

May 7, 2002

MEDICAID DRUG REBATE PROGRAM

RELEASE #54

For Participating Drug Manufacturers

REBATE/REIMBURSEMENT POLICY

Recently, a state Medicaid agency requested clarification of a rebate policy. In one scenario the agency indicated that there was no state Medicaid reimbursement to a pharmacy provider as a result of a primary payer payment and the beneficiaries' copayment requirement. However, the state Medicaid agency did pay its pharmacy processor for the associated claims processing fees in the Point-of-Sale System and performed drug utilization review on the claim. A manufacturer disputed the rebate for the drug arguing that since the state Medicaid agency did not reimburse the provider for the drug there was no rebate associated with the drug.

In this case, the manufacturer was correct to withhold payment of rebates for the drugs. As discussed in previous releases, if a state Medicaid agency paid **any** portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug. Although the state Medicaid agency may pay their respective claims processors for their services, these payments are not to be included in the provider reimbursement for costs of the drug. Therefore, in all instances in which the state Medicaid agency makes **no** payment **for the drug product itself**, no rebate is due.

If you have questions regarding this issue, please contact Kim Howell on 410-786-6762 or at KHowell@cms.hhs.gov.

IMPROPER REBATE WITHHOLDING & INTEREST IMPLICATIONS FOR MANUFACTURERS

It has come to our attention that several manufacturers are withholding current rebates from states' current invoices to recover amounts previously paid by the manufacturer but now determined by the manufacturer to not be due the states. In short, some manufacturers are automatically withholding amounts without initiating or reaching dispute resolution with the state. States have reported that some manufacturers have taken credit (that is, reduced or withheld current rebate payments) without first notifying the state and properly disputing past rebates.

CMS has consistently maintained that current rebates may not be reduced for “prior quarters” disputes until dispute resolution has occurred. Dispute resolution means that agreement between the state and manufacturer on disputed rebates has been reached. Absent this agreement, a determination by a manufacturer that amounts paid were not due and a subsequent withholding from current rebate payments without dispute resolution being achieved with the state may be considered violations of the rebate agreement.

The rebate agreement requires that current rebates owed and not properly disputed must be paid timely. It is also a requirement of the rebate agreement that manufacturers formally notify and work with states on disputes found in previously paid quarters. Manufacturers that withhold or reduce rebate payments from current quarters based on disputes they find in previously paid quarters **without first reaching dispute resolution with states** will owe interest on the amount improperly withheld. Further, as stated earlier, we consider this practice a violation of the rebate agreement and manufacturers that do not cease this practice will be at risk of termination from the rebate program.

If you have any questions on this or any other dispute resolution issue, please continue to contact any of the regional office (RO) Dispute Resolution Program (DRP) Team staff, Diane Dunstan, Lead DRP RO Coordinator at ddunstan@cms.hhs.gov, Tami Bruce, DRP CO Coordinator at tbruce@cms.hhs.gov or Mike Keogh, DRP Team Leader at mkeogh1@cms.hhs.gov.

FDA/MDRI PRODUCT MATCH

Last year, in state release #107, dated June 27, 2001 and labeler releases #51 and #52, dated June 27, 2001 and September 19, 2001, respectively, I told you about a new operations initiative where we would be matching the MDRI master file to the FDA drug file and removing those products and /or package sizes that were not reported to the FDA as required under the FDA Drug Listing act of 1972. We did an initial match in October, sent the results to each affected labeler, and gave them a 2 quarter lead time to report them to the FDA so they would stay on the MDRI master file as covered drugs.

This month after we “shut down” for the q1/2002 Unit Rebate Amount (URA) processing, we will again perform the FDA/MDRI match. A file of non-matches (i.e., NDCs on the MDRI but not on the FDA file) will be supplied to each state, with a cover letter explaining that these NDCs are being deleted from the MDRI master file and will not be carried or covered by the drug rebate program beginning July 1, 2002. It will be each state’s responsibility to assure non-coverage of these NDCs. A listing of the deleted NDCs for each labeler code will be generated and sent to the affected labelers.

There have been several calls to the operations staff from labelers during the past month expressing their concern that their drug reports to the FDA may not have made it on the FDA listed/pending file before the March 31 cutoff. In order to assist in this area, we will be matching the (above mentioned) deleted NDCs to the FDA file after the **q2/2002** URA run, in mid-August. Those NDCs that missed the March 31 date, but are on the June 30 FDA file will be restored (including pricing history) to the MDRI master file. A report of these will be sent to each state and they will be instructed that these NDCs are to be restored and covered as of q4/2002, thus having their coverage terminated for only one quarter. Listings to affected labelers will also be provided.

Please contact a member of the drug rebate operations staff listed in section “O” of the operations guide with questions regarding this procedure. **Any questions regarding products/NDCs on the deleted list that you think should be on the FDA file, are to be reported to THE FDA !! Please DO NOT contact CMSO operations staff about this issue. It can ONLY be resolved between you and the FDA.**

ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period February 26, 2001, 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

2 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

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
02-26-01	4.835	09-24-01	2.429	04-22-02	1.720
03-05-01	4.822	10-01-01	2.364	04-29-02	1.760
03-12-01	4.638	10-09-01	2.222	05-06-02	1.773
03-19-01	4.482	10-15-01	2.243		
03-26-01	4.305	10-22-01	2.214		
04-02-01	4.228	10-29-01	2.089		
04-09-01	3.912	11-05-01	2.012		
04-16-01	4.150	11-13-01	1.850		
04-23-01	3.741	11-19-01	1.936		
04-30-01	3.978	11-26-01	1.955		
05-07-01	3.745	12-03-01	1.769		
05-14-01	3.716	12-10-01	1.704		
05-21-01	3.622	12-17-01	1.760		
05-29-01	3.688	12-26-01	1.752		
06-04-01	3.671	12-31-01	1.740		
06-11-01	3.590	01-07-02	1.684		
06-18-01	3.512	01-14-02	1.558		
06-25-01	3.451	01-22-02	1.700		
07-02-01	3.663	01-28-02	1.748		
07-09-01	3.643	02-04-02	1.769		
07-16-01	3.630	02-11-02	1.748		
07-23-01	3.561	02-19-02	1.760		
07-30-01	3.561	02-25-02	1.769		
08-06-01	3.508	03-04-02	1.793		
08-13-01	3.426	03-11-02	1.858		
08-20-01	3.405	03-18-02	1.874		
08-27-01	3.426	03-25-02	1.854		
09-04-01	3.434	04-01-02	1.821		
09-10-01	3.251	04-08-02	1.740		
09-17-01	2.612	04-15-02	1.712		

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