November 21, 1997

MEDICAID DRUG REBATE PROGRAM

Release Number 71

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

NOTE TO: All State Medicaid Directors

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, Manufacture 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 Page 4 –

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 is 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 alleged that at least one state has adamantly 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.

DRUG LABELERS

New Labelers

Horus Therapeutics (Labeler Code 59229) is to be reinstated into the program effective October 1, 1997. Pricing and rebate functions for their drug products will be administered by Monarch Pharmaceuticals until further notice.

The following labelers entered into drug rebate agreements with an effective date of participation in the rebate program of October 1, 1997:

Evans Medical (Labeler Code 19650); and

Hi-Tech Pharmacal Co., Inc. (Labeler Code 60569).

The following labelers entered into drug rebate agreements with an effective date of participation in the rebate program of January 1, 1998:

Vital Signs, Inc. (Labeler Code 08166);

Neurex Corporation (Labeler Code 62860); and

Sky Pharmaceuticals Packaging, Inc. (Labeler Code 63739).

Terminations

The following drug companies are terminating effective January 1, 1998:

Richardson-Vicks, Inc. (Labeler Code 23900);

IYATA Pharmaceutical, Inc. (Labeler Code 59291);

Sequus Pharmaceuticals, Incorporated (Labeler Code 61471);

DermaRite Industries LLC (Labeler Code 61924); and

Boscogen, Inc. (Labeler Code 62033).

OTHER ATTACHMENTS

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period of September 15, 1997 through November 17, 1997 are 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 or in State release #53.

/s/

Sally K. Richardson
Director
Center for Medicaid and State Operations

2 Attachments
cc:
All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid