



December 15, 2006

MEDICAID DRUG REBATE PROGRAM**Release No. 144****For State Medicaid Directors****IMPLEMENTATION OF THE DEFICIT REDUCTION ACT OF 2005 (DRA)**

The Deficit Reduction Act of 2005 (DRA), Public Law 109-171, made changes that will affect State payment and rebates for prescription drugs under the Medicaid program. While we have issued State Medicaid Director letters concerning the return and crediting of unused drugs in nursing facilities and physician-administered drugs, we expect that other provisions of the DRA will be addressed in the Federal regulations. Until the regulations are published, we are issuing this release to provide guidance with respect to the DRA provisions.

Section 6001 of the DRA amended section 1927(e) of the Social Security Act (the Act) to provide that the Federal upper limits (FULs) be calculated based on 250 percent of the average manufacturer price (AMP) (computed without regard for customary prompt pay discounts extended to wholesalers) for the least costly therapeutically equivalent drug instead of 150 percent of the published price for the least costly therapeutically equivalent drug as listed in published compendia of cost information for drugs available for sale nationally. Section 6001 also revised section 1927(b) of the Act to require that, effective January 1, 2007, manufacturers report AMP on a monthly basis.

Section 6001 also amended section 1927(b)(3)(D) of the Act to provide for the release of AMP to States and to require that CMS disclose AMP on its website. In accordance with these provisions, we expect to post monthly and quarterly AMPs beginning in late spring 2007. We expect to issue further clarification of AMP in the final regulation, which may result in changes to reported AMPs. States should consider that the AMPs posted would not necessarily reflect the mark-up from the wholesaler to the retail pharmacy or the varying prices paid by individual pharmacies for drugs. Changes made to the current Medicaid payment rates require submission and approval of a State plan amendment (SPA).

CMS also expects to provide States a monthly national survey of retail prices beginning in January 2007. States may use these data to revise or validate their current drug payment

methodologies. When using these new drug data sources, States should reexamine and reevaluate the reasonableness of the dispensing fee paid as part of the pharmacy claim. If States adjust their payment methodologies to reflect the ingredient cost of the prescription drug, we suggest that they also reevaluate their dispensing fees to ensure that these fees are reasonable. As noted above, changes made to the current Medicaid payment rates, including the dispensing fees, require submission and approval of a SPA.

The following guidance is being provided to drug manufacturers to implement sections 6001 and 6003 of the DRA prior to a final regulation taking effect.

RELEASE TO DRUG MANUFACTURERS –

IMPLEMENTATION OF THE DEFICIT REDUCTION ACT OF 2005 (DRA)

The Deficit Reduction Act of 2005 (DRA), Public Law 109-171, was enacted on February 8, 2006. Sections 6001 and 6003 of the DRA address prescription drugs under the Medicaid program. The law requires that we implement many of the requirements of the provisions in these sections beginning January 1, 2007, without regard to whether or not final regulations to carry out such amendments have been promulgated by that date. While we are making every effort to publish the regulation as quickly as possible, the final regulation will not be published in time to be effective January 1, 2007. Until the regulations are published, we are issuing this release to provide guidance with respect to the DRA provisions.

Section 6001 of the DRA amended section 1927(e) of the Social Security Act (the Act) to provide that the Federal upper limits (FULs) be calculated based on 250 percent of the average manufacturer price (AMP) (computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutically equivalent drug instead of 150 percent of the published price for the least costly therapeutically equivalent drug as listed in published compendia of cost information for drugs available for sale nationally. Section 6001 also revised section 1927(b) of the Act to require that manufacturers report AMP on a monthly basis, effective January 1, 2007. Note that after the final regulation takes effect, the AMPs reported by manufacturers may change due to clarifications provided in the final rule. Therefore, we are urging States to be cautious when considering using the newly available AMPs to set payment rates for non-FUL drugs. Changes made to the current Medicaid payment rates require submission and approval of a State plan amendment.

In accordance with the provisions of the DRA, beginning with the month of January 2007, drug manufacturers should report the following data to CMS:

AMP: *In accordance with the DRA, drug manufacturers are required to report AMP data on a monthly basis to CMS. Monthly AMPs should reflect that month's transactions. In accordance with the current timeframes for reporting quarterly AMPs, manufacturers will have 30 days following the last day of the month to submit the monthly AMP data. Because we expect to send AMP data to States and post the AMP data on the CMS website on a monthly basis beginning in late spring 2007, we request that manufacturers not submit adjustments to monthly AMP reported data after the end of the 30-day reporting period. Adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission.*

Drug manufacturers should continue to report quarterly AMPs within 30 days after the last day of each calendar quarter. Quarterly AMPs will continue to be used in the calculation of rebate amounts for drugs and States will invoice drug manufacturers for Medicaid rebates using these amounts.

Drug manufacturers are to exclude customary prompt pay discounts extended to wholesalers in the determination of monthly and quarterly AMPs beginning in January 2007. We expect to address how to make this calculation in the final regulation; in the interim, we suggest that drug manufacturers make reasonable assumptions consistent with the statutory provisions. In accordance with section 6003 of the DRA, drug manufacturers must also include sales of authorized generic drugs in the determination of AMP. For purposes of this release, an authorized generic is any drug product marketed under the innovator or brand manufacturer's original new drug application (NDA), but labeled with a different NDC than the innovator or brand product.

Basedate AMP: *We are aware of concerns regarding the calculation of basedate AMP and we expect to address this policy in the final regulation.*

Best Price: *Beginning with January 2007 data, in accordance with the DRA, drug manufacturers should modify their methodology for reporting best price. Specifically, the exclusion of nominal price sales from the best price calculation will be limited to sales to certain entities. Accordingly, for purposes of best price, only sales by a manufacturer at nominal prices to the following entities may be considered to be "merely nominal in amount" -- (1) a covered entity described in section 340B(a)(4) of the Public Health Service Act; (2) intermediate care facilities for the mentally retarded, and (3) State-owned or operated nursing facilities. Nominal sales to other entities must be included in best price.*

In accordance with the DRA, sales of authorized generics must also be included in the determination of best price.

Nominal Price: *CMS will issue guidance on nominal price at a later time.*

NEW MEDICAID DRUG DATA SUBMISSION METHOD

Concurrent with the above-mentioned data reporting requirements, CMS is developing a new, web-based application that all manufacturers will be able to use to submit data beginning with the first monthly and quarterly data submissions in 2007. The new application, Drug Data Reporting (DDR) for Medicaid, will contain each manufacturer's data by labeler code, including all drug products and pricing data. DDR will be a secure system and will require both a CMS user ID and password for all manufacturer contacts responsible for data submission. Specific information on the application process for obtaining a CMS user ID and password was e-mailed to all current manufacturer technical contacts on December 13, 2006.

PUBLICATION OF REGULATION

We are issuing the notice of proposed rulemaking regarding the provisions of the DRA on Medicaid prescription drugs. While the final rule will not be in effect by January 1, 2007, we will issue the final regulation as quickly as possible in order to meet the July 1, 2007 statutory

deadline. We expect the regulation to address our policies for computing AMP and other issues related to Medicaid prescription drugs and rebates. We encourage everyone to review this regulation and provide comments as appropriate during the public comment period.

IMPLEMENTATION OF NATIONAL PROVIDER IDENTIFIER AND 340B PROGRAM

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services adopt a standard, unique health identifier for health care providers. On January 23, 2004, the Secretary published a Final Rule that adopted the National Provider Identifier (NPI) as this identifier.

One of the standard transactions will require the use of the NPI by clinics participating in the 340B Drug Pricing Program administered by the Health Resources and Services Administration's Office of Pharmacy Affairs (OPA). In the past, 340B covered entities (as that term is defined in the Veterans Health Care Act of 1992 (P.L. 102-585)) that billed Medicaid for drugs purchased at 340B prices were required to submit to OPA their Medicaid Provider Numbers, which were subsequently posted on the OPA website's Medicaid Exclusion Files. The posting of this Medicaid Provider Number allowed State Medicaid agencies to exclude purchases made by these clinics to ensure that manufacturers were not giving additional discounts on 340B purchases – sometimes referred to as a “duplicate discount.”

As clinics, hospitals, and others begin to use NPIs in their standard transactions, the OPA is requesting the assistance of State Medicaid agencies to ensure a smooth transition from the Medicaid Provider Number to the NPI. All States are encouraged to participate in a Medicaid Exclusion Workgroup formed by OPA. Several States are already engaged in this Workgroup, including Texas, Louisiana, Florida, Utah, California, Massachusetts, and North Carolina. States wishing to participate may email Ms. Sharley Chen at Sharley.Chen@hrsa.hhs.gov. Please ensure that the appropriate individual in your agency is notified of this Workgroup.

NON-DRUG DELETIONS FROM MDR SYSTEM

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 January 01, 2007:

00904-5118, Pediatric Electrolyte Fruit Flavored
00904-5119, Pediatric Electrolyte Bubblegum
00904-5276, Pediatric Electrolyte Grape Dyed
00904-7659, Pediatric Electrolyte Solution Unflavored
00904-7660, Pediatric Electrolyte Solution Fruit Flavored
00904-7850, Pediatric Electrolyte/Bubble Gum Flavor
66977- 0222, Oramagicrx

The above-mentioned 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.

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

Labelers provided a DESI Code 2 (safe and effective) on the following drugs, although the FDA has determined that to be incorrect. Please be aware that these drugs will no longer be eligible for Federal financial participation or rebate billing beyond December 31, 2006. If your system can process an immediate change, please do so. The 4th quarter, 2006 CMS tape to states will reflect the DESI Code 5 or 6 status.

The DESI Codes for the following NDCs have been changed to DESI Code 5 (less than effective):

NOOH published July 1, 1998 (53 FR 25013)

Ferndale Laboratories, Inc., 00496-778-04 and 64, Analpram HC Cream 1%

DESI 7661 NOOH published April 14, 2003 (68 FR 17953)

Lannett Company, Inc., 00527-1409-01, Methyltestosterone and Esterified Estrogen

Lannett Company, Inc., 00527-1410-01 and 10, Methyltestosterone and Esterified Estrogen

DESI 10110 February 12, 1972 (37 FR 3202)

Major Pharmaceuticals, 00904-3678-22, Balsa-Derm Spray

Major Pharmaceuticals, 00904-5157-22, Granul Aerosol

Onset Therapeutics, 16781-0116-95, Optase

Delta Pharmaceuticals, Inc., 53706-1001-01 and 02, TBC

Healthpoint, LTD., 00064-3900-30 and 60, Xenaderm Rx

The DESI Codes for the following NDCs have been changed to DESI Code 6 (less than effective-drug withdrawn from market):

DESI 10110 February 12, 1972 (37 FR 3202)

Qualitest Pharmaceuticals, Inc., 00603-1270-54, Granul Derm Aero

Mylan Bertex Pharmaceuticals, Inc., 62794-0002-50 and 51, Granulex Topical Spray

NEW LABELERS

	Mandatory Coverage	Optional Coverage
KVK-Tech, Inc., 10702	01/01/2007	10/10/2006
OTN Generics, Inc., 15210	01/01/2007	09/02/2006
Azur Pharma, Inc., 18860	01/01/2007	10/10/2006
Provident Pharmaceutical, Inc., 20091	04/01/2007	11/14/2006
Heritage Pharmaceuticals, Inc., 23155	04/01/2007	11/09/2006
Idenix Pharmaceuticals, 24108	04/01/2007	11/03/2006
Jazz Pharmaceuticals, Inc., 68727	07/01/2006	07/01/2006
Stat-Trade, Inc., 68850	01/01/2007	10/25/2006

Contact information for labelers is attached for your convenience.

TERMINATED LABELERS

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

Biocraft Laboratories, Inc., 00332
Propst Pharmaceuticals, Inc., 65581

The following labeler codes are being terminated effective 04/01/2007:

Knoll Pharmaceutical Company, 00044
GlaxoSmithKline, 00214
Pfizer, Inc., 00905
Magna Pharmaceuticals, Inc., 58407
GlaxoSmithKline, 58437
Shire US, Inc., 58521
GlaxoSmithKline, 74684

VOLUNTARILY TERMINATED LABELERS

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

Lotus Biochemical Corporation, 59417

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 remember to direct your drug rebate questions to MDROperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

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

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		
10-24-05	3.942	05-22-06	4.828		
10-31-05	3.983	05-30-06	4.843		
11-07-05	3.963	06-05-06	4.833		
11-14-05	4.004	06-12-06	4.926		
11-21-05	4.034	06-19-06	4.958		
11-28-05	3.994	06-26-06	5.036		
12-05-05	4.025	07-03-06	5.088		
12-12-05	3.911	07-10-06	5.056		
12-19-05	3.988	07-17-06	5.098		
12-26-05	3.999	07-24-06	5.108		
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 - STATE MEDICAID RELEASES 1 - 144

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
CMS R-144 (State Invoice) – Changes	143
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
Deficit Reduction Act of 2005 (DRA)	144
Deleted Products-No Termination Date	139
Depot Prices-TRRx	137
DESI Code Change	137, 140, 142, 144
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, 143
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

TOPIC	RELEASE #
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
HRSA – NPI	144
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

TOPIC	RELEASE #
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
New Drug Products	41
New Rebate Agreement Status	23
Non-Drug Products Coverage	132, 134
Non-Drug Products Deleted	133, 134, 136, 137, 138, 139, 140, 142, 143, 144
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

TOPIC	RELEASE #
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
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	132, 133, 134, 136, 137, 138, 139, 140, 142, 143
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