October 28, 1996

MEDICAID DRUG REBATE PROGRAM

Release Number 63

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

NOTE TO: All State Medicaid Directors

CHAPTER 11 FILING BY ALIGEN INDEPENDENT LABORATORIES, INC. (Labeler Code 00405)

As many of you are aware, Aligen Laboratories filed a Chapter 11 bankruptcy in the United States Department of Justice, Office of the United States Trustee, District of Delaware. As we stated in a prior notice concerning bankruptcy filings by participating drug labelers (Release Number 61, page 1), States are expected to file a proof of claim for their drug rebates in any bankruptcy proceeding of a drug manufacturer from whom a drug rebate is owed. In this particular case, the attorney assigned to this case is John D. McLaughlin, Jr. who can be reached by telephone at (215) 597-4411 or by facsimile transmission at (215) 597-5795. The counsel for committee is identified as Steven Z. Jurista, Esquire, who can be reached by telephone at (201) 467-2700. Our thanks to Wave Hamilton in Michigan for sharing this information.

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.

We suggest that States use Attachment A to record those drug labelers that fall into this category. Send completed forms to HCFA via fax at (410) 786-0390 or mail to:

Health Care Financing Administration
Drug Rebate Program
P.O. Box 26686
Baltimore, MD 21207

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 will 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 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.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on January 1, 1997:

Consolidated Pharmaceutical Group, Inc. (Labeler Code 61423);

DermaRite Industries LLC (Labeler Code 61924);

Boscogen, Inc. (Labeler Code 62033);

A & Z Pharmaceutical Inc. (Labeler Code 62211); and

Eisai, Inc. (Labeler Code 62856).

DRUG LABELER REINSTATEMENTS

Dawn Pharmaceuticals, Inc. (Labeler Code 58865) and Amkas Laboratories, Inc. (Labeler Code 61073) have submitted missing

drug prices for all quarters and signed new rebate agreements. Their next period of participation in the drug rebate program will begin on January 1, 1997.

LABELER TERMINATIONS

The following labelers are being terminated effective January 1, 1997 for failure to submit pricing data:

Dunhall Pharmaceuticals, Incorporated (Labeler Code 00217);

Pharm Tech Incorporated (Labeler Code 29294); and

Bard Patient Care Division (Labeler Code 51459).

Med-Pro, Incorporated (Labeler Code 53978) has requested to be terminated from the program effective January 1, 1997.

ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 2, 1996 through October 21, 1996 are attached. We have also attached a listing of monthly CPI-U rates, current to September, 1996.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 53.

/s/
Judith D. Moore
Acting Director
Medicaid Bureau

4 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

ATTACHMENT A

DRUG LABELERS NOT PAYING REBATES AND HAVE NOT NOTIFIED THE STATE OF DISPUTES

STATE_____

NAME OF DRUG LABELER	LABELER CODE	QTRS INVOLVED (e.g. 1/96)