



6325 Security Boulevard
Baltimore, MD 21207

MAR 17 1994

MEDICAID DRUG REBATE PROGRAM

Release Number 38



* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

NEW DRUG LABELER

The following drug labeler is joining the program with an effective date of April 1, 1994:

Glasgow Pharmaceutical Corporation (Labeler Code 60809).

The parent company for this new labeler is Medical Technology Systems, Incorporated which also owns Vanguard Laboratories, Incorporated (Labeler Code 00615). We were told that this new company is a joint venture between Medical Technology Systems and Creighton Products Corporation (Labeler Code 50752), a subsidiary of the Sandoz Corporation. The drug rebate agreement was received by HCFA on March 16, 1994 which normally would call for an effective date of July 1, 1994. However, since the new labeler is a subsidiary of a participating parent corporation, they are being allowed to join the drug rebate program effective April 1, 1994.

SEPARATE MEDICAID DRUG REBATE AGREEMENTS WITH MANUFACTURERS

We are providing the following reminders regarding the proper procedure for obtaining approval for separate Medicaid drug rebate agreements with manufacturers. Most importantly, all separate Medicaid drug rebate agreements between States and manufacturers require HCFA approval. If a State and manufacturer wish to enter into a separate agreement, the State must submit the agreement to the appropriate HCFA Regional Office (RO). The RO performs an initial review of the agreement and submits its recommendation of approval or disapproval to the Medicaid Bureau.

The Medicaid Bureau will then make a determination and notify the RO, which, in turn, will notify the State. The State should then notify the manufacturer of our determination.


If approved, the additional rebates paid to the State under the terms of the separate Medicaid drug rebate agreement must be excluded by the manufacturer from the calculation of AMP and best price. Similarly, the State must report the rebates received under the separate Medicaid drug rebate agreements on the HCFA-64r. If you have any questions on the approval of separate agreements, contact your RO. A separate listing of the contact persons in each RO is attached.

In no case should a State advise a manufacturer that a separate agreement has been approved by HCFA without being notified of the approval by the RO. If a State enters into a separate agreement which is disapproved by HCFA, the State is at risk of loss of Federal financial participation for covering any affected drugs and the manufacturer may not exclude rebates paid under disapproved separate agreements from the calculation of AMP and best price.

COVERAGE AND REIMBURSEMENT FOR THE NEW DRUG, BETASERON

In response to numerous inquiries from States, we are taking this opportunity to provide information on Betaseron, a drug approved by the Food and Drug Administration for the treatment of certain Multiple Sclerosis patients. For purposes of the Medicaid drug rebate program, Berlex Laboratories is the manufacturer of Betaseron. Because of the limited supply of Betaseron, patients who are to receive this drug are selected by the manufacturer. Since Berlex is a participating manufacturer and Betaseron is a covered outpatient drug, States must provide coverage of the drug for Medicaid beneficiaries for whom it is prescribed and, like any other drug, reimburse for it according to the methodology in the State plan. Likewise, rebates are due from the manufacturer in accordance with the rebate agreement.

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

1 Attachment

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

REGIONAL OFFICE DRUG REBATE CONTACT PERSONS

Region I - Boston

Ray Porter (617) 565-1260 Fax 565-1339
Jim Myers (617) 565-1291

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Region II - New York

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