February 23, 1995

MEDICAID DRUG REBATE PROGRAM

Release Number 48

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

REMITTANCE ADVICE REPORT (RAR)

The proposed RAR developed by the Dispute Resolution Workgroup is finalized. The RAR functions as a reconciliation report to reduce disputes by standardizing data exchange and improving communication between manufacturers and States.

Pending the publication of the drug rebate regulation mandating the RAR, we are encouraging all manufacturers to voluntarily use the draft RAR to report the remittance of rebate payments, adjustments to previous rebate payments, and disputed rebate amounts. The proposed RAR, instructions, data definitions, automated reporting format, and a listing of the adjustment and dispute codes have been made available to manufacturers for their immediate use. We are attaching these documents for your information. At this time, we do not anticipate any changes to the proposed RAR.

TOLERANCE THRESHOLD FOR INTEREST

In those instances where the administrative cost of recovering interest payment(s) exceeds the interest payable to the State,

the State may apply the \$50 tolerance level per labeler to interest payments. Application of this tolerance is optional for States; that is, any State may choose to invoice a labeler for interest amounts at or below the tolerance level. In all cases where a State chooses to apply tolerance levels, adequate documentation should be maintained by both the States and the labeler.

USE OF INFORMATION FROM OUTSIDE SOURCES

We have been made aware of a situation where some States are relying on information furnished by an organization other than HCFA to determine whether to buy drug products marketed by a participating drug labeler. The organization in question furnishes data on virtually every drug product being marketed. Individual drug product data include an indicator that purports to verify that a drug labeler is paying rebates. In several instances, the indicator was found to be less than 100 percent reliable and caused public relations problems on a national scale. Also, we continue to receive complaints from drug labelers that one or more States do not have selected drug

products in their formularies despite receiving that data from HCFA.

Please remember that the use of additional data furnished by outside organizations is not endorsed by HCFA in the drug rebate program due to the many problems that can occur. Whenever these types of questions occur, you are strongly encouraged to notify HCFA to get the matters resolved.

STATE APPLICATION OF THE FEDERAL UPPER LIMIT (FUL) PROGRAM

It has come to our attention that a brand name drug that exceeds the Federal Upper Limit established for it may actually cost the State less than generic versions when rebates are paid for that brand name drug.

We would like to remind you that States are permitted to raise the FUL of any drug product provided the State lowers the FUL of another drug product so that in the aggregate the State pays no more than it would have had the State implemented the FULs as established. This can be done by looking at last year's paid claims to determine the number of tablets/capsules purchased and multiplying that number by the amount it wishes to raise the FUL. This amount is the shortfall the State must recover.

The shortfall can be recovered by lowering the FUL for another drug product by an amount equal to the number of units paid for last year multiplied by the amount the State lowers that FUL. If the State enters this information in its file and can demonstrate that it has made these changes based upon last year's paid claims experience, the State will be held harmless should utilization change and a shortfall result. If this methodology is used, these numbers must be updated annually in accordance with 42 CFR 447.333. Questions on this topic should be referred to Pete Rodler at (410) 966-4582.

NEW LABELERS

We received a rebate agreement from MedImmune, Incorporated (Labeler Code 60574) which is the selling agent for a product owned by Mass Public Health Bio Lab (Labeler Code 14362). MedImmune will be joining the rebate program retroactive to January 1, 1995.

We also received a rebate agreement from American Pharmacal, Incorporated (Labeler Code 60574) which is the parent company for Innercare (Labeler Code 53723). American Pharmacal will be joining the rebate program retroactive to January 1, 1995.

The following labeler has entered into a drug rebate agreement and will join the rebate program on April 1, 1995:

Warner-Lambert (Labeler Code 00501).

Also, the following labeler has entered into a drug rebate agreement and will join the rebate program on July 1, 1995:

Nomax, Incorporated (Labeler Code 51801).

LABELER TERMINATION

Pharmakraft, Incorporated (Labeler Code 59516) has requested termination from the program to be effective on April 1, 1995.

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of July 5, 1994 through February 21, 1995 are attached.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

> Sally K. Richardson Director Medicaid Bureau

3 Attachments

cc:

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

PAGE 1 OF 8

DATA ELEMENT NAME: Company Name DATA DEFINITION: Name of company as it appears on the signed rebate agreement. Alpha-numeric values, first twenty-five SPECIFICATIONS: positions of company name, left justified, blank filled. DATA ELEMENT NAME: Labeler Code First segment of National Drug Code that DATA DEFINITION: identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug. Numeric values only, 5 positions right SPECIFICATIONS: justified, zero filled; no blanks. DATA ELEMENT NAME: Period Covered DATA DEFINITION: Calendar quarter and year covered by this report. SPECIFICATIONS: Numeric values, 3 position field, QYY; no blanks Valid values for Q: 1 = January 1 - March 31 2 = April 1 - June 303 = July 1 - September 30 4 = October 1 - December 31Valid values for YY: Last two digits of calendar year covered.

PAGE 2 OF 8

DATA ELEMENT NAME: Contact DATA DEFINITION: Labeler's contact person receiving the State invoice. SPECIFICATIONS: Alpha-numeric values, twenty positions, left justified, first name and last name separated by 1 blank. DATA ELEMENT NAME: Phone Telephone number of contact person. DATA DEFINITION: SPECIFICATIONS: Alpha-numeric values, ten positions, area code and phone number. DATA ELEMENT NAME: Fax DATA DEFINITION: Telephone Fax number of contact person. SPECIFICATIONS: Alpha-numeric values, ten positions, area code and phone number. DATA ELEMENT NAME: State DATA DEFINITION: State postal abbreviation. SPECIFICATIONS: Alpha values, 2 position field; no blanks DATA ELEMENT NAME: Invoice Number DATA DEFINITION: Identification number of invoice submitted by State and associated with this report. invoice contains no identification number, this field will be blank. Alpha-numeric values, 10 position field, right SPECIFICATIONS:

justified.

PAGE 3 OF 8

DATA ELEMENT NAME: Product Code DATA DEFINITION: Second segment of National Drug Code. SPECIFICATIONS: Alpha-numeric values, 4 position field, right justified, zero filled; no blanks. Package Size Code DATA ELEMENT NAME: DATA DEFINITION: Third segment of National Drug Code. SPECIFICATIONS: Alpha-numeric values only, 2 digit field, right justified, zero filled; no blanks. DATA ELEMENT NAME: Product Name First ten positions of product name as it DATA DEFINITION: appears in the product description submitted to HCFA. SPECIFICATIONS: Alpha-numeric values, 10 positions, left justified; blank filled. DATA ELEMENT NAME: Rebate Amount Per Unit DATA DEFINITION: HCFA-calculated rebate amount per unit as shown on the State invoice (if present). Numeric values, 11 positions: 5 whole numbers SPECIFICATIONS: and 6 decimals, right justified. If not available, this field will be zero filled; no blanks.

PAGE 4 OF 8

DATA ELEMENT NAME: Units Invoiced DATA DEFINITION: State-calculated number of units paid for. the number of units has been adjusted through correspondence or telephone contact between the State and the manufacturer, the Units Invoiced will reflect the adjusted number. Numeric values, 12 positions: 9 whole numbers SPECIFICATIONS: and 3 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Units Paid DATA DEFINITION: Manufacturer-calculated number of units paid for. Numeric values, 12 positions: 9 whole numbers SPECIFICATIONS: and 3 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Rebate Amount Invoiced DATA DEFINITION: State-calculated rebate amount invoiced by the State per NDC. Numeric values, 9 positions: 7 whole numbers and SPECIFICATIONS: 2 decimals, right justified. If not available, this field will be zero filled; no blanks. DATA ELEMENT NAME: Rebate Amount Paid Amount per NDC that the manufacturer is DATA DEFINITION: remitting to the State with this report. SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified; No blanks.

PAGE 5 OF 8

DATA ELEMENT NAME: Adjusted Rebate Per Unit

DATA DEFINITION: Rebate amount per unit if different than the

rebate amount per unit as shown on the State

invoice (if present).

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers

and 6 decimals, right justified. Calculate to

7 decimals and round to 6; No blanks.

DATA ELEMENT NAME: Adjustment Codes

DATA DEFINITION: Reason(s) manufacturer has adjusted the rebate

per unit or the number of units invoiced. Refer to the page 3 of the automated reporting format

or the RAR form for values.

SPECIFICATIONS: Alpha-numeric, 3 positions.

Valid values: 1 through 6.

Maximum: 3 Adjustment Codes per NDC

................

DATA ELEMENT NAME: Credit/Debit Indicator

DATA DEFINITION: Indicator to determine if the Invoice

Adjustment Amount is added to or subtracted from

the Rebate Amount Invoiced.

SPECIFICATIONS: Alpha-numeric, 1 position, blank filled.

Valid values:

C = Credit (Subtract this amount from the

rebate amount invoiced.)

D = Debit to manufacturer (Add this amount to

the rebate amount invoiced.)

PAGE 6 OF 8

Invoice Adjustment Amount DATA ELEMENT NAME: DATA DEFINITION: Amount of the credit or debit resulting from the adjustment to the Rebate Amount Invoiced by the State for the period covered by this report. Numeric values, 11 positions: 5 whole numbers SPECIFICATIONS: and 6 decimals, right justified. DATA ELEMENT NAME: Dispute Codes DATA DEFINITION: Reason(s) manufacturer has disputed the invoice submitted by the State. Refer to page 3 of the automated reporting format or the RAR form for values. SPECIFICATIONS: Alpha-numeric, 3 positions. Valid values: A through I. Maximum: 3 Dispute Codes per NDC DATA ELEMENT NAME: Withheld Invoice Amount DATA DEFINITION: The rebate amount invoiced by the State that the manufacturer is disputing for the period covered by this report. SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. DATA ELEMENT NAME: Total Units Invoiced Total number of State-calculated units DATA DEFINITION: invoiced. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified.

PAGE 7 OF 8

DATA ELEMENT NAME: Total Units Paid DATA DEFINITION: Total number of manufacturer-calculated units paid. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified. DATA ELEMENT NAME: Total Rebate Amount Invoiced Total rebate amount the State invoiced the DATA DEFINITION: labeler for all NDCs for the period covered by this report. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Total Rebate Amount Paid Total amount of rebate the labeler paid to the DATA DEFINITION: State for all NDCs for the period covered by this report. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Total Invoice Adjustment Amount DATA DEFINITION: Total amount of adjustments the labeler made to the rebate amount invoiced by the State for all NDCs for the period covered by this report. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.

DATA ELEMENT NAME: Total Withheld Invoice Amount

DATA DEFINITION: Total amount the labeler is withholding from the rebate amount invoiced by the State for all NDCs for the period covered by this report.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.

FAB134:Dmccarthy, 63314.

state48.WP