



December 15, 2006

MEDICAID DRUG REBATE PROGRAM**Release No. 76**

Bulletin

For Participating 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 While we are making every effort to publish the regulation as quickly as possible, the final regulation will not be published in time to be effective January 1, 2007.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.

OTHER ATTACHMENTS

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 questions to MDROperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

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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