February 19, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #129

For State Medicaid Directors

<u>DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING –</u> <u>APRIL 19 – 23, 2004, Registration Due by April 2, 2004</u>

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 <u>http://www.cms.hhs.gov/medicaid/drugs/drpmtgs.asp</u> 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/drp/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 <u>DRP@cms.hhs.gov</u>.

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**.

T-BILL RATES WEBSITE

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

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage <u>Date</u>
Morepen Max, Inc. (Labeler Code 67836)	07/01/2004	02/03/2004
Primus Pharmaceuticals, Inc. 02/02/2004 (Labeler code 68040)	07/01/2004	
Praecis Pharmaceuticals Incorporated (Labeler code 68158)	07/01/2004	02/04/2004
Alamo Pharmaceuticals, LLC (Labeler Code 68322)	07/01/2004	02/11/2004
Corban Pharmaceuticals, LLC (Labeler code 68549)	04/01/2004	01/07/2004

Contact information for new labelers is attached for your convenience.

TERMINATED LABELER

The following labeler code is being voluntarily terminated effective July 1, 2004:

Muro Pharmaceutical, Inc. (Labeler Code 00451).

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 <u>Medicaid Drug Rebate Operational Training Guide</u>.

/s/ Edward C. Gendron Director Finance, Systems and Budget Group

2 Attachments

cc: All State Drug Rebate Technical Contacts All Regional Administrators

WEEKLY U.S. T-BILL DISCOUNT RATE

weekly 90-day treasury bill auction rates

Date of	Discount	Date of	Discount	1 [Date of	Discount
Auction	Rate	Auction	Rate		Auction	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			

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