

February 19, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #63

For Participating Drug Manufacturers

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NOTIFICATION BY CMS OF RECEIPT OF YOUR QUARTERLY DATA

The number of labelers asking for acknowledgment of receipt of their quarterly data has increased dramatically over the past few quarters. Because of this, we have (immediately) instituted the following requirement of labelers wishing this acknowledgment.

Diskette users requiring acknowledgment of our receipt of their diskette must include a stamped, self-addressed postcard with their submission. This postcard will be date stamped and returned **BUT** will only acknowledge the fact that the diskette has been received. Data errors causing records to reject will be included on an edit listing that will go to the **technical contact** after the diskette is uploaded and processed. If the diskette is unreadable, has the wrong data set name, is in the wrong format, is blank or, in any other way cannot be processed by us, a phone call to the **technical contact** will be made. The problem(s) with the diskette will be discussed and the **technical contact** will be reminded of the timeframe to get the (corrected) diskette back to us in order to have their pricing data included in that quarter's file to the states. Diskettes will **NOT** be returned under ANY circumstances.

Paper submitters requesting this acknowledgment must also include a stamped, self-addressed postcard. If your paper submittal is faxed to CMS, your acknowledgment can be performed by your own fax machine. We are not able to confirm fax submittals by phone.

Sterling submitters already receive an acknowledgment from Sterling and are not included in this process.

**AMENDMENTS TO BEST PRICE UNDER THE MEDICARE
PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT
OF 2003 ENACTED DECEMBER 8, 2003**

Discount Card Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA) establishes a Medicare Prescription Drug Discount Card and Transitional Assistance Program at section 1860D-31 of the Social Security Act (the Act). The discount card program must begin no later than June 8, 2004. Under the discount card program, drug card sponsors will negotiate discounted drug prices with drug manufacturers on behalf of Medicare beneficiaries using the card. Section 103(e)(1) of MPDIMA amends section 1927(c)(1)(C)(i) of the Act by adding an exemption to best price in a new subclause (V). Under subclause (V), prices negotiated with drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D-31 of the Act are exempt from best price. Negotiated prices take into account negotiated price concessions, such as discounts, direct or indirect subsidies, and direct or indirect remunerations, for covered part D drugs. Due to the temporary nature of the discount card program, which will be replaced by the new Medicare part D drug benefit in January 2006, this best price exemption will apply for a limited time.

Medicare Part D Drug Benefit

The MPDIMA also establishes a voluntary prescription drug benefit for Medicare beneficiaries as of January 1, 2006. Section 103(e)(1) of MPDIMA also amends section 1927(c)(1)(C)(i) of the Act by adding an exemption to best price in a new subclause (VI). Under subclause (VI), any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a Medicare Advantage plan that provides qualified prescription drug coverage, or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of title XVIII are exempt from best price. This exemption shall apply to prices charged for drugs dispensed on or after January 1, 2006.

**DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING –
APRIL 19 – 23, 2004, Registration Due by April 2, 2004**

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We are pleased to announce that the next National DRP meeting will be held April 19-23, 2004 in Baltimore, Maryland. While this meeting is open to all states and manufacturers, 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 so we are requesting that you register PROMPTLY by completing the registration form on our web page at <http://www.cms.hhs.gov/medicaid/drugs/drpmtdgs.asp> and submitting it electronically. Whenever possible, priority scheduling will be afforded those who respond first. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses.

You should begin planning now in order to obtain accommodations in Baltimore. We are requesting that, if possible, states plan on arriving in Baltimore in time to attend a "State-only" meeting with the DRP Team on Monday morning April 19th. Meeting details and hotel accommodations may be found on our web page at: <http://www.cms.hhs.gov/medicaid/drugs/drpd/default.asp>.

Feel free to contact any of the RO DRP Team members for any state specific DRP issues. Any non-state specific DRP questions or issues concerning the April meeting may be emailed to DRP@cms.hhs.gov.

RECORDKEEPING REGULATIONS ISSUED JANUARY 6, 2004

Interim Final Rule with Comment Period: Effective January 1, 2004-December 31, 2004.

Effective January 1, 2004 through December 31, 2004, CMS has established a 10-year recordkeeping requirement for drug manufacturers that participate in the drug rebate program through an interim final rule with comment period (CMS-2175-IFC). The provisions of the interim final rule replace the 3-year recordkeeping requirement that CMS issued in a final rule with comment period (CMS-2175-FC) on August 29, 2003. Now, manufacturers must retain data for ten years from the date the data is first reported to CMS. The data must be retained beyond the 10-year period if the records are the subject of an unresolved audit or government investigation related to the pricing data.

Public comments on the temporary 10-year recordkeeping requirement will be accepted until March 8, 2004. Instructions on how to submit public comments can be found in the **Federal Register** document (69 FR 508-514).

Notice of Proposed Rulemaking

CMS also proposed to make permanent the 10-year recordkeeping requirement for drug manufacturers that participate in the drug rebate program through a notice of proposed rulemaking (CMS-2188-P). The provisions of the proposed rule would permanently replace the 3-year recordkeeping requirement that CMS issued in a final rule with comment period (CMS-2175-FC) on August 29, 2003.

Public comments on the proposed 10-year recordkeeping requirement will be accepted until March 8, 2004. Instructions on how to submit public comments can be found in the **Federal Register** document (69 FR 565-568). We will respond to comments on the proposed rule in a subsequent document that we publish in the **Federal Register**.

EMAIL ADDRESS

In an effort to improve communication and increase the efficiency of our responses, the drug rebate staff will expand its use of email to all manufacturers. Currently, we respond by email only to those manufacturers who email us. We would like to be able to initiate email to any particular manufacturer's **TECHNICAL CONTACT** when the need arises. Please take a moment to submit your Technical Contact's email address and corresponding labeler code(s) to DRUGREBATEAGREEMENT@cms.hhs.gov. Do not use this email address for any other purpose. We appreciate your cooperation in this effort.

Attached for your information is a list of the email addresses for the operational drug rebate staff which will be included in the next update to the Operational Training Guide.

CONTACT INFORMATION - REMINDER

Please remember to use the forms in section "M" of the operations guide when a contact name, address, phone number or fax number changes. Manufacturer releases are mailed to the **TECHNICAL** contact listed for your company. Also, your contact information is included on the CMS quarterly tape to states who use that information to submit invoices to your **INVOICE** contact.

T-BILL RATES WEBSITE

The current and historic T-bill rates can be found at www.publicdebt.treas.gov. Under Treasury Bills, Notes, and Bonds, click on Current and Historical Auction . . . Information. Please remember to select the 13-week rates when prompted.

OTHER ATTACHMENT

A copy of the current listing of the 90-day Treasury bill auction rates beginning with the period November 18, 2002, 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

2 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

DRUG REBATE OPERATIONAL STAFF

EMAIL ADDRESSES

Tamara Bruce	Tbruce@cms.hhs.gov
Chris Holmes	Cholmes@cms.hhs.gov
Karen Leshko	Kleshko@cms.hhs.gov
Vince Powell	Vpowell@cms.hhs.gov
Sue Williams	Swilliams1@cms.hhs.gov

NOTE: To expedite our response, please email any inquiry to the staff person responsible for your area of concern. A list of our staff's primary functions is located in section O of the Operational Training Guide.

Please remember that the MDRtech@cms.hhs.gov email box **MUST** be used for the following:

- - Requesting an additional rebate tape
- - Technical questions regarding rebate tapes
- - Utilization Tape submission errors/questions
- - Requesting a diskette program (new or replacement)
- - MDR diskette program assistance/questions
- - Errors encountered with the diskette program

WEEKLY U.S. T-BILL DISCOUNT RATE
 weekly 90-day treasury bill auction rates

Date of Auction	Discount Rate	Date of Auction	Discount Rate	Date of Auction	Discount Rate
11-18-02	1.227	06-16-03	0.854	01-12-04	0.887
11-25-02	1.228	06-23-03	0.830	01-20-04	0.891
12-02-02	1.231	06-30-03	0.903	01-26-04	0.907
12-09-02	1.215	07-07-03	0.907	02-02-04	0.939
12-16-02	1.219	07-14-03	0.895	02-09-04	0.939
12-23-02	1.207	07-21-03	0.911		
12-30-02	1.207	07-28-03	0.964		
01-06-03	1.207	08-04-03	0.964		
01-13-03	1.199	08-11-03	0.960		
01-21-03	1.179	08-18-03	0.964		
01-27-03	1.159	08-25-03	0.997		
02-03-03	1.175	09-02-03	0.988		
02-10-03	1.171	09-08-03	0.951		
02-18-03	1.179	09-15-03	0.947		
02-24-03	1.195	09-22-03	0.953		
03-03-03	1.198	09-29-03	0.953		
03-10-03	1.077	10-06-03	0.939		
03-17-03	1.137	10-14-03	0.923		
03-24-03	1.174	10-20-03	0.939		
03-31-03	1.121	10-27-03	0.960		
04-07-03	1.158	11-03-03	0.960		
04-14-03	1.186	11-10-03	0.951		
04-21-03	1.182	11-17-03	0.951		
04-28-03	1.141	11-24-03	0.946		
05-05-03	1.117	12-01-03	0.943		
05-12-03	1.089	12-08-03	0.915		
05-20-03	1.040	12-15-03	0.903		
05-28-03	1.121	12-22-03	0.884		
06-02-03	1.133	12-29-03	0.901		
06-09-03	1.024	01-05-04	0.939		