

October 29, 1996

MEDICAID DRUG REBATE PROGRAM Release No. 24

\* \* \* IMMEDIATE ATTENTION REQUIRED \* \* \*

NOTE TO: All Participating Drug Manufacturers

FAILURE OF MANUFACTURERS TO NOTIFY STATES OF DISPUTES OR PAY  
REBATES

Several States have advised us of situations when a manufacturer fails to pay the rebates invoiced or fails to notify the States of disputes in accordance with the rebate agreement. Reports from the States indicate that the manufacturers involved are non-responsive to the States' requests for payment of the rebates. Further, it has come to our attention that this practice occurs frequently with the same manufacturers.

Effective immediately, HCFA is requesting States to identify those drug labelers that are at least two quarters in arrears in paying rebates and have not initiated the dispute resolution process by notifying States, by NDC, which rebate amounts are being disputed. We expect that we will notify those drug labelers identified in this category that they are in violation of the rebate agreement, and that they will be given a final opportunity to comply with the rebate agreement before termination actions are initiated. Those manufacturers will also be notified that their continued non-compliance with the rebate agreement in this regard will be considered good cause for termination, and they will be notified that this situation will not be allowed to continue. We anticipate that terminations from the drug rebate program for these violations will be for a period of at least one calendar quarter, and the terminated manufacturers will not be eligible for reinstatement until all rebate quarters are resolved.

Questions in this area should be directed to Al Beachley at (410) 786-3276.

## MORE ON DISPUTE RESOLUTION EFFORTS

Recently, a situation arose in our Dispute Resolution meetings in Denver which requires comment. As many of you are aware from your participation in similar meetings in Boston or Denver, we have additional expectations beyond the obvious goal of resolving disputes. It is also our intention to identify the necessary steps needed in order to ultimately settle the disputes, agree to time frames for those actions to occur and, in general, establish clear communication between manufacturers and States. With regional office and central office support, we believe it is reasonable to expect the States and manufacturers involved to comply with agreements reached during the meetings.

Our specific concern involves a manufacturer and State which, through the meetings, reached agreement on the types of additional data the manufacturer required from the State to support the State's utilization data. The State fully complied with the manufacturer's request. However, after reviewing the additional data, the manufacturer continued to withhold payment of the rebates, and finally admitted to the State that the reason for non-payment was the level of Medicaid reimbursement, rather than overstated utilization. In fact, the additional data provided to the manufacturer in our opinion supported the utilization data.

We will address this particular situation separately with the manufacturer involved. However, we remind all manufacturers that the level of Medicaid reimbursement is not a factor either in the calculation or the payment of rebates. We recognize that it is a common practice by many manufacturers to consider the amount of Medicaid reimbursement as one of the factors in identifying potential disputes. Nonetheless, the statute and rebate agreement are clear as to the method of computing rebates, neither of which contemplate the level of Medicaid reimbursement. Moreover, failure to comply with the terms of the rebate agreement for calculating rebates may be considered basis for good cause termination from the Medicaid drug program.

Conversely, we believe it is equally appropriate that if the exchange of data between a State and manufacturer provides basis for the State to adjust its utilization data and reduce the rebate amounts, then the State must take the necessary action to reflect the adjustment.

Our ongoing efforts in conducting Dispute Resolution meetings have clearly demonstrated that it is only through mutual good faith efforts that disputes are resolved. As part of HCFA's role in dispute resolution, we will continue to intervene when necessary to ensure that manufacturers and States fulfill

agreements reached through these meetings. Please do not

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hesitate to contact the appropriate regional office coordinator if either a State or manufacturer encounters situations which impede the resolution of disputes. If you require further assistance, please contact Mike Keogh at (410) 786-5910 or Vince Powell at (410) 786-3314.

#### RECALCULATING UNIT REBATE AMOUNTS (URA)

We are continually requested by States to remind labelers that it is the responsibility of the labelers to recalculate incorrect URAs AND submit the corrected amount with the next rebate payment. HCFA may include a zero URA on a quarterly tape to the States for several reasons; e.g., the quarterly pricing for that NDC was not submitted, or it was submitted and rejected, or it was submitted after the system was shut down for the quarter and missed being included on the quarterly tape. The quarterly pricing submission may also have caused the URA to calculate as +/- 50% different from the previous quarter, resulting in a zero URA on the tape. Regardless of the cause, it is the responsibility of the labeler to calculate and use the correct URA, and reflect that URA on the next payment to affected States. Prior Period Adjustments (PPAs) from HCFA are sent to States; however, these are NOT to be used by States to make adjustments in their next invoices. These are for the States to use to verify that a URA change from the labeler is the same as a URA change sent from HCFA. URA corrections are THE RESPONSIBILITY OF THE LABELER.

When you are correcting a prior quarter's AMP/BP, Baseline AMP, and/or Market Date, or when you are paying an invoice that contains a zero URA, the calculation of the corrected URA and new amount due to States is your responsibility. The new calculation should be done and reflected on the invoice immediately following the change/correction.

Questions or comments should be directed to Vince Powell on (410) 786-3314.

#### OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of September 5, 1995 through October 21, 1996 are attached. We have also attached a listing of monthly CPI-U values, current to September, 1996.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18.

Judith D. Moore  
Acting Director  
Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid