



MAR 1 1993

6325 Security Boulevard
Baltimore, MD 21207**MEDICAID DRUG REBATE PROGRAM**

Release Number 28

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

DRUG LABELER TERMINATIONS**Bioline Laboratories (Labeler Code 00719):**

The diskette with the latest version of drug labeler names, addresses and telephone numbers that you just received contains an erroneous termination date of July 1, 1992 for Bioline Laboratories. We did receive a request from Goldline Laboratories (which owns Bioline) to terminate Bioline effective July 1, 1992 since virtually all of their drug products have expired shelf dates. However, since the labeler code was not being turned back to the Food and Drug Administration, the request was not honored. The error has been corrected on our records. We will send corrected data to you on the first quarter pricing tape for calendar year 1993.

Columbia Laboratories (Labeler Code 55056):

This drug labeler was terminated effective July 1, 1992. While the termination data are contained on the diskette you received, we did not follow our standard practice and failed to highlight this event.

Our thanks to the New Hampshire drug rebate staff for finding these two inconsistencies which allowed us to correct the HCFA records.

After receiving several inquiries from State Medicaid personnel, we have decided to modify our termination language to labelers to ensure that all terminations occur on the last day of a calendar quarter. However, the notices for The American Way and the three labelers shown on page 2 were generated before our legal staff had an opportunity to approve our new termination language.

The following terminations are being enforced due to the drug labelers not submitting timely pricing data; the termination date for all three labelers is April 11, 1993 which is 60 days from the date of the termination notice sent to each labeler.

Concord Laboratories, Incorporated (Labeler Code 20254);

Merit Pharmaceutical Company (Labeler Code 30727);

Omega Laboratories (Labeler Code 54124).

The following terminations are voluntary and are effective on April 1, 1993:

Milex Products, Incorporated (Labeler Code 00396);

C & M Pharmacal, Incorporated (Labeler Code 00398).

NEW LABELER CODE (Contact information is attached)

Luitpold Pharmaceuticals, owner of American Regent Laboratories (Labeler Code 00517), has another company marketing drug products. The new company is Luitpold Pharmaceuticals, Incorporated (Labeler Code 10797). The effective date for this new labeler is retroactive to October 1, 1991. At present, labeler code 10797 only markets veterinary products.

The following drug companies signed rebate agreements which are effective on April 1, 1993. Contact information is attached.

American Pharmaceutical Company (Labeler Code 00084);

Vintage Pharmaceuticals, Incorporated (Labeler Code 00254);

Almay, Incorporated (Labeler Code 00311);

Inagra (Labeler Code 41701);

ICN Pharmaceuticals, Incorporated (Labeler Code 53095);

Med-Pro Incorporated (Labeler Code 53978);

Roberts Laboratories, Incorporated (Labeler Codes 54092 and 59441);

Lane Pharmaceuticals, Incorporated (Labeler Code 54943);

Tri-Med Laboratories, Incorporated (Labeler Code 55654);

Medtronic, Incorporated (Labeler Code 58281);

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Stratus Pharmaceuticals, Incorporated (Labeler Code 58980);

Pratt Pharmaceuticals (Labeler Code 59012);

Oaktree Products, Incorporated (Labeler Code 59256);

TMK Pharmaceuticals (Labeler Code 59582) - contact information was included with release 27;

Global Source Management and Consulting, Incorporated (Labeler Code 59618);

Horizon Pharmaceutical Corporation (Labeler Code 59630);

Unlimited Beverages, Incorporated (Labeler Code 59640);

ADH Health Products, Incorporated (Labeler Code 60142);

The following drug companies signed rebate agreements which are effective on July 1, 1993. Contact information is attached.

Ram Laboratories (Labeler Code 49729);

Bio-Pharm, Incorporated (Labeler Code 59741).

DRUG LABELER INFORMATION CHANGES (Contact information attached)

Adria Laboratories (Labeler Code 00013) - change to technical contact;

G.D. Searle and Company (Labeler Codes 00014 & 00025) - change to financial and technical contacts;

Allergan, Incorporated (Labeler Codes 00023 & 11980) - change to legal and financial contacts;

Boots Pharmaceuticals, Incorporated (Labeler Codes 00048, 00524 & 00822) - change to technical contact;

Stiefel Laboratories, Incorporated (Labeler Code 00145) - change to financial and technical contact;

Fujisawa USA, Incorporated (Labeler Codes 00469 & 57317) - change to financial contact;

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Bradley Pharmaceuticals, Incorporated (Labeler Code 00482) - change to legal and technical contacts;

Bock Pharmacal Company (Labeler Code 00563) - change of address for all contacts;

Major Pharmaceuticals, Incorporated (Labeler Code 00904) - change of address for technical contact;

Alza Corporation (Labeler Code 17314) - change to financial and technical contacts;

Solopak Pharmaceuticals, Incorporated (Labeler Code 39769) - change to financial and legal contacts;

Baxter Healthcare Corporation (Labeler Code 47679) - change to address for technical contact;

Janssen Pharmaceutica, Incorporated (Labeler Code 50458) - change to financial and technical contact;

Family Pharmacy (Labeler Code 52735) - change of address for all contacts;

Able Laboratories, Incorporated (Labeler Code 53265) - all contacts are changed.

Curatek Pharmaceuticals (Labeler Code 55326) - change to all contacts.

CIBA Vision Ophthalmics (Labeler Code 58768) - address change for all contacts;

Glades Pharmaceuticals (Labeler Code 59366) - change to financial and technical contacts.

LABELER CODE CLARIFICATION

In Release Number 25 dated September 24, 1992, we highlighted Nephro-Tech Incorporated joining the rebate program effective October 1, 1992. Also, we stated that the labeler code was 56528. This is incorrect. The correct labeler code is 59528 which was the number used on the diskette containing labeler contact information that we sent to you in December.

WEEKLY U.S. TREASURY BILL DISCOUNT RATE

The latest weekly 90 day treasury bill auction rates beginning with June 3, 1991 are as follows:

<u>DATE</u>	<u>RATE</u>	<u>DATE</u>	<u>RATE</u>	<u>DATE</u>	<u>RATE</u>
06/03/91	5.765	01/21/92	3.878	09/28/92	2.787
06/10/91	5.777	01/27/92	3.944	10/05/92	2.726
06/17/91	5.785	02/03/92	3.964	10/13/92	2.941
06/24/91	5.752	02/10/92	3.817	10/19/92	3.003
07/01/91	5.762	02/18/92	3.931	10/26/92	3.035
07/08/91	5.752	02/24/92	4.067	11/02/92	3.117
07/15/91	5.731	03/02/92	4.117	11/09/92	3.17
07/22/91	5.777	03/09/92	4.117	11/16/92	3.198
07/29/91	5.752	04/06/92	4.043	11/23/92	3.341
08/05/91	5.682	04/13/92	3.684	11/30/92	3.386
08/12/91	5.463	04/20/92	3.778	12/07/92	3.365
08/19/91	5.326	04/27/91	3.798	12/14/92	3.333
08/26/91	5.567	05/04/92	3.737	12/21/92	3.231
09/03/91	5.504	05/11/92	3.724	12/28/92	3.292
09/09/91	5.45	05/18/92	3.696	01/04/93	3.218
09/16/91	5.347	05/26/92	3.839	01/11/93	3.137
09/23/91	5.335	06/01/92	3.839	01/19/93	3.096
09/30/91	5.264	06/08/92	3.798	01/25/93	3.043
10/07/91	5.19	06/15/92	3.745	02/01/93	3.035
10/15/91	5.137	06/22/92	3.757	02/08/93	3.003
10/21/91	5.19	06/29/92	3.671	02/16/93	2.994
10/28/91	5.137	07/06/92	3.3	02/22/93	3.023
11/04/91	4.877	07/13/92	3.292		
11/12/91	4.774	07/20/92	3.231		
11/18/91	4.712	07/27/92	3.251		
11/25/91	4.565	08/03/92	3.271		
12/02/91	4.515	08/10/92	3.198		
12/09/91	4.325	08/17/92	3.17		
12/16/91	4.252	08/24/92	3.208		
12/23/91	3.849	08/31/92	3.239		
12/30/91	4.013	09/08/92	2.974		
01/06/92	3.952	09/14/92	2.954		
01/13/92	3.931	09/21/92	2.974		

DRUG LABELER RELEASE NUMBER 6

Attached is a copy of Release Number 6 that we sent to each drug labeler on February 8, 1993. The primary purpose of that note was to explain the new requirements mandated by Public Law 102-585, The Veterans Health Care Act of 1992.

SUBMITTING INVOICES TO DRUG LABELERS

Please submit invoices to the financial contact, Richard Fried,
for:

Stiefel Laboratories, Incorporated (Labeler Code 00145) and
Glades Pharmaceuticals (Labeler Code 59366).

Please continue to contact us for all other concerns by using the
Drug Rebate Hotline at (410) 966-3249.



Rozann Abato
Acting Director
Medicaid Bureau

2 Attachments

cc:

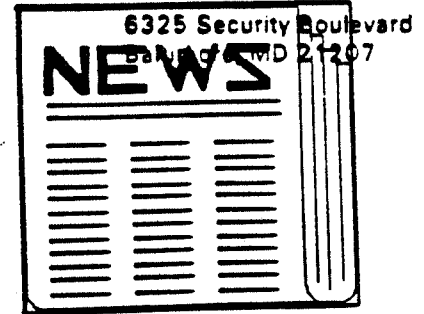
All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid



SEP 9 1993

**MEDICAID DRUG REBATE PROGRAM Release No. 6***** * * IMMEDIATE ATTENTION REQUIRED * * *****NOTE TO: All Participating Drug Manufacturers****THE VETERANS HEALTH CARE ACT OF 1992**

The Veterans Health Care Act of 1992 (VHCA) (Public Law 102-585), enacted on November 4, 1992, amends section 1927(a) of the Social Security Act (the Act) which affects the Medicaid drug rebate program and Medicaid coverage of manufacturers' drugs. The related areas of concern and our policy positions on the issues are discussed below.

**PUBLIC HEALTH SERVICE (PHS) AND
DEPARTMENT OF VETERANS AFFAIRS (DVA) AGREEMENTS**

To continue receiving Medicaid coverage of a manufacturer's drugs, the law requires all manufacturers to enter into a drug pricing agreement with the PHS. Additionally, a manufacturer of single source drugs, innovator multiple source drugs, biologicals, or insulin must also enter into a master agreement with the DVA. Medicaid coverage will be discontinued for drugs of manufacturers not meeting these requirements.

To prevent a major disruption of the Medicaid drug program which creates uncertainty with States and providers about coverage for certain drugs, we will not begin termination proceedings until both the PHS and the DVA provide us with their final lists of manufacturers that have signed their agreements. At that time, we will send written notices to manufacturers that have not signed the PHS and DVA agreements terminating them from the Medicaid drug rebate program. At the same time, we will notify States of those manufacturers' drugs that will not be covered under Medicaid.

MECHANISM TO PREVENT DUPLICATE PAYMENTS

The law requires a system to be put in place by November 5, 1993 to prevent a manufacturer from paying a Medicaid rebate on discounted drugs sold to PHS covered entities. We are discussing with PHS a strategy that is administratively feasible for all parties involved to prevent that situation from occurring. We will inform you as soon as possible of our plans to carry out this provision.

MINIMUM REBATE PERCENTAGE AND REBATE CAP

Section 601(c) of the VHCA changed the rebate calculation under the Social Security Act for Medicaid. The law provides that effective October 1, 1992 through December 31, 1992 the rebate calculation for single source and innovator multiple source drugs is either the greater of 15.7 percent of the average manufacturer price (AMP) or AMP minus best price.

A strict legal reading of section 601(c) of the VHCA appears to remove the 50-percent cap of AMP. However, we have been informed by several members of Congress that removing this cap prior to January 1, 1993 was not the Congressional intent and is the result of a drafting error in the final version of the VHCA legislation. We have been requested by Congressional members to implement the Medicaid provisions of the statute as though the 50-percent cap remains in effect since Congress intends to enact a technical correction to restore the 50-percent cap for October 1 through December 31, 1992.

At this time, manufacturers are legally responsible for paying Medicaid rebates for the October-December 1992 quarter without a 50-percent cap. However, to allow Congress time to technically amend this provision, manufacturers shall only pay rebates for this quarter up to 50 percent of AMP. If Congress fails to enact a technical correction which restores the cap, we will notify you that manufacturers are liable for retroactively recalculating and paying the remaining rebates above 50 percent of AMP for the October-December 1992 quarter.

In the event manufacturers are liable for the remaining rebates, we will specify the date the rebate payments will be due. However, these rebates would not be subject to interest payments during the time period that we have delayed implementing this provision of the VHCA. Payments after the specified due date would be subject to the balance due plus a reasonable rate of interest in accordance with the interest provision in section V(b) of the national rebate agreement.

BEST PRICE

Effective October 1, 1992, manufacturers must exclude from their best price calculation any prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a State home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service or any entity described in section 340B(a)(4) of the PHS Act; the Federal Supply Schedule; and, a State pharmaceutical assistance program. The PHS has provided manufacturers with a list of entities under section 340B(a)(4) subject to the exclusion. The DVA has also provided, or is in the process of providing, a list of its excluded entities. A manufacturer's pricing data for the quarter ending December 31, 1992 must reflect these exclusions. Manufacturers may only submit prior period adjustments for these exclusions for up to four quarters beyond December 31, 1992.

MONTHLY CONSUMER PRICE INDEX (URBAN) (CPI-U)

The latest CPI-U values are as follows:

09/90	132.7	06/91	136.0	04/92	139.5
10/90	133.5	07/91	136.2	05/92	139.7
11/90	133.8	08/91	136.6	06/92	140.2
12/90	133.8	09/91	137.2	07/92	140.5
01/91	134.6	10/91	137.4	08/92	140.9
12/91	137.9	11/91	137.8	09/92	141.3
02/91	134.8	12/91	137.9	10/92	141.8
03/91	135.0	01/92	138.1	11/92	142.0
04/91	135.2	02/92	138.6	12/92	141.9
05/91	135.6	03/92	139.3		

REBATES ON OVER-THE-COUNTER (OTC) DRUG PRODUCTS

We have been told by several State Medicaid agencies that there are drug labelers refusing to pay rebates for their OTC drug products. Section 1927(k)(4) of the Social Security Act permits their inclusion as covered outpatient drugs. Therefore, both prescribed and OTC drug products are included and are subject to rebates.

CHANGES IN OWNERSHIP OR CONTACT INFORMATION

By chance, we had occasion to contact two different drug labelers for purposes of obtaining quarterly pricing data. In the course of the discussions, we were told that both drug labelers had been purchased by other drug companies. Additionally, personnel at the new, controlling companies were unaware of both the Medicaid Drug Rebate program and the quarterly requirement to submit pricing data. We mention this situation to remind personnel at drug companies being sold that they should inform the purchasers of the existence of the rebate agreement and should ensure that all pertinent drug rebate information is transferred to the buyer.

Additionally, please review the contact information you submitted to ensure that the names, addresses and telephone numbers (including area codes) are still correct. Changes should be mailed or sent to us via facsimile transmission at your earliest opportunity. The telephone number for our facsimile machine is (410) 966-0390. Correct contact information enables each State Medicaid agency to send their invoices to the proper address and to call the right person whenever personal contact is necessary.

MAILING PRICING DATA TO HCFA

When sending drug product/pricing data to HCFA via first class mail, please use the following address:

Health Care Financing Administration
Medicaid Drug Rebate Program
Post Office Box 26686
Baltimore, MD 21207

The following address should be used for express mail:

HCFA, Medicaid Drug Rebate Program
Room 233 EHR
6325 Security Boulevard
Baltimore, MD 21207

STATE CONTACT INFORMATION

Attached is the latest information concerning State contacts. Where known, we have included the State facsimile telephone number.

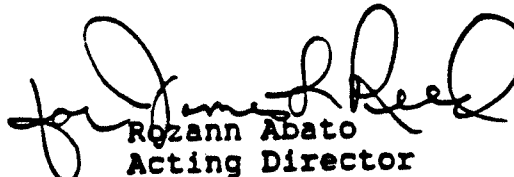
INDIVIDUAL CO-PAYMENTS OR INSURANCE PAYMENTS FOR PRESCRIPTIONS

There are many instances where the costs of Medicaid prescriptions are partially offset by collecting co-payments from Medicaid recipients or by submitting claims to third party insurers. This situation has no bearing on Medicaid rebates which must be computed by using the unit rebate amount and the number of units purchased. However, third party payments and individual co-payments will be subtracted from the Total Reimbursement field amount for affected NDCs.

DRUG PURCHASE PRICES DO NOT DETERMINE REBATE APPLICABILITY

Pharmacies can purchase products directly from the manufacturer or from wholesalers, at special deal prices or at non-profit prices available to entities such as nursing home pharmacies. Because of estimated acquisition cost methodologies, pharmacy price discounts are not always passed to the State Medicaid programs. Therefore, you must remember that prescriptions are not exempt from the stipulations of OBRA 90 based solely on the purchase prices of drugs or payments made by State Medicaid agencies.

Please continue to refer your questions to us by calling the drug rebate hotline at (410) 966-3249.


Rozann Abato
Acting Director
Medicaid Bureau

Attachment

cc: Regional Administrators, HCFA