



July 3, 2006

**MEDICAID DRUG REBATE PROGRAM****RELEASE #142****For State Medicaid Directors****DRA REQUIREMENT TO PROVIDE AMP TO STATES  
BEGINNING JULY 1, 2006**

In accordance with section 6001 of the Deficit Reduction Act (DRA) of 2005, CMS will be providing the most recently reported Average Manufacturer Prices (AMPs) via compact disc (CD) for single source and multiple source drugs each month from July 2006 – December 2006. The data on each CD will be in flat file format, which can be read by multiple programs (e.g., Word, Excel, etc.). The CDs will be mailed to the technical contact at each state and information to assist in importing the flat file will be included with the CDs.

Please note that section 1927(b)(3)(D) of the Social Security Act (the Act) requires that, notwithstanding any other provision of law, these AMPs be kept confidential and shall not be disclosed by a State agency (or contractor therewith) in a form which discloses the identity of the manufacturer or any prices charged for drugs by that manufacturer. States are restricted from disseminating, distributing, or using AMP data, except as specifically authorized by the drug rebate statute.

**CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE**

These products were reported by the labelers as DESI Code 2 (safe and effective). The FDA has determined that these drugs are less-than-effective, or a DESI Code 5 (Federal Register Notice 46 FR 46404).

Please be aware that these drugs will not be eligible for Federal financial participation or rebate billing for any product dispensed beyond June 30, 2006. If your system can process an immediate change, please do so. The 2Q2006 CMS tape will reflect the DESI Code 5 status.

00496-0800, Analpram HC Cream  
60258-0425, Pulmari-GP Syrup  
66663-0112, Migraten  
66992-0120, Betavent Syrup

**NON-DRUG DELETION 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 as shown below:

7/1/06            NDC 00145-4200-01 (MimYx)

10/1/06            00067-0125, Slow Fe Tabs  
                      00182-4476, Slow Fe  
                      68712-0007, Bionect Cream  
                      68712-0008, Bionect Gel  
                      68712-0009, Bionect Spray

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.

**PERSONNEL/STAFF CHANGES**

After 30 years of service, Sue Williams retired from CMS effective June 30, 2006.

Effective immediately, Samone Angel has joined the drug rebate Operations staff.

Page O2 of the Operational Training Guide has been revised to reflect these changes and is attached to this release.

**UPDATES TO THE OPERATIONAL TRAINING GUIDE**

In addition to page O2, pages F20 and F22 have been revised to reflect an addition to the address for sending the state utilization tapes.

**NEW LABELERS**

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Centrix Pharmaceutical, Inc. (Labeler Code 11528)	07/01/2006	04/27/2006
Coria Laboratories, LTD. (Labeler Code 13548)	04/01/2006	04/01/2006
Sun Pharmaceutical Industries, Inc. (Labeler Code 14508)	07/01/2006	03/08/2006
Carwin Associates, Inc. (Labeler Code 15370)	10/01/2006	06/16/2006
Insmmed, Inc. (Labeler Code 16249)	07/01/2006	03/27/2006
Cobalt Laboratories, Inc. Labeler Code 16252	10/01/2006	06/01/2006
Laser Pharmaceuticals, LLC (Labeler Code 16477)	07/01/2006	04/04/2006
Onset Therapeutics (Labeler Code 16781)	07/01/2006	04/17/2006
Deston Therapeutics, LLC (Labeler Code 16881)	10/01/2006	06/12/2006
Vernalis Pharmaceuticals, Inc. (Labeler Code 16887)	10/01/2006	06/15/2006
Zerxis Pharma, L.L.C. (Labeler Code 18011)	10/01/2006	06/20/2006
Plymouth Pharmaceuticals, Inc. (Labeler Code 61480)	10/01/2006	06/14/2006
ANIP Acquisition Company (Labeler Code 62559)	07/01/2006	04/08/2006
Sun Pharmaceutical Industries Ltd. (Labeler code 62756)	07/01/2006	04/26/2006
CV Therapeutics, Inc. (CVT) (Labeler Code 67159)	07/01/2006	03/15/2006

**REINSTATED LABELERS**

Jubilant Pharma, Inc. (Labeler Code 59746) has signed a new rebate agreement and was reinstated in the drug rebate program effective 07/01/2006.

Select Brand Distributors (Labeler Code 15127) and Shionogi USA, Inc. (Labeler Code 45809) have signed new rebate agreements and are reinstated in the drug rebate program effective 10/01/2006.

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

**TERMINATED LABELERS**

The following labeler codes are being terminated effective July 1, 2006:

GSP Company	Labeler Code 15020
Creekwood Pharmaceutical, Inc.	Labeler Code 15310
R.I.D., Inc.	Labeler Code 54807
Econolab	Labeler Code 55053
World Gen LLC	Labeler Code 66814

The following labeler codes are being terminated effective October 1, 2006:

Forum Products Inc.	Labeler Code 13863
DiHoMA Chemical & Manufacturing, Corporation	Labeler Code 62294

The following labeler codes have voluntarily terminated effective July 1, 2006:

Hampton-Laine, LLC	Labeler Code 15704
R&S Northeast	Labeler Code 17236
Medisca, Inc.	Labeler Code 38779

The following labeler code has voluntarily terminated effective October 1, 2006:

Knoll Pharmaceutical Company	Labeler Code 00048
------------------------------	--------------------

**OTHER ATTACHMENT**

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period March 7, 2005, is attached.

Please remember to direct your drug rebate questions to [MDROperations@cms.hhs.gov](mailto:MDROperations@cms.hhs.gov)

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

<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>
03-07-05	2.767	10-03-05	3.606	05-01-06	4.807
03-14-05	2.792	10-11-05	3.714	05-08-06	4.864
03-21-05	2.859	10-17-05	3.875	05-15-06	4.864
03-28-05	2.839	10-24-05	3.942	05-22-06	4.828
04-04-05	2.792	10-31-05	3.983	05-30-06	4.843
04-11-05	2.767	11-07-05	3.963	06-05-06	4.833
04-18-05	2.864	11-14-05	4.004	06-12-06	4.926
04-25-05	2.941	11-21-05	4.034	06-19-06	4.958
05-02-05	2.931	11-28-05	3.994	06-26-06	5.036
05-09-05	2.911	12-05-05	4.025		
05-16-05	2.859	12-12-05	3.911		
05-23-05	2.957	12-19-05	3.988		
05-31-05	2.998	12-26-05	3.999		
06-06-05	3.029	01-02-06	4.169		
06-13-05	3.039	01-09-06	4.252		
06-20-05	3.029	01-17-06	4.377		
06-27-05	3.147	01-23-06	4.397		
07-05-05	3.214	01-30-06	4.485		
07-11-05	3.204	02-06-06	4.485		
07-18-05	3.292	02-13-06	4.553		
07-25-05	3.420	02-21-06	4.563		
08-01-05	3.477	02-27-06	4.625		
08-08-05	3.539	03-06-06	4.615		
08-15-05	3.549	03-13-06	4.625		
08-22-05	3.539	03-20-06	4.662		
08-29-05	3.575	03-27-06	4.610		
09-06-05	3.513	04-03-06	4.651		
09-12-05	3.529	04-10-06	4.688		
09-19-05	3.575	04-17-06	4.719		
09-26-05	3.518	04-24-06	4.755		

## TOPICAL INDEX - STATE MEDICAID RELEASES 1 - 142

TOPIC	RELEASE #
1A Drug Listing	11
Additional Copies of Releases to SMDs	40
Adjustment Code for Forms CMS-304 & CMS-304a	57
Allscripts Pharmaceuticals, Inc.	65, 68, 69
AMP Recalculations	107, 109, 110, 112, 140
AMP to states	142
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, 141
Confidential Information Release	17
Constant Disputes by Drug Labelers	23
Contact Information	65, 92
CPI-U Information	09, 102
Database Backup Files	140
Dataset Name Changes on Quarterly Rebate Tapes	41
Deleted Products-No Termination Date	139
Depot Prices-TRRx	137
DESI Code Change	137, 140, 142
Dipyridamole Issue	26
Dispute Resolution:	
Definition	19
E-Mail Address	128
Issues	55, 65, 71, 86, 108
Meetings	117, 123, 129, 132, 136, 138, 140
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

<b>TOPIC</b>	<b>RELEASE #</b>
Drug Emporium, Inc. Effective Date	65
Duplicate Discount/Rebate Mechanism Implementation	33
Effective Date(s) of Rebate Agreements	97
E-mail Address (Operations)	140
Enteral Nutritional Products - Coverage	30
Enteral Products	19
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/New Webpage Address	61, 85, 105, 117, 140
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



<b>TOPIC</b>	<b>RELEASE #</b>
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
New Drug Products	41
New Rebate Agreement Status	23
Non-Drug Products Coverage	132, 134
Non-Drug Products Deleted	28, 132, 133, 134, 136, 137, 138, 139, 140, 142
Novartis Rounding All URAs Back to 1991	117
OBRA '93	40
OIG Reports/Reviews	120, 140
Ortho Evra Replacement Patch	134
Overpayments Due to AMP Recalculations	57, 107
Personnel Changes	124, 130, 139, 142
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

<b>TOPIC</b>	<b>RELEASE #</b>
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
Standard Summary Record Format	13
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	
Exemption From Medicaid Best Price	140
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
Technical Contact E-mail Address	140
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, 139, 140, 142
Unit-Dose Packaging	15
Unit Per Package Size	03
Change for Beohringer Ingelheim Product	123

**TOPIC****RELEASE #**

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
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 Discrepancy Report	139
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