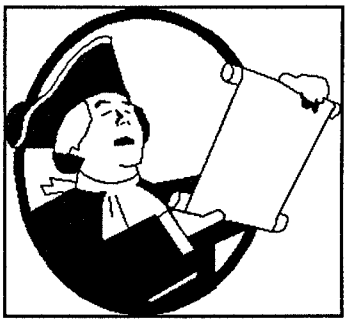
DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

OCT 3 1991



MEDICAID DRUG REBATE PROGRAM

Release No. 15

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

NEW DRUG LABELER CODES

Novo Nordisk (Labeler Code 50445) has acquired another labeler code, 00169, to add to its rebate agreement. While the effective date is retroactive to January 1, 1991, we have been assured that there are no drug products with that labeler code on the market. They forecast their first product(s) to be marketed no earlier than mid-October, 1991. Contact information is attached.

CIBA-GEIGY Corporation (Labeler Codes 00028, 00083 and 57267) has added labeler code 58887 (Basel Pharmaceuticals) as a new addition to its corporation. The effective date for this new labeler code is retroactive to January 1, 1991, per legal opinion of OBRA 90. Contact information is attached.

The Seatrace Company (Labeler Code 00551) will be added to this program effective January 1, 1992. Contact information is attached.

LPI Holdings, Inc. dba LEXIS Laboratories (Labeler Code 00454) will be added to this program effective January 1, 1992. Contact information is attached.

Baron Pharmaceuticals, Inc. (Labeler Code 58570) will be added to this program effective January 1, 1992. Contact information is attached.

TERMINATIONS

Although we previously notified you in release number 13 dated July 22, 1991, this is an additional reminder that effective October 1, 1991, rebate agreements are being terminated for the following drug labelers:

Label Code	Name
08189	Can-Am Care Corporation
12462	Chester Labs Incorporated

Laboratory A (Labeler Code 54538) has requested termination of their rebate agreement. The effective termination date will be January 1, 1992. Also, several State agencies erroneously invoiced this company for the first two calendar quarters of 1991 even though the rebate agreement was not effective until July 1.

DRUG LABELER INFORMATION CHANGES

- **Pfizer-Roerig (Labeler Codes 00049, 00069, 00662, 00663 and 00995)**

  Change all financial contacts to:

  Michael McEnroe
  Pfizer, Inc.
  235 E. 42nd Street
  5th Floor - Mail Stop 3
  New York, NY 10017
  (212) 573-1682

- **Sandoz Pharmaceuticals Corporation (Labeler Codes 00043, 00078 and 58345)**

  Change all financial contacts to:

  Albert L. Dessertine
  (201) 503-8665
  Sandoz Pharmaceuticals Corporation
  59 Route 10
  East Hanover, NJ 07936

- **Reid-Rowell (Labeler Code 00032)**

  Change the company name to: Solvay Pharmaceuticals. All other information stays the same.

- **Berlex Laboratories (Labeler Code 50419)**

  Contact information changes - See attachment.

- **Wyeth Laboratories, Inc. (Labeler Code 00008)**

  Change to financial address - See attachment.

- **Pharmics, Inc. (Labeler Code 00813)**

  Change to mailing address. - See attachment.

- **Labeler Code 00575**

  Carter-Wallace included this labeler code in their rebate agreement since they had purchased the only drug product, Doral, manufactured by the selling company, Baker Cummins, and believed that they were gaining legal title to the labeler code. That is not correct.

  Effective October 1, 1991, the name of the company associated with this labeler code is Baker Cummins. Rebate requests for labeler code 00575 should be sent to Baker Cummins. The other labeler code for Baker Cummins is 58174 with an effective date of October 1, 1991. Contact information is attached.

- **Labeler Code 00585**

  Fisons Pharmaceuticals has a new technical contact. Effective immediately, please change the name and telephone number to: Ms. Laura O'Neill at (716) 274-5704. The mailing address remains the same.

- **Labeler Code 57664**

  Caraco Pharmaceutical Labs, Ltd., has a new financial contact. Effective immediately, please change the name to Mr. Fred Malecki. The telephone number and mailing address are unchanged.

- **Immunex (Labeler Code 58406)**

  The list of manufacturers sent to you on March 15, 1991 incorrectly listed Leukine as the manufacturer for labeler code 58406. The correct name of the manufacturer is Immunex. This company originally reported their corporation name as Leukine which, in fact, is the name of one of their drug products.

MANUFACTURER BILLING ADDRESSES

Unless notified by a manufacturer, you are reminded to send your rebate requests to each manufacturer using the technical contact name and address provided to us by each drug labeler.

MAGNETIC MEDIA SHIPMENTS

There are two items that require discussion.

1. When participating drug labelers have large inventories of covered outpatient drug products, we strongly urge you to send your invoices to them using magnetic media. It is extremely difficult for them to process requests from all States within 30 days when more than 300 individual unit rebate calculations must be checked for each State.

If you can generate a drug product invoice on paper from your computer system, it is very simple to direct that output to magnetic media (tape, cassette, cartridge, diskette, or telecommunications) using the specified record format.

Remember, you were advised to negotiate the medium with each drug labeler!

2. Several States are sending their tapes and cartridges to us at the wrong address. The correct address for shipping magnetic media to HCFA is:

Health Care Financing Administration
Lyon Building
7131 Rutherford Road
Baltimore, MD 21207
Attention: Tape Library

Also, the address for submission of shipment confirmation letters has been changed to:

Health Care Financing Administration
6325 Security Boulevard
2-A-1, Security Office Park Building
Baltimore, MD 21207
Attention: Al Kemezys

UNIT-DOSE PACKAGING

Abbott Laboratories sent a July 1, 1991 letter to all Medicaid Administrators which included a copy of the Abbott/Ross Pharmaceuticals price catalog. The cover letter stated that "All outpatient products (excluding Unit Dose) contained herein are covered under the Abbott/HCFA Medicaid Contract." Abbott Laboratories is incorrect in making this statement.

Unit-dose drug products are covered under the Drug Rebate Program and must be included in a manufacturer's list of covered outpatient drugs. Unit-dose products must also be included in a drug's average manufacturer price. We are writing to the manufacturer to inform them that unit-dose drug products are included in the rebate program.

Over-the-Counter (OTC) Drugs

OTC drugs are not excluded from the definition of single source/innovator multiple source drugs. An OTC drug is considered to be an innovator drug if it was approved by the Food and Drug Administration (FDA) under an original New Drug Application (NDA). This includes a drug that has been converted from a legend drug (to be dispensed by prescription only) to an OTC drug if the legend version of the drug was approved under an original NDA.

Interest under Section 1903(d)(5) of the Social Security Act

Under section V, Dispute Resolution, of the rebate agreement, a manufacturer or State must pay or credit a reasonable rate of interest on a disputed rebate amount after the dispute is resolved. The interest rate is based on section 1903(d)(5) of the Social Security Act (the Act) and codified at 42 CFR §433.38(d). The interest rate is the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. For purposes of §1903(d)(5) of the Act, the investment yield is considered the bond equivalent rate.

Auctions of 90-day Treasury bills are held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Thursday. Information on the rates is available from the Federal Reserve Bank's (Richmond, VA) recorded telephone message on the day following the auction. States can obtain the investment yield (bond equivalent rate) of the 90-day Treasury bill by calling the Federal Reserve Bank's information line on (804) 697-8355 on Tuesday of each week. The message will state the date of the auction, Treasury bill, discount rate and investment yield. Newspaper reports of the auctions are a possible alternate source for Treasury bill information.

States can calculate the interest rate to be applied to disputed rebate amounts as follows:

1. Total the bond equivalent rates (investment yield rate) of each weekly auction of 90-day Treasury bills during the period for which interest would be charged.

2. Divide the total from Step 1 by the number of rates to determine the average interest rate.

The period for which interest will be charged on disputed amounts will begin on the 31st day after a manufacturer receives utilization data from a State. Interest will accrue on the disputed amount until the dispute has been resolved and the check has been disbursed to the State.

MAGNETIC MEDIA REJECTIONS

Finally, we are attaching a copy of a new form that will be sent to you whenever your magnetic tape or cartridge is unable to be processed at the HCFA Data Center. Additional information regarding this new procedure can be obtained by calling Al Kemezys on (301) 597-3894.

Please continue to refer your questions to us by using the Drug Rebate Hotline number at (301) 966-3249.

for Christine Nye
Director
Medicaid Bureau

10 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators for Medicaid

DATE:

NOTE TO: State Medicaid Director for (Name of State)

FROM: Medicaid Bureau, HCFA

HCFA has received the Drug Rebate Utilization magnetic tape/cartridge from your State agency for the period of Q/YY.

The HCFA Data Center has attempted to process the tape/cartridge and has rejected it for the reason(s) mentioned below:

- The data are in a physically unreadable format.
- The data are in compressed format which is unreadable by HCFA.
- Numeric fields are blank and not zero filled.
- Numeric fields are signed; they should not be signed.
- The data are in an unrecognizable format; consult the HCFA record specifications that were sent to you.
- The Logical Record Length (LRECL) is not 80.
- The external file name does not agree with the internal data set name.

Please correct the problem(s) and submit a new magnetic tape/cartridge to HCFA.