Duplicate Discount/Rebate Mechanism Implementation	33
Effective Date(s) of Rebate Agreements	97
Enteral Nutritional Products - Coverage	30
Enteral Products	19

TOPIC

RELEASE #

Eon Labs Product	117
Experimental Drugs - Coverage	43
Failure of Manufacturers to Notify States of Disputes or Pay Rebates	63
FDA/MDRI Data Match	107, 115
Generic Substitution Laws	67
Goldline OTC Vitamin	102
Haldol Rebates	75
Heparin/Saline Flush Syringes & Other Non-Drug Products	132, 134, 136
Herceptin: Genentech New Product	85
HIPPA – Prescription Numbers	124
Hotline	53
HRSA Notice Published/Exclusion File	98, 101, 106
Improper Rebate Withholding/Interest Implications	114
Index for Drug Rebate Notes	31
Information Sharing	57
Interest Calculation under Section V(b)	29, 88, 98
Interest:	
Failure to Pay	65
When PPAs are Submitted	121
Internet:	
Home Page	61, 85, 105, 117
Prescription Reimbursement Information	123
Pharmacy Plus Demonstrations	123
Invoices:	
Correct Labeler Address	36
Format	03
Incomplete Drug Labeler Data	18
Incorrect Invoicing	26
Remittance Advice Report Survey	35
Submission	19
Submitting for Multiple Quarters	36
Submitting to Drug Labelers	28
Labeler Contact File Changes	26, 32, 128, 132
Lovenox Prefilled Syringes	91
LTE/IRS Drugs	26
Magnetic Media	
New Address for Shipping (Effective 6/1/95)	52
Rejections	15
Shipments	15, 23
Specification Revisions	14, 72, 73
Manufacturer Information Record Specification	20
Manufacturer Name & Address Contact Info Diskette	27
MDR Technical E-mail Address	124, 137
Medical Supplies & Devices	03, 16, 26
Metric Conversion/Rounding	18
MMA of 2003	128, 130
Multiple Package Size-Pricing Inconsistency	123

**TOPIC**

**RELEASE #**

New Drug Products

41

New Rebate Agreement Status	23
Non-Drug Products Coverage	132, 134
Non-Drug Products Deleted	123, 128, 132, 133, 134, 136, 137, 138
Novartis Rounding All URAs Back to 1991	117
OBRA '93	40
OIG Reports/Reviews	120
Ortho Evra Replacement Patch	134
Overpayments Due to AMP Recalculations	57, 107
Personnel Changes	124, 130
PHS Drug Pricing Program	44
Point-of-Sale System (POS) in Pharmacies	85
Policy E-Mail Address	113, 117
Prior Authorization	55
Prior Period Adjustments	14, 16, 60, 87
Prior Period Adjustments - Eli Lilly & Company	37
Prior Quarter Adjustment Statement (PQAS) Approval	60
Proposed Discount Equal Access Legislation	51
Publication of Drug Rebate Regulations CMS-2175-FC	126
Publication of Drug Rebate Regulations MB-46-P	55
Quarterly Prices, Late Submission	33
Quarterly Reporting - Form CMS-64.r	40
Quarterly Tape Submission to CMS	60, 72, 130
Quarterly Update File	14
Questions and Answers	65
Rebate Agreements:	
Start Date Procedures	102
Separate/Supplemental	102
Rebate/Reimbursement Issues	64, 113
Rebates:	
Calculation Formula	07
Drugs Purchased Through the FSS	113
Less than Administrative Costs	40
Nonpayment	94
Partial Payments	55
Remittance/Check Address	30
Reconciliation of State Invoice (ROSI) Approval	60
Recordkeeping Regulations	129
Regulation (CMS-2175-F)	136
Rejection of State Records Matching LTE Drugs	41
Remittance Advice Report/Workgroup	48, 52, 53, 56
Rescission of Termination for Novopharm USA	39
S-TAG (Systems Technical Advisory Group)	85
Separate Rebate Agreements with Manufacturers	38, 113
Special Advisory Group	16
Special Study – Anti-Load Viral/AIDS Drugs	102
Staff Listing	53
Staff Relocation	52, 83
<b>TOPIC</b>	<b>RELEASE #</b>

State Application of the FUL Program	48
State Contact Information	23, 26, 41, 98
State Coverage:	
LTE & IRS Drugs	40
Unit-Dose Drugs	19
State Data Validation Edits	33
State Hearing Process	44
State Invoices Containing Universal Product Codes	51
State Pharmacy Assistance Programs-Revised Criteria	124
State Plan Amendment Requirement	47
State Quarterly URA Tape	
Labeler Contact Information	134
Mailing	133
State Responsibility - Terminated Drugs	19
State Utilization Data Study (SUDS)	33
T-bill Rates	83, 86, 132
Termination Date (NDC)	79
Terminated/Deleted Records	44
Termination From Program	55
Therapeutic Equivalency Code	64
Timely Receipt of Tapes/Notices of Mailing	45
Tolerance Threshold Clarification	
For Interest	48
Rebate Amount Adjustments	44
Training Guide	130, 132, 133, 134, 136, 137, 138
Unit-Dose Packaging	15
Unit Per Package Size	03
Change for Beohringer Ingelheim Product	123
Unit Rebate Amount (URA):	
Additional Amounts in 3/1998 File	85
Edits	43
Erroneous Amounts	51
First-Time Reporting on State Tape	132
Incorrect Amounts for 1Q98	79, 80
Invoice when the Amount is Zero	44
New Rounding Method	98, 100, 101, 106
Recalculations	111
Unit Type:	
Changes and Prior Period Adjustments	43
Conversion Date Changed	34
Revisions	32, 83
UPPS Less Than 1.0	19
UPPS Used for Calculating Utilization	61
Use of Information from Outside Sources	48
Utilization Adjustments for Prior Calendar Quarters	67, 72
Receipt	29, 31

**TOPIC**

**RELEASE #**

Utilization Data:	
Changes to Labelers	57

Corrections/Problems	18, 51, 72
Late Submission	18
Record Format	08, 13, 72
Set Naming Requirements	19
Tapes/Confirmation Letter	19, 30, 40, 45, 58, 72, 82
Transmitting Corrections/Adjustments to CMS	16, 40, 72
Utilization Tape Record Specification	67, 72, 73, 98, 105
Vaccine:	
Deletions	26
Exclusions	19, 23
Policy Clarification	25
Viagra Coverage	81
Vitasert	64
Warrick Pharmaceuticals (Sodium Chloride Solution)	98
Xenical Coverage	97
Y2K	72, 87