## For

# Participating Drug Manufacturers

#### DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETINGS

We are pleased to announce that the next National DRP meetings will be held during the week of June 24-27, 2002, in Denver. These meetings will be our first DRP meetings since September 2001, and are a continuation of the highly successful meetings held in Denver since 1998. Nearly \$1 billion in formerly disputed rebates have been resolved through the DRP and these meetings have been cited by many states and manufacturers as essential to the resolution of outstanding rebate disputes.

While these meetings are open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. Since it is unclear at this time because of budget and resource limitations as to whether we will be conducting other DRP meetings beyond these, it is profoundly important that you take advantage of the opportunity to attend these meetings in June. Further, we are requesting that, if possible, states plan on arriving in Denver in time to attend a "States-only" meeting with the DRP Team on Monday morning, June 24<sup>th</sup>. We will provide details on that meeting later.

As in the past, prior planning is absolutely imperative to the success of these meetings so we are requesting that you PROMPTLY complete the attached registration form

and return it as instructed to Diane Dunstan, the National DRP Regional Office (RO) Coordinator. 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. Equally important, you should begin planning now in order to obtain satisfactory accommodations in Denver.

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Please feel free to contact any of the RO DRP Team members for any dispute-related issue and they will coordinate with Diane, the RO lead in Denver. Of course, you may contact Tami Bruce, the DRP Central Office (CO) Coordinator or Mike Keogh, the DRP Team Leader, on any rebate dispute matter. Tami may be reached at (410) 786-1519 or <a href="mailto:tbruce@cms.hhs.gov">tbruce@cms.hhs.gov</a> and Mike at (410) 786-5910 or <a href="mailto:mkeogh1@cms.hhs.gov">mkeogh1@cms.hhs.gov</a>.

If you have any specific questions regarding the National DRP meeting in Denver, please contact Diane Dunstan at (303) 844-7040 or ddunstan@cms.hhs.gov.

#### PRICING/PRODUCT DISKETTES

For all labelers wishing to submit quarterly data to CMS via diskette, we have a PC system on diskette that we supply at no cost. This is a user-friendly, menu-driven system that comes with operating documentation, record layouts, etc. We have been asked, on occasion, if our diskette program is the only one that can be used or if a labeler, or its contractor, can create its own.

The answer is, and always has been, yes, you can develop and use your own system, as long as the files and records your system produces matches those produced by our system. One thing we cannot do is allow several different record layouts or naming conventions.

To this end, we have been receiving a few diskettes that are generated by a private PC program and either do not match our file name or are not in the required record layout. As we receive these, they are sent back immediately, reminding the labeler of its obligation to match our data completely or to stop using that system and immediately begin using our system in order to have the quarterly data accepted.

All diskette submitters using PC programs other than the CMS supplied system, please review your file structure and record layout to assure that you are meeting the CMS requirements for your quarterly submissions.

#### **QUARTER 3/2001 DATA LATE DUE TO ANTHRAX PROBLEMS**

Due to the problems with federal mail being tainted with anthrax, CMS as well as all other government agencies had incoming mail stopped for a period of time. For weeks after deliveries resumed, we continued to experience delays. Unfortunately, this hit at the end of October when much labeler quarterly data was sent to CMS for processing. Because we provide states with Unit Rebate Amount (URA) data within 45 days after the end of a quarter, we were forced to shut down for the 3/2001 quarter with only about 72% of the pricing data received. This caused a large number of NDCs to be sent to states with zeros in the URA field for that quarter.

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I am taking this opportunity to suggest to labelers that mail their quarterly data to us (paper or diskette) to consider using one of the overnight mail services that deliver directly to the analyst's desk. This would help avoid delays like the one recently experienced should an emergency ever occur again. Please refer to the Operational Training Guide for the overnight mailing address. I am also taking this opportunity to remind each of you that, per your signed rebate agreement, quarterly data is **DUE** to us **WITHIN 30** days after a quarter ends, **NOT** postmarked 30 days after a quarter ends. The earlier you can get your data to us the better for all concerned.

# SEPARATE OR SUPPLEMENTAL MEDICAID DRUG REBATE AGREEMENTS

This is to reiterate that the approval process for separate or supplemental Medicaid drug rebate agreements as specified in Release #48 for Drug Manufacturers and Release #102 for State Medicaid Directors requires the State to submit the proposed agreement to the appropriate CMS Regional Office.

Please note that the CMS contact has changed. If you have any questions regarding separate or supplemental Medicaid drug rebate agreements please contact Kim Howell at <a href="mailto:khowell@cms.hhs.gov">khowell@cms.hhs.gov</a> or (410) 786-6762.

# REBATES FOR DRUGS PURCHASED THROUGH THE FEDERAL SUPPLY SCHEDULE

It has come to our attention that certain Indian Health Service (IHS) facilities that are purchasing drugs from the Federal Supply Schedule (FSS) may be dispensing these drugs to their Medicaid patients and billing the State Medicaid agencies for these drugs. Staff with the Department of Veterans Affairs (DVA) have informed us that under the requirements of the FSS program, these drugs should not be billed to a third party payor, such as Medicaid. IHS facilities should maintain a separate inventory of drugs purchased at open market prices dispensed to Medicaid patients which can then be billed to Medicaid for Medicaid eligible patients.

Accordingly, all participating manufacturers are required to pay rebates on drugs billed by IHS facilities to State Medicaid agencies, provided that those facilities do not participate in the 340B drug pricing program for Medicaid. We do not view this as a revision to our earlier policy that rebates are not due on drugs purchased through the FSS. Our earlier position continues to be based on the understanding that IHS facilities are prohibited from billing their FSS-obtained drugs to the Medicaid program. If you suspect that your FSS drugs are being diverted to Medicaid patients, we recommend that you pursue the issue with the IHS facilities directly and with the DVA, if necessary.

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### NEW--DRUG REBATE POLICY E-MAIL ADDRESS

Drug rebate policy questions may now be sent to the following email address: DrugRebatePolicy@cms.hhs.gov

Your questions will be reviewed and forwarded to appropriate staff for a response. Please note that this is an email address for policy issues only and that inquiries on other areas of the Medicaid drug rebate program should continue to be communicated as before.

Please use this email address for informal inquiries only. Formal inquiries where you wish a formal response should continue to be addressed to the appropriate CMS official in the normal manner.

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## **ATTACHMENTS**

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period July 31, 2000, 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.

David McNally, Deputy Director

Finance, Systems and Quality Group

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

## **ATTENTION: DIANE DUNSTAN**

FAX: 303.844.3753

National Drug Rebate Program

Denver, Colorado

June 24 - 28, 2002

I/WE WILL	BE ATTENDING	THE DRP N	MEETINGS	IN JUNE:
NIAME:				

STATE/LABELER:	
PHONE:	FAX:
E-MAIL:	
NAME:	
STATE/LABELER:	
PHONE:	FAX:
E-MAIL:	
NAME:	
STATE/LABELER:	
PHONE:	FAX:
E-MAIL:	

## PLEASE PRINT REQUESTED INFORMATION

## WEEKLY U.S. T-BILL DISCOUNT RATE

weekly 90-day treasury bill auction rates

Date of	Discount	Date of	Discount	Date of	Discount	

Auction	Rate	Auction	Rate	Auction	Rate
07-31- 00	6.269	02-26- 01	4.835	09-24- 01	2.429
08-07- 00	6.278	03-05- 01	4.822	10-01- 01	2.364
08-14- 00	6.269	03-12- 01	4.638	10-09- 01	2.222
08-21- 00	6.291	03-19- 01	4.482	10-15- 01	2.243
08-28- 00	6.323	03-26- 01	4.305	10-22- 01	2.214
09-05- 00	6.245	04-02- 01	4.228	10-29- 01	2.089
09-11- 00	6.121	04-09- 01	3.912	11-05- 01	2.012
09-18- 00	6.137	04-16- 01	4.150	11-13- 01	1.850
09-25- 00	6.183	04-23- 01	3.741	11-19- 01	1.936
10-02- 00	6.257	04-30- 01	3.978	11-26- 01	1.955
10-10- 00	6.257	05-07- 01	3.745	12-03- 01	1.769
10-16- 00	6.261	05-14- 01	3.716	12-10- 01	1.704
10-23- 00	6.344	05-21- 01	3.622	12-17- 01	1.760
10-30- 00	6.365	05-29- 01	3.688	12-26- 01	1.752
11-06- 00	6.406	06-04- 01	3.671	12-31- 01	1.740
11-13- 00	6.369	06-11- 01	3.590	01-07- 02	1.684

11-20- 00	6.360	06-18- 01	3.512	01-14- 02	1.558
11-27- 00	6.344	06-25- 01	3.451	01-22- 02	1.700
12-04- 00	6.137	07-02- 01	3.663	01-28- 02	1.748
12-11- 00	6.071	07-09- 01	3.643	02-04- 02	1.769
12-18- 00	5.939	07-16- 01	3.630	02-11- 02	1.748
12-26- 00	5.864	07-23- 01	3.561	02-19- 02	1.760
01-02- 01	5.864	07-30- 01	3.561	02-25- 02	1.769
01-08- 01	5.188	08-06- 01	3.508		
01-16- 01	5.361	08-13- 01	3.426		
01-22- 01	5.229	08-20- 01	3.405		
01-29- 01	5.114	08-27- 01	3.426		
02-05- 01	5.053	09-04- 01	3.434		
02-12- 01	5.032	09-10- 01	3.251		
02-20- 01	5.036	09-17- 01	2.612		

#### **TOPICAL INDEX - DRUG LABELER RELEASES 1 - 53**

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