For Participating Drug Manufacturers

CMS-2175-F: REGULATION ISSUED NOVEMBER 26, 2004

On November 26, 2004, CMS issued the regulation entitled, Medicaid Program; Time Limitation on Recordkeeping Drug Rebate Program. This final rule makes permanent the temporary 10-year timeframe for pharmaceutical manufacturers to retain pricing records under the Medicaid drug rebate program. The final rule also finalizes the requirement that pharmaceutical manufacturers must retain records beyond the 10-year timeframe if the records are known by the pharmaceutical manufacturer to be the subject of an audit or a government investigation and if the audit findings or investigation related to the pricing records have not been resolved. The new regulation became effective January 1, 2005. The temporary recordkeeping requirement put in place January 2004 expired December 31, 2004.

<u>DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING - APRIL 11-15, 2005.</u> Registration Due by March 28, 2005

We are pleased to announce that the next National DRP Meeting will be held April 11-15, 2005 in Baltimore, Maryland at the Tremont Suite Hotel, 222 St. Paul Place. This meeting is a continuation of the highly successful DRP meetings held in Baltimore in recent years.

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; therefore, we are requesting that you register PROMPTLY by completing the registration form on our web page at http://www.cms.hhs.gov/medicaid/drugs/drpmtgs.asp and submitting it electronically. Whenever possible, priority scheduling will be afforded those who register earliest. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses.

If possible, states should plan on arriving in Baltimore in time to attend a "state-only" meeting with the DRP Team the morning of Monday, April 11th. Meeting details and hotel registration information is provided on our web page.

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.

UPDATES TO THE OPERATIONAL TRAINING GUIDE

Page O2 of the Operational Training Guide has been revised to add the e-mail addresses for the Operations/DRP staff and to delete some members from the Policy staff. Pages O5 through O7 are now deleted and replaced with a new page O5. Please replace the attached page O2 and O5 in your guide.

<u>UPDATED VERSION OF DISKETTE PROGRAM AND STERLING DATA</u> <u>REPORTING</u>

CMS is developing an updated version of the diskette reporting program. The new version will be available on CD, however, diskette will still be supported. The update is mainly to provide a more current edition of the Windows application. Additionally, and just as important, the update will allow for more user-friendly data entry, reports, and downloading data for CMS. Enhancements include, but are not limited to, alerting data entry user to program changes/requirements such as the 3-year rule for pricing changes, OBRA '93 rules for Baseline AMP, and AMP/BP for multiple package size reporting.

At the same time, we are also updating the Sterling data reporting to change the file structure of the record layout. The revised record layout will require the transmission of only two (2) records instead of the current three (3).

Although we have no deadline for finalizing either of these updates, a sufficient amount of lead time will be given to all affected labelers. Any input you wish to offer is greatly appreciated. You may contact any of the operations staff listed on page O2 of the Operational Training Guide.

A copy of the current listing of the 91-day Treasury bill auction rates beginning with the period June 16, 2003, 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

3 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	Invest.	
Auction	Rate	
06-16-03	0.854	
06-23-03	0.830	
06-30-03	0.903	
07-07-03	0.907	
07-14-03	0.895	
07-21-03	0.911	
07-28-03	0.964	
08-04-03	0.964	
08-11-03	0.960	
08-18-03	0.964	
08-25-03	0.997	
09-02-03	0.988	
09-08-03	0.951	
09-15-03	0.947	
09-22-03	0.953	
09-29-03	0.953	
10-06-03	0.939	
10-14-03	0.923	
10-20-03	0.939	
10-27-03	0.960	
11-03-03	0.960	
11-10-03	0.951	
11-17-03	0.951	
11-24-03	0.946	
12-01-03	0.943	
12-08-03	0.915	
12-15-03	0.903	
12-22-03	0.884	
12-29-03	0.901	
01-05-04	0.939	

Date of	Invest.	Date of	Invest.
Auction	Rate	Auction	Rate
01-12-04	0.887	08-09-04	1.497
01-20-04	0.891	08-16-04	1.498
01-26-04	0.907	08-23-04	1.541
02-02-04	0.939	08-30-04	1.607
02-09-04	0.939	09-06-04	1.663
02-17-04	0.931	09-13-04	1.671
02-23-04	0.947	09-20-04	1.716
03-01-04	0.957	09-27-04	1.741
03-08-04	0.945	10-04-04	1.716
03-15-04	0.961	10-12-04	1.711
03-22-04	0.945	10-18-04	1.803
03-29-04	0.961	10-25-04	1.890
04-05-04	0.945	11-01-04	1.987
04-12-04	0.929	11-08-04	2.084
04-19-04	0.949	11-15-04	2.115
04-26-04	0.985	11-22-04	2.197
05-03-04	1.001	11-29-04	2.380
05-10-04	1.078	12-06-04	2.253
05-17-04	1.058	12-13-04	2.243
05-24-04	1.066	12-20-04	2.223
05-31-04	1.150	12-27-04	2.269
06-07-04	1.251	01-03-05	2.320
06-14-04	1.413	01-10-05	2.376
06-21-04	1.336	01-18-05	2.407
06-28-04	1.381	01-24-05	2.366
07-05-04	1.344	01-31-05	2.525
07-12-04	1.336	02-07-05	2.530
07-19-04	1.352	02-14-05	2.592
07-26-04	1.449		
08-02-04	1.490		_