

June 29, 1994

MEDICAID DRUG REBATE PROGRAM Release No. 12

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



NOTE TO: All Participating Drug Manufacturers

REPORTING REQUIREMENTS FOR ALL DRUG LABELERS

At the end of every calendar quarter, we continue to experience difficulty in receiving pricing data from a number of participating drug labelers. Additionally, we have encountered many instances where data for selected drug products have not been submitted.

Therefore, we are reiterating the reporting requirements for all drug products.

These requirements are set forth in the drug rebate agreement, Part II, Manufacturer's Responsibilities, which were agreed to by each participating drug labeler upon entering into the drug rebate agreement.

1. Deadline for Submitting Drug Pricing Data

Data pertaining to the average manufacturer price (and the best price for innovator drugs) are due to HCFA within 30 days after the end of each calendar quarter. Even drugs which had no sales for that quarter are to be reported using pricing data identical to the previous quarter. Over 30 drug labelers have been terminated for failure to comply with this requirement.

2. Drug Product Reporting

All drug products marketed by a drug labeler that are identified by a National Drug Code (NDC) are to be reported even when they are intended for inpatient use only. Too often, we find that treatment for a specific medical condition or the prescribing of medications to treat that condition have been shifted to an outpatient setting. In these situations, while we expect the drug labeler to question the place of service where the drug product was dispensed, the drug labeler should ensure that the product and pricing data for that drug product have been reported to HCFA.

3. Reporting Correct Data for Less-Than-Effective (LTE) or Identical, Related or Similar (IRS) Drugs

A study recently concluded by the Office of the Inspector General (OIG) in Philadelphia found over 200 NDCs that had been incorrectly identified as effective drugs. The Food and Drug Administration (FDA) confirmed the OIG findings and has shared the data with HCFA. We are changing the DESI Code field values for approximately 115 NDCs to a "5" and have notified each affected drug labeler. Additionally, there were about 85 NDCs not reported to HCFA that the FDA identified as LTE/IRS. We will be sending notices to each drug labeler that failed to report one or more LTE/IRS drugs.

We urge every drug labeler to ensure that the information reported to HCFA for any drug product is complete and accurate. Manufacturers are responsible for knowing the status of LTE/IRS drugs by reviewing DESI notices published in the Federal Register by the FDA.

The OIG will initiate on-site audits of drug labelers in the near future to ensure that correct information is being submitted to HCFA. In accordance with section 1927(b)(3)(C)(ii) of the Social Security Act, the OIG has the authority to impose Civil Monetary Penalties (CMPs) up to \$100,000 for each item of false information that was knowingly provided to HCFA. In addition to CMPs, HCFA could terminate a manufacturer's rebate agreement because it is not in compliance with section 1927 of the Act and the national rebate agreement.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1994 through June 27, 1994. By law, these rates are to be used to calculate interest owed States on overdue rebates.

REBATE PERCENTAGES FOR 1994

As stated in Public Law 101-508 dated November 5, 1990, the rebate percentage for non-innovator drugs changes to 11% for calendar quarters beginning after December 31, 1993.

The percentage to use for the basic rebate for innovator drugs in 1994 is 15.4%.

TOPIC INDEX

For your convenience, attached also is an index by topic of all topics covered in prior releases to you.

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

2 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators Division of Medicaid