November 28, 1997

MEDICAID DRUG REBATE PROGRAM Release No. 31

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

NOTE TO: All Participating Drug Manufacturers

ZERO UNIT REBATE AMOUNT (URA) AMOUNT ON INVOICE

We are constantly hearing from states about labelers that pay rebates but ignore any National Drug Codes (NDCs) on the invoice that have zeros in both the URA and amount due to state fields. When an invoice is submitted to you with zeros showing in one or more URA field(s), it is an indication that one of the following conditions occurred:

a. You did not supply pricing data to HCFA in time for the quarterly URA calculation and inclusion on the state file;

b. Your pricing data were supplied to HCFA but they rejected and you did not get corrected pricing data to HCFA before the deadline;

c. Your pricing data were accepted by HCFA but they caused an exception on the 50/50 report since this quarter's URA for that NDC differed by at least 50% from the URA for the last quarter. You receive a copy of the 50/50 report each quarter, if this condition occurs.

If an invoice is sent to you with one or more NDCs showing zeros in the URA field, it does NOT mean that you owe nothing. It means that it is YOUR RESPONSIBILITY to calculate the correct URA and include the proper rebate to the state with that quarter's rebate payment.

Failure to properly pay when this situation occurs could cause you to owe interest when you do finally pay, or, if you persist in not paying, could result in termination from the program.

MDRI DISKETTE USERS

Each quarter, we receive diskettes that have no data files on them. We contact these companies and ask for a new diskette and their assurance that the data files have been properly generated BEFORE sending them to us. This causes many hours of lost time by both of us. After you generate the quarterly product/pricing files, please assure that the files are ACTUALLY on the diskettes BEFORE sending them to us. The easiest way to do this is to do a DIRECTORY (DIR A:) of the diskette AFTER the data are downloaded to verify their existence on the diskette. The two files on the diskette should be the PRODFILE.TXT and PRICFILE.TXT. Questions regarding this should be directed to Judy Allison on (410) 786-3330 or Vince Powell on (410) 786-3314.

DRUG PRODUCT TERMINATION DATES

There continue to be several problems associated with the termination date field that need to be addressed by all drug labelers.

The first issue concerns the failure to provide HCFA with the date whenever a particular drug product is being phased out and the effective “shelf life” of the last batch is known. Without the termination date being present for any NDC, the HCFA automated system will continue to generate notices requesting quarterly pricing if average manufacturer prices and best prices are not submitted to HCFA.

The second problem deals with the submission of erroneous termination dates. On page F7 of the HCFA Medicaid Drug Rebate Operational Training Guide, the termination date is defined as either the date the drug was removed for safety/health reasons or the shelf life date of the last batch sold. However, our conversations with drug company personnel indicate that we are often given the last sales date or the date the last batch was made instead of the defined termination date. We urge you to review the drug product termination dates for your company and submit corrections to HCFA as necessary.

ZERO OR NEGATIVE AVERAGE MANUFACTURER PRICES (AMPs)

We have been noticing problems with and receiving calls about quarterly AMP pricing when the calculation for the AMP causes it to result in a value of zero or a negative amount. Fluctuations to AMP are expected on occasion. Zero and negative AMP amounts, however, are not valid. Should you have any questions regarding this issue, please call Vince Powell at (410) 786-3314.

MISCELLANEOUS ITEMS REGARDING DISPUTE RESOLUTION ISSUES

At the request of numerous pharmaceutical and state representatives participating in our Dispute Resolution Project (DRP) and various drug rebate conferences, we are taking this opportunity to provide guidance on a few recurring items and issues related to drug rebate disputes. This guidance is not intended as all inclusive nor does it attempt to address all situations. Rather, our intention is to publish a "Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program" later in 1998 in which we will include more comprehensive information for all states, pharmaceutical manufacturers and regional offices. At this time, however, we believe it is appropriate to provide some samples of situations encountered through the DRP. We are including this information in both the current state and manufacturer releases.

o Interest

Interest accrues on any and all rebate amounts not paid timely. Interest is not applicable to rebate payments due to recalculated URAs (prior period adjustments) or rebate payments made timely on utilization changes unrelated to disputes.

Example 1: Manufacturer A is invoiced for 1,000 units by State B. Manufacturer A pays rebates timely for 600 units, withholds payment on 400 units pending dispute resolution. Subsequently, (after the 38-calendar day time frame to pay rebates timely) Manufacturer A agrees that 300 units of the unpaid 400 units should be paid, State B agrees to reduce the utilization by the remaining 100 units.

Manufacturer A asserts that interest is not due on the 300 units because it's a utilization change.

Answer: INCORRECT! Since the Manufacturer A did not timely pay rebates on the 300 units originally invoiced and subsequently agreed to do so, interest is due on those 300 units.

Example 2: Same scenario as Example 1, except that Manufacturer A paid rebates timely on the full 1,000 units then subsequently disputed 400 units. As a result of dispute resolution, State B agrees to reduce the utilization by 100 units.

Manufacturer A asserts that it is due credit for 100 units, plus interest on the 100 units reduced but paid timely.

Answer: CORRECT! Since Manufacturer A paid rebates timely on 1,000 units but subsequent dispute resolution agreement resulted in a reduction of 100 units, credit for 100 units plus interest is due to Manufacturer A. However, there is no interest due if the state agrees to credit the manufacturer for the 100 units within 38 calendar days of notification of the dispute.

Example 3: State C invoices Manufacturer D for 1,500 units and Manufacturer D timely pays rebates in full. Subsequently, State C discovers an additional 500 units that should have been included with that quarter's invoice.

State C asserts interest is due on the additional 500 units retroactive to the rebate due date of the first invoice.

Answer: INCORRECT! The additional 500 units are an initial utilization adjustment and interest is not due in this situation unless Manufacturer D subsequently fails to pay the additional rebates on the 500 units timely, then this situation is treated the same as an initial rebate dispute.

Example 4: Manufacturer E submits a unit rebate adjustment which results ultimately in a reduction of rebates already paid. Manufacturer E reduces current rebate payments by taking a credit for the previously overpaid amount plus interest.

Answer: This situation should be handled as follows: Manufacturer E should first notify HCFA of the unit rebate amount change. After HCFA approval, Manufacturer E should make the necessary adjustments on the current quarters invoice and provide documentation of the adjustment/credit to the state. However, interest is never due on unit rebate adjustments.

Example 5: Manufacturer F timely paid rebates in full in the amount of $86,000 for State G for 1Q94. During dispute resolution meetings in 1996, it is initially discovered that due to an accounting and disbursement problem within Manufacturer F, a duplicate check for $86,000 was simultaneously issued with the original check to State G.

Manufacturer F asserts that a credit of $86,000 plus interest accruing from 1Q94 is due.

Answer: Clearly, a credit of $86,000 is due. But, based on these facts, we do not believe that interest is due.

Example 6: State H invoices Manufacturer I for 700 units; Manufacturer I pays nothing and disputes the entire 700 units. As a result of dispute resolution, State H agrees to reduce units by 600, leaving rebates for 100 units due.

Manufacturer I asserts that no interest is due since the state adjusted units.

Answer: INCORRECT! The unit adjustment was based on dispute resolution for rebates not paid timely by Manufacturer I. Interest is due on the 100 units, accruing from the rebate due date of the original invoice. Please refer to Example 3 for a situation where interest is not due on a unit adjustment.

Example 7: State J invoices Manufacturer K for 30,000 units; Manufacturer K pays nothing and does not notify State J of its intent to dispute. On the 50th day after Manufacturer K received the invoice, the manufacturer pays rebates on 10,000 units, without interest.

Answer: In this situation, Manufacturer K failed to pay timely on any portion of the rebate amount. Interest is due on the 10,000 units, calculated from the rebate due date of the original invoice. Additionally, assuming that the state does not reduce its utilization, interest continues to accrue from the rebate due date of the original invoice on the remaining 20,000 units until the dispute is resolved.

Please refer to Section I of the Medicaid Drug Rebate Operational Training Guide for interest calculations.

If you have any general questions on interest, please contact Sue Gaston at (410) 786-6918.

o Thresholds/Tolerance Levels

It has come to our attention that there are still instances of states invoicing for rebates or interest in amounts as low as or less than $1.00. We are strongly recommending that states give thoughtful consideration of applying threshold levels to amounts that are clearly not cost effective
to pursue. Please refer to Section F, Page 18 of the Medicaid Drug Rebate Operational Training Guide for tolerance thresholds for invoicing rebates and Section I for interest thresholds.

o Failure to Pay Rebates and/or Interest

Generally, manufacturers are paying rebates timely, displaying good faith efforts to resolve disputes and paying interest on untimely payments. However, we are aware of a few manufacturers that unreasonably and routinely withhold rebate payments or fail to pay interest.

We will continue our attempts to address these isolated problems with the specific manufacturers through our dispute resolution efforts but in those situations where we are unsuccessful, we will

be contacting appropriate manufacturer officials to address ongoing problems. It is not our intention to terminate manufacturers from the program but we are resolved to ensure compliance with the terms of the rebate agreement. We are committed to assisting states and manufacturers resolve disputes but it is discouraging to find a few manufacturers failing to demonstrate a willingness to comply with the responsibilities of the rebate agreement. Particularly disturbing are situations where, through our dispute resolution meetings, a manufacturer and state come to agreement on specific issues then, subsequently, a manufacturer fails to fulfill those agreements. We will aggressively pursue resolution in these cases and consider termination if warranted.

o States' Refusal to Review Data or Resolve Disputes

It has been said that at least one state has allegedly refused to review any disputed items identified by manufacturers; rather, the state threatens prior authorization of the manufacturer's products unless full rebates are paid without discussion or review of potential utilization errors. While 100% accuracy is a desirable goal for state utilization, our extensive experience in dispute resolution clearly indicates that such perfection is unlikely absent foolproof edits, the verifiable impossibility of pharmacy mis-coding or rounding errors or the absolute elimination of human error. That's why we encourage a mutual exchange of information and open lines of communication to reasonably identify possible errors, correct them and settle disputes. We will be contacting this state to identify any potential problems and to assist it in establishing an effective dispute resolution process.

o Resource Limitations

Please be cognizant of the resource limitations facing states and manufacturers to varying degrees and the budget limitations on HCFA, which present challenges to timely resolution of disputes. It is not possible for HCFA to simultaneously conduct meetings with all states and manufacturers, nor is it reasonable for a state to expect that all manufacturers resolve all disputes with that particular state first, or vice versa.

Additionally, experience has shown that effective dispute resolution is most likely accomplished when sufficient advance planning occurs. To that end, we intend on formulating an ambitious but manageable schedule of Dispute Resolution Project (DRP) meetings for 1998 as outlined in the following item. The DRP to date has demonstrated that when manufacturers and states have a clear understanding as to the specific dispute issues to be discussed at the meetings, there is increased potential for reaching resolution. With effective advance planning, all parties will be better prepared for substantial progress in resolving disputes.

o Future Dispute Resolution Initiatives

Budget permitting, we plan to continue the DRP in 1998. Since 1994, we have been successful in assisting states and manufacturers resolve over $190 million in rebate disputes through the DRP. Current plans for 1998 include the continuation of DRP meetings in the Western and Southern Consortia, the implementation of DRP meetings in the Midwest Consortium and possibly the resumption of meetings for the Northeast Consortium states. Also, for states not able to participate in the consortia DRP meetings, we are considering individual state meetings or smaller groups of state meetings as budget limitations permit. We will be coordinating the scheduling of the DRP meetings with the consortia and regional office drug rebate coordinators who will subsequently contact individual states and manufacturers. We expect to announce the meeting schedules for the rest of FY 1998 by the end of December. States and manufacturers are encouraged to strongly consider attending the DRP meetings and to continue open communication with each other in pursuit of dispute resolution.

Please contact the DRP coordinators if you have any questions on any dispute related issue. Mike Keogh may be reached at (410) 786-5910 and Vince Powell may be reached at (410) 786-3314. You may also fax any questions to their attention at (410) 786-0390.

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of September 15, 1997 through November 24, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18 or section “O” of the operations guide.

Sally K. Richardson
Director
Center for Medicaid and State Operations

2 Attachments

cc:
Regional Administrators
All Associate Regional Administrators, Division of Medicaid