March 5, 1997

MEDICAID DRUG REBATE PROGRAM Release No. 27

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

NOTE TO: All Participating Drug Manufacturers

SPECIAL RELEASE TO ALL PARTICIPATING LABELERS

We are sending this special release to all participating manufacturers to bring to your attention our profound concern regarding the following examples of practices demonstrated by some manufacturers throughout the dispute resolution process. Although most of the information and guidance provided in this release has previously been addressed in other releases, we believe it necessary to devote this special release exclusively to these issues.

Generally, we believe it is inappropriate for a manufacturer to dispute each quarter for the same recurring reasons in those situations when a state has already demonstrated in a prior quarter that the utilization is reasonably accurate. Further, the rebate agreement requires that disputes be identified on an NDC/quarter/reason basis; thus, it is inappropriate for a manufacturer to withhold payment of an entire invoice because of an apparent discrepancy or error in a line item. Rather, payment should be made timely on that portion of the invoice not in dispute in accordance with the rebate agreement. Another option chosen by some manufacturers is to pay the invoice timely in its entirety, then dispute shortly thereafter when the manufacturer may believe better data are available. This action effectively eliminates the manufacturer's liability on the accrual of interest insofar as the rebate amount is paid timely in accordance with the rebate agreement. If dispute resolution subsequently results in a reduction of the rebates already paid, the state must credit the appropriate amount, with interest, to the manufacturer.

Many states have reported that some manufacturers continue to dispute rebates on the basis of "low" Medicaid reimbursement. We recognize that manufacturers frequently use various methodologies to identify potential disputes, including comparing the amount of Medicaid reimbursement to the manufacturer's estimate of the lowest available selling price. However, the level of Medicaid reimbursement is not a factor in calculating rebates and violates the formula as contained in the rebate agreement and in accordance with the statute. As we have consistently maintained throughout the rebate program, disputes must be settled on the basis of units, irrespective of the level of Medicaid reimbursement. If the methodologies applied by the manufacturer identify erroneous units and the state agrees, then the appropriate revisions to that data must be made and the resultant rebate amounts must be adjusted accordingly. However, absent a mutually agreeable unit adjustment, it is unacceptable for a manufacturer to withhold rebates solely on the amount of Medicaid reimbursement.

We have encountered instances through our dispute resolution efforts when a manufacturer initially alleges that a state's utilization is erroneous and the resultant rebates excessive because of the level of Medicaid reimbursement. Often, states and manufacturers have agreed to an exchange of more detailed data. For example, the state may agree to conduct a sample audit of manufacturer-selected pharmacies for specific drugs with the understanding that if the data or audit findings supported the units invoiced, the manufacturer would pay the rebates (and interest) due. Conversely, if the findings indicated a reduction in the units was warranted, the state would revise its units and reduce the rebate amount invoiced. However, in the former scenario where the state's data were supported, there have been instances when the manufacturer subsequently continued to withhold payment of the rebates based on the level of Medicaid reimbursement, irrespective of units. At a minimum, we believe that this behavior fails to demonstrate good faith attempts to resolve disputes. Manufacturers who continue this practice may be risking termination from the program.

Apart from the above, we have learned through our dispute resolution meetings and other contacts with states that there can be other factors involved related to the level of Medicaid reimbursement. For example, Medicaid is the payer of last resort and there may be other third party payments associated with a Medicaid claim. Thus, the Medicaid reimbursement is not the total of payment received by the pharmacist on those claims. It is not uncommon for some pharmacies, most notably major chains, to accept low reimbursement for a drug's ingredient costs from Medicaid, with the knowledge that dispensing fees and additional unrelated sales of other products offset any disparity in pharmacy acquisition costs and reimbursement levels. The acceptance of low reimbursement for brand name drugs is also sometimes a result of state law and Federal law. An example described by several states is the situation where state law prohibits a pharmacy from dispensing a generic if the prescriber checks, signs, or initials a box or printed statement on the prescription form which indicates "dispense as written."

Federal law, however, limits payment for a brand name drug to the generic limit unless the prescriber hand-writes "brand medically necessary" on the form. In this scenario, the pharmacist must dispense the brand name drug to comply with state law and accept the generic reimbursement in accordance with Federal law. Given that we believe that this is a reasonable explanation for "excessive" Medicaid utilization relative to Medicaid reimbursement, we believe it is inappropriate for manufacturers to routinely, quarter after quarter, dispute rebates in these situations. In all cases, we are reiterating that the level of Medicaid reimbursement is not a factor in the calculation or payment of rebates under current law.

Regarding interest, it has also come to our attention that some manufacturers fail to pay interest on untimely rebate payments. We have asked states to monitor those manufacturers that fail to pay interest as required by the rebate agreement and report them to us. We are increasing our efforts in coordination with the Office of Inspector General to ensure compliance with the law regarding the payment of interest. As indicated in earlier releases, it is the manufacturers' responsibility to calculate and pay interest on all rebates not paid timely.

It is not our intention in this notice to address all situations of concern regarding disputes; rather, we have expressed our concerns on specific activities and practices reported to us by states or through our dispute resolution meetings which we believe are barriers to effective dispute resolution and, in some cases, may be violations of the rebate agreement. Soon, we will be notifying individual manufacturers separately and will conduct meetings at HCFA headquarters in Baltimore with the appropriate representatives from those identified manufacturers to discuss specific issues with them. However, the examples of manufacturer behavior described in this release will no longer be tolerated and those manufacturers that persist in violating the rebate agreement or withholding rebate payments inappropriately will be at risk for termination from the program.

While we have provided a few examples of unacceptable methods and tactics some manufacturers employ under the drug rebate program, we would be remiss if we failed to acknowledge that the majority of manufacturers participating in the program comply fully with the requirements in the rebate agreement. Further, the cooperation and good faith displayed by most of the manufacturers participating in our dispute resolution efforts has been encouraging. We sincerely appreciate the support and continued spirit of partnership shown by the overwhelming majority of states and manufacturers. With continued effort by all of us, we can improve the Medicaid Drug Rebate Program.

If you have any questions or require additional information on our ongoing dispute resolution efforts, please contact Mike Keogh at (410) 786-5910 or Vince Powell at (410) 786-331

Judith D. Moore
Acting Director
Medicaid Bureau

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