

August 1, 1994

MEDICAID DRUG REBATE PROGRAM

Release Number 41

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

NOTE TO: All State Medicaid Directors

REJECTION OF STATE RECORDS MATCHING LESS-THAN-EFFECTIVE (LTE) DRUGS

Effective with processing State utilization tapes received on or after March 8, 1994, HCFA began rejecting State records that matched HCFA records having a DESI Code field value of "5" or "6." As you are aware, federal financial participation funds are not available when State Medicaid agencies reimburse pharmacies for dispensing LTE drugs.

There will be situations where State records will be rejected inadvertently for this condition because a drug product could have been classified as an effective drug at the time the drug claim was paid by the State but can now be rated as LTE when the State utilization tape for that calendar quarter is received and processed by HCFA.

State records in this category should be re-submitted to HCFA with a value of "2" placed in the correction field located in position 79 of the State utilization record. This will allow the record to properly post to the HCFA system. As previously stated, changes to the DESI code field values contained on the quarterly pricing tape are effective for the next calendar quarter that begins after receipt of the tape.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on October 1, 1994:

Marsam Pharmaceuticals, Incorporated (Labeler Code 00209);

Rystan Company, Incorporated (Labeler Code 00263);

U.S. Apothecary (Labeler Code 05940);

Leader Brand Products (Labeler Code 37205);

Gallipot Incorporated (Labeler Code 51552);

D.S.C. Laboratories, Div. of DSC Products, Incorporated (Labeler Code 52316);

Allied-Med, Division of Pharmed Group (Labeler Code 58859);

King Pharmaceuticals, Incorporated (Labeler Code 60793); Please note that this corporation recently purchased the In-Source Williams Company (Labeler Codes 49137 and 51728 which are known as Williams Generics, Incorporated).

Horizon Pharmaceuticals, Incorporated (Labeler Code 60904);

Flemming Pharmaceuticals, Incorporated (Labeler Code 60976);

Welgen - A Division of BW Co. (Labeler Code 61054); and

Yorpharm, Incorporated (Labeler Code 61147); the parent corporation is Apotex, Incorporated (Labeler Code 60505).

#### LABELER TERMINATIONS

The following labelers are terminating effective October 1, 1994:

Freeda Vitamins, Incorporated (Labeler Code 10432);

Advanced Nutritional Technology, Incorporated (Labeler Code 10888);

New York Blood Center (Labeler Code 13143);

Wilcole Pharmaceuticals, Incorporated (Labeler Code 58918);

ADH Health Products, Incorporated (Labeler Code 60142); and

Finally Natural Care Corporation (Labeler Code 60762).

Primus Pharmaceuticals (Labeler Code 55762) was purchased in 1993 by Wakefield Pharmaceuticals, Incorporated which is relinquishing labeler code 55762 back to the FDA. The four products for labeler code 55762 reached their shelf life termination dates in 1993. Please ensure that any invoices for labeler code 55762 are sent to Wakefield Pharmaceuticals (Labeler Code 59310) by January 1, 1995 which is the termination date for labeler code 55762.

#### CORRECT REBATE FOR BURROUGHS WELLCOME PRODUCT

For the 93-4 quarterly prices, there was an error reported for a Burroughs Wellcome drug product, ALKERAN (MELPHALAN) TABLETS (NDC 00081-0045-35). The pricing was corrected prior to the generation of the 94-1 pricing tape but a logic error prevented the correct unit rebate amount (URA) from being computed and hindered the creation of prior period adjustments (PPAs) on this drug product. Correct PPAs will be included for this drug product on the 94-2 pricing tape.

#### DATASET NAME CHANGES ON QUARTERLY REBATE TAPES

The HCFA Data Center recently instituted new naming conventions for (foreign) tapes being sent out from the HCFA Data Center. The changes affect the dataset names on the quarterly drug rebate tapes. We are including the new names as Attachment 1 to this note.

#### NEW DRUG PRODUCTS

It has come to our attention that some States continue to refuse to pay for any new drug product from participating drug labelers. Each participating drug labeler is identified by its labeler code which makes it easier for States to make coverage determinations on new

drug products. Drug labelers are told that unless selected drug products are specifically excludable by law, their complete inventory is covered for rebate purposes. States cannot arbitrarily withhold or delay coverage of new drug products of participating drug companies that are not specifically excludable in section 1927(d) of the Social Security Act.

Drug labelers often find it difficult to sell new products or new package sizes of existing products in many States because the NDC is not currently on a State's data base. States should tell their pharmacy communities that unless specifically excluded by State notification, all drug products of a participating drug labeler identified by NDC are covered by the drug rebate program except that States may exclude some package sizes of a drug if the drug is available in more than one size. States are free, however, to subject any drug, including new drugs, to prior authorization if the State meets the requirement for such programs.

Any questions concerning new drug products should be referred to the technical contact at each drug labeler. Updated contact information is provided to the States each quarter by HCFA. If, after contacting the drug company, you still have questions about a new drug product, you should call the drug rebate hotline at (410) 966-3249.

#### NORPLANT REPLACEMENT KITS

Wyeth-Ayerst Laboratories, manufacturers of Norplant (NDC 00008-2564-01), has a Norplant Patient Support Program whereby a replacement kit will be supplied to a physician when a Norplant removal occurs within 180 days of insertion. The manufacturer has indicated that the physician will contact their Wyeth-Ayerst manager to complete the appropriate form to receive a replacement kit, which will be sent directly to the physician.

Medicaid claims for Norplant removals occurring within 180 days of insertion should be examined to determine whether the drug costs should be adjusted to reflect the replacement kit. This will assure that the Medicaid billing and rebate claim(s) are correct. If States have any other arrangements with Wyeth-Ayerst concerning the Norplant replacement kits, please make sure that the arrangement, likewise, assures the correctness of the Medicaid billing and rebate claim(s).

States may contact their Wyeth-Ayerst State Government Relations Manager for more information on the Norplant Patient Support Program or write to:

Michael Josephson  
Assistant Vice President of Trade  
and State Government Relations  
555 E. Lancaster Avenue  
St. Davids, PA 19087

OTHER ATTACHMENTS

Copies of the State Tapes Status Report, topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 3, 1994 through July 25, 1994 are attached.

STATE CONTACT NAMES

We are receiving complaints from drug labelers that the persons designated as the technical and/or policy contact people in some States are not the people that, ultimately, provide the answers to drug labeler questions.

Therefore, we ask that you review the names shown as the contact persons in your State and ensure that they are the people that can answer the questions in those areas. (e.g. Can the technical person answer a question concerning a selected item on your invoice to the manufacturer? If not, you should consider changing the technical contact to the name of the person who can answer the question.)

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

4 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

## STATE REBATE DATASET NAME CHANGES

For Data Cartridges:

OLD NAMES: FOREIGN.FCCART.DRqyy.xx - Rebate File  
 FOREIGN.FCCART.LABELER.CONTACT - Labeler Contact  
 FOREIGN.FCCART.ENTITY -----3  
 FOREIGN.FCCART.FUNDAFIL 3 - PHS Files  
 FOREIGN.FCCART.MEDICAID -----3

NEW NAMES: FOREIGN.OPCART.DRqyy.xx - Rebate File  
 FOREIGN.OPCART.LABELER.CONTACT - Labeler Contact  
 FOREIGN.OPCART.ENTITY -----3  
 FOREIGN.OPCART.FUNDAFIL 3 - PHS Files  
 FOREIGN.OPCART.MEDICAID -----3

For Round Reel Tapes:

OLD NAMES: FOREIGN.FSTAPE.DRqyy.xx - Rebate File  
 FOREIGN.FSTAPE.LABELER.CONTACT - Labeler Contact  
 FOREIGN.FSTAPE.ENTITY -----3  
 FOREIGN.FSTAPE.FUNDAFIL 3 - PHS Files  
 FOREIGN.FSTAPE.MEDICAID -----3

NEW NAMES: FOREIGN.OPREEL.DRqyy.xx - Rebate File  
 FOREIGN.OPREEL.LABELER.CONTACT - Labeler Contact  
 FOREIGN.OPREEL.ENTITY -----3  
 FOREIGN.OPREEL.FUNDAFIL 3 - PHS Files  
 FOREIGN.OPREEL.MEDICAID -----3

q=quarter  
 yy=year  
 xx=state code

FAB134:ABeachley, 63325, 07-11-94, 07-18-94, 07-19-94, 07-21-94,  
07-26-94, HOTFAX41.WP