

February 8, 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