DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

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 DATE 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		08-21-04	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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