

May 21, 1994

MEDICAID DRUG REBATE PROGRAM

Release Number 40

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All State Medicaid Directors

OMNIBUS BUDGET RECONCILIATION ACT OF 1993 (OBRA '93)

On August 10, 1993, Congress enacted OBRA '93 (P.L. 103-66). The major changes which affect the drug rebate program and drug rebate policy in this area are described in the summary which is attached. (Attachment 1)

CLARIFICATION OF STATE COVERAGE OF PRE-1962 LESS THAN EFFECTIVE (LTE) AND IDENTICAL, RELATED OR SIMILAR (IRS) DRUGS UNDER REVIEW--(DESI Code 3 Drugs)

Prior to the enactment of OBRA '93, section 1927(d)(2) of the Act permitted States to exclude or restrict certain LTE/IRS drugs. These drugs were reported to HCFA by the manufacturer as DESI Code 3.

OBRA '93 amended section 1927(d)(2) of the Act to no longer allow States to have the option to exclude from coverage or restrict these LTE/IRS (Code 3) drugs. A State must cover LTE/IRS drugs of a participating manufacturer which meet the definition of a covered outpatient drug, as defined in the OBRA '93 summary attached, but for which a Notice of Opportunity of Hearing (NOOH) has not been issued for some or all of the drug's labeled indications. This includes LTE/IRS drugs that have not been reviewed by the FDA or are still under review and, therefore a NOOH has not been issued. Federal financial participation funds continue to be available for DESI Code field values 2, 3, and 4 and the drugs are subject to a rebate.

ADDITIONAL COPIES OF RELEASES TO STATE MEDICAID DIRECTORS (SMD)

The drug rebate hotline continues to receive numerous requests for copies of releases which we send to the States. In addition to sending copies to each SMD and each State technical contact via facsimile transmission and United States Postal Service, we have an additional mailing list for various national drug and medical associations and, therefore, cannot accommodate every request to be added to this supplementary list.

We ask that the recipients of our correspondence share this information with other individuals within the State agencies, particularly with outside contractors and fiscal agents such as Electronic Data Systems (EDS). Our policy is to send releases only to the SMDs and those persons identified as being a contact for each State.

Please remember to notify us of any contact changes in order to assure that the proper person receives the releases at the right address in a timely manner. Anyone who needs these program releases, and is not listed in our files as a contact person, should contact their State Medicaid agency to obtain copies of releases.

NEW LABELERS

We received a rebate agreement from Endo Laboratories (Labeler Code 60951) which is a new company owned by the Dupont Merck Pharmaceutical Company. Since their parent company is already a participating labeler, Endo Laboratories will be joining the rebate program retroactive to April 1, 1994.

The following labeler codes have entered into drug rebate agreements and will join the rebate program on July 1, 1994:

Henley International (Labeler Code 57437);

Penn Labs, Incorporated (Labeler Code 58437);

Pecos Pharmaceutical (Labeler Code 59879);

Edyn Corporation (Labeler Code 60619);

Finally Natural Care Corporation (Labeler Code 60762);

Pennex Laboratories, Incorporated (Labeler Code 60814);

ABG Laboratories, Incorporated (Labeler Code 60999); and

Amkas Laboratories, Incorporated (Labeler Code 61073).

The Lannett Company, Incorporated (Labeler Code 00527) will be re-joining the drug rebate program effective July 1, 1994. Please remember that two records (one for the prior period of enrollment and one for the new period of enrollment) are present on the contact file for all reinstated drug labelers.

LABELER TERMINATIONS

We have been unable to contact LPI Holdings, Incorporated (Labeler Code 00454), the parent company of Lexis Laboratories. Mail was returned as undeliverable and the telephone number has been disconnected. It is apparent this company is no longer in business. Therefore, this labeler is being terminated effective July 1, 1994.

Trinity Technologies Corporation (Labeler Code 53020), which filed for Chapter 7 bankruptcy, is being terminated effective July 1, 1994, for failure to submit pricing data for calendar quarters 3/93 and 4/93.

Genetco, Incorporated (Labeler Code 00302) submitted a new drug rebate agreement which was effective on January 1, 1994. However, the company has requested termination from the program and we are terminating this labeler effective July 1, 1994.

STATE UTILIZATION TAPES

There are many States that continue to be late in submitting to HCFA the quarterly tapes containing the utilization data invoiced to drug labelers. The latest version of the System Performance Review contains a new factor (28) pertaining to the timely submission of the utilization data tape and the notice to HCFA that a tape has been sent.

Information from your data tapes is used to generate the annual drug rebate and the quarterly best price reports that are submitted to the Congress. Your timely submission of the utilization tapes and your cooperation is greatly appreciated. A copy of the latest State Tape Status Report is attached.

QUARTERLY REPORTING OF DRUG REBATE DATA ON FORM HCFA-64.9r

In our review of drug rebate data reported for the quarter ending December 31, 1993, we found that too many States are not adhering to the reporting requirements for page 2 of the Form HCFA-64.9r as shown in the State Medicaid Manual in Section 2500.6 on page 2-114.8. We are using that information to see where your rebate dollars are being held in an effort to track the top 15 to 20 disputing drug companies and get disputes resolved. Your identification of the drug labelers on page 2 of the HCFA-64.9r will enable us to concentrate our efforts in resolving those disputes where the most dollars are at stake.

REBATES LESS THAN ADMINISTRATIVE COSTS

As we advised all States in Release Number 19, dated May 18, 1992, in any quarter, States need not invoice a manufacturer for rebate amounts that do not exceed the administrative costs associated with preparing the invoice. We consider rebate amount requests of \$10 or less to meet this tolerance. States may set a smaller tolerance and should maintain documentation of instances when the tolerance is applied. While the application of this tolerance is optional, we believe a reminder may be in order since we recently received copies of invoices for amounts less than \$1.00.

TWO MONTHS FREE COVERAGE OF BETASERON

Berlex Laboratories, the manufacturer of the drug Betaseron, offers two months free coverage of the drug to patients taking the drug for ten months. This offer is extended to all patients, including Medicaid beneficiaries. PCS, Inc., the company which administers all aspects of the distribution of Betaseron, monitors the dispensing of the drug on a patient-by-patient basis through its pharmacy network. The system is supposed to automatically alert the pharmacist to collect no payment for the two months of free coverage. We recommend, however, that each State agency notify its pharmacies that Medicaid claims for the two free months should not be submitted. Since the drug has been marketed for several months, each agency should send out the reminder notices soon.

PUBLIC HEALTH SERVICE (PHS) DATA FILES

Effective with the pricing tape for 1-94 calendar quarter, you will receive a copy every quarter of the PHS covered entity data that are available via the PHS bulletin board. This third data set on the pricing tape contains the following three files:

1. FOREIGN.FCCART.FUNDAFIL (cartridge)
FOREIGN.FSTAPE.FUNDAFIL (tape)
2. FOREIGN.FCCART.MEDICAID (cartridge)
FOREIGN.FSTAPE.MEDICAID (tape)
3. FOREIGN.FCCART.ENTITY (cartridge)
FOREIGN.FSTAPE.ENTITY (tape)

The record specifications for the three files are attached. Questions concerning the data should be directed to the PHS at (301) 594-4354

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 3, 1994 through May 9, 1994 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

5 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

FAB134:ABeachley, 63325, CHolmes, 63326, 3-28-94, 3-29-94,
4-29-94,5-5-94, 5-9-94, 5-13-94, 5-17-94
HOTFAX40.WP