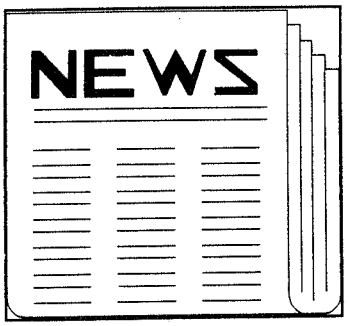
DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

SEP 17 1997



MEDICAID DRUG REBATE PROGRAM Release No. 30

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

NOTE TO: All Participating Drug Manufacturers

LISTING DRUGS WITH THE FDA

It has come to the attention of both HCFA and the Food and Drug Administration (FDA) that not all drug products included with your quarterly drug rebate pricing submission are being listed with the FDA, as required by the FDA's Drug Listing Act.

Determination of a drug product's eligibility for inclusion in the Drug Rebate Program as a covered outpatient drug is based on several factors, including information from the FDA regarding the regulatory status of that drug product. The comparison of HCFA and FDA databases helps assure that a drug company accurately reports all of its drug products for inclusion in the Drug Rebate Program. That is one reason why it is important that manufacturers report accurate drug product information to the FDA's Drug Listing database.

The FDA's Drug Listing Regulations require a drug company to list ALL of its drug products with the FDA within five days after it begins operation. Thereafter, the drug company is required, at a minimum, to report to the FDA any additions, changes and deletions each June and December. We suggest that these (add, change and delete) updates be reported to the FDA prior to submitting them as part of your quarterly pricing submission to HCFA.

Please review your product line to determine any drug products not as yet reported to the FDA. Complete and submit the proper forms to the FDA for these products as soon as possible. Should you have any questions about completing these forms, kindly contact the FDA Information Management Team at (301) 594-1086. All completed forms should be forwarded to:

Food and Drug Administration
Information Management Team, HFD-95
5600 Fishers Lane
Rockville, MD 20875

CLARIFICATION OF BEST PRICE AND AVERAGE MANUFACTURER PRICE CALCULATIONS FOR PHARMACY BENEFIT MANAGERS - MANUFACTURER RELEASE NUMBERS 28 AND 29

We have been informed that there may have been some confusion concerning the intent of the information published in Manufacturer Release Numbers 28 and 29 pertaining to the Best Price and Average Manufacturer Price Calculations for Pharmacy Benefit Managers (PBMs). This information was published to clarify, not change or further confuse, the issue with respect to the inclusion or exclusion of sales to and through PBMs. HCFA intended no change to the requirements of the drug rebate program by our latest release. We are currently re-examining the issue and hope to clarify our position in the near future.

VITAMINS AND NON-DRUG PRODUCTS

As a general rule, only those vitamins that are prescription vitamins meet the definition of a covered outpatient drug, as defined at section 1927(k)(2)(A) of the Social Security Act (the Act). The Food and Drug Administration (FDA) staff have informed us that only prescription vitamins should be assigned National Drug Codes (NDCs). Generally, nonprescription vitamins are considered dietary food supplements, not drugs, and should not have NDCs assigned to them. Based on the FDA's criteria and the definition of a covered outpatient drug, over-the-counter (OTC) vitamins would not be considered covered outpatient drugs. At state option, prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations, may be excluded or restricted for coverage as stated in section 1927(d)(2) of the Act.

If any of your non-drug products (vitamins or other products) have been improperly assigned an NDC and included in your submission of covered outpatient drugs to the HCFA, please notify HCFA staff so that those items can be deleted from the HCFA and state data systems. Any changes should also be reported to the FDA Information Management Team at (301) 594-1086.

HCFA and FDA personnel have been working cooperatively to share this type of pertinent drug product information to assure that both databases are as accurate as possible. Future plans will include a cooperative effort to identify data inconsistencies and notification of appropriate manufacturers.

NEW PHONE NUMBER FOR DIANE DUNSTAN

Diane Dunstan, HCFA Denver Regional Office Drug Rebate Coordinator, has a new telephone number. That number is: **(303) 844-2121 x452.** Please make a note of Diane's new number. The telephone number for her facsimile machine remains unchanged at (303) 844-3753.

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of December 30, 1996 through September 8, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18 or section "O" of the operations guide.

Wilbert C. Beachley

for Sally K. Richardson
Director
Center for Medicaid and State Operations

2 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid