October 5, 1995

MEDICAID DRUG REBATE PROGRAM Release No. 19

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

NOTE TO: All Participating Drug Manufacturers

DISPUTE RESOLUTION ISSUES

We would like to take this opportunity to address several issues of concern regarding dispute resolution. We are providing this information to all States and manufacturers.

We have consistently maintained that disputes must be based on utilization data, which is consistent with the terms of the rebate agreement. While we recognize that manufacturers often review Medicaid reimbursement amounts for individual drugs to determine if the respective rebate amounts are appropriate, only units are subject to dispute. Further, the statute and rebate agreement clearly specify the formula for calculating rebates. The rebate calculation is that specified in the statute and rebate agreement irrespective of Medicaid reimbursement costs. It is a violation of the rebate agreement and the statute for a manufacturer to calculate rebates on any alternative formula other than that required by law and the rebate agreement. Consequently, the only basis upon which a manufacturer may dispute rebates is on utilization data and not on unit rebate amounts or Medicaid reimbursement.

It has been brought to our attention that some manufacturers have proposed settlements on disputed rebate amounts to States based solely on a dollar amount or a percentage of the disputed amount and have cited HCFA endorsement of their proposals. Such proposals for settlements on any basis other than units are unacceptable as we do not endorse any settlement which is not based on utilization changes. States and manufacturers assume the risks of audits and potential Federal recoupment actions by settling disputes on any basis other than units.

TERMINATION FROM THE REBATE PROGRAM

We have been notified by drug labelers that selected States are advising drug labelers that the States may terminate them from the Medicaid drug rebate program. Such threats are typically in response to a labeler's persistent reluctance to pay rebates to the State. A State does not have the authority to terminate a labeler from the national Medicaid drug rebate agreement and we have requested States to cease such notifications. Rather, we suggest that the State advise its respective regional office drug rebate coordinator if a labeler does not pay rebates. By law, the Secretary of DHHS retains the authority (which is delegated to the Medicaid Bureau within HCFA) to determine when termination action is necessary.

PRIOR AUTHORIZATION

Several drug labelers have reported States which place the entire drug formulary of a labeler on prior authorization, citing non-payment of rebates as the justification. Again, if a manufacturer refuses to pay rebates, the regional office should be notified. However, any State has the authority to place any drugs it chooses on prior authorization, provided the statutory requirements of a 24-hour response and 72-hour emergency supply are met.

PARTIAL DRUG REBATE PAYMENTS

We have received reports of States receiving partial payments of rebate amounts from labelers with a letter specifying that unless the State advises the labeler within a specified number of days to the contrary, the labeler will consider the partial payment as being payment in full and the dispute resolved. We do not consider a dispute to be settled until both the State and the labeler agree that it is settled and documented.

When a labeler submits a partial payment, the labeler must identify the unpaid units and amounts by National Drug Code.

The items described in this release are not intended to be all-inclusive of the problems inherent in the dispute resolution process and we intend to provide additional guidance in future letters. Meanwhile, we would like to reiterate that labelers and States are encouraged to resolve disputes in good faith and in a timely manner. We have significantly increased our focus in dispute resolution and, through our regional offices, we will enhance our efforts to more closely monitor the progress of States and labelers in resolving disputes.

If a State or manufacturer need additional assistance in dispute resolution after notifying the appropriate HCFA regional office drug rebate coordinator, please contact Mike Keogh, Medicaid Bureau Drug Rebate Team, at (410) 786-5910.

PUBLICATION OF DRUG REBATE REGULATIONS MB-46-P

The Medicaid drug rebate regulation, MB-46-P, was published in the Federal Register on September 19, 1995, 60 FR 48442-48490. The proposed rule specifies requirements for State Medicaid agencies and conditions under which Federal payments will be made under Medicaid for covered outpatient prescription drugs.

The 60-day comment period on the rule ends November 20, 1995. All written comments will be considered in the final rule.

Copies of the proposed rule are available through the following sources:

1. Federal Register.--To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

2. Internet.--HCFA's World Wide Web Home Page on the internet contains HCFA's regulations. HCFA's web site address is:

http://www.ssa.gov/hcfa/hcfahp2.html

3. CD-ROM.--HCFA's laws, regulations, and manuals are also available on CD-ROM. HCFA's latest update to CD-ROM included the Medicaid drug rebate regulation, MB-46-P. Interested parties can order this information from the following source:

Government Printing Office
Sales Order and Information Desk
(202) 512-1800

HCFA's Laws, Regulations and Manuals on CD-ROM
Stock Number: 717-139-00000-3
Price: $30.00 for each edition, $246.00 per year

Questions in this area should be referred to Estelle Chisholm at (410) 786-3286.

PRIOR PERIOD ADJUSTMENT (PPA) PROCESSING

In release #18, dated August 16, 1995, we covered the processing of PPAs and how they were to be initiated by the labelers to the States with subsequent follow-up to HCFA for verification.

Please remember that PPAs for **DRUG CATEGORIES** **"S"** and **"I"** will result whenever **BASELINE AMP** and/or **MARKET DATE** changes occur. When this happens, you are responsible for recalculating Unit Rebate Amounts (URAs) for any and all affected quarters (potentially back as far as calendar quarter 1-91) and for showing the differences to each State during the next billing cycle.

Additionally, baseline changes for Baseline AMP and Market Date made for products having multiple package sizes **MUST** have the same change made (and reflect all URA changes) to **ALL** package sizes. Any change that will cause URAs to be recalculated **MUST** be done by you and reported to HCFA and States in the very next reporting period.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1995 through October 2, 1995.

TOPIC INDEX

For your convenience, attached is a topic index of all items covered in prior releases.

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

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

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