August 9, 1991

Release No. 2

NOTE TO: Participating Drug Manufacturers

SUBJECT: Medicaid Drug Rebate Program

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

On July l5, we provided to all States an updated data file for the January-March l99l quarter. The file reflected all additions and corrections we received from you through July l1. Attached for your information is a copy of our July 22 letter to all States, which transmitted a summary record that we recommend States use if they elect to include a summary record with their utilization reports to you. Both States and manufacturers had suggested we develop a standard summary record, to promote uniformity in State reporting. As we emphasized in the July 22 all-State letter, we strongly encourage, but do not require, States to use this summary record format. In contrast, we do require that States send their quarterly utilization data to you using the record formats for both paper and electronic reporting that we distributed last Spring. Those record formats were distributed with our April 25 letter to participating manufacturers, and are also included with the attached July 22 State letter.

Reporting Requirements

Please note that Section II of the Rebate Agreement requires each participating manufacturer to submit to HCFA a listing of all covered outpatient drugs and other information described in Appendix A to the Agreement, within 30 days of signing the rebate agreement. The manufacturer must update all this information within 30 days after the end of each quarter; (e.g., April 30, July 30, October 30 and January 30 for the quarters ending March 3l, June 30, September 30 and December 31, respectively). **The Average Manufacturer Price (AMP) is calculated as a weighted average based on sales, whereas the Best Price (BP) is the lowest price for a drug product in any package size for any quantity sold. It is not weighted but represents the single best price (that is not nominal) at which any package size of the product was sold in the quarter.**

Each quarterly update is to include baseline data for new NDCs, as well as AMPs, and BPs (only for single source/multiple source innovator drugs) for all NDCs, including both new drugs and those drugs which are no longer marketed, but still have an active shelf life. It is important that you anticipate receiving rebate claims for terminated drug products for up to one year after the effective shelf life ends since States are submitting their utilization data based on date paid rather than date of service. Changes to baseline data must include all data for each affected NDC, rather than only those data elements which have changed since the previous quarterly submission.

Failure to provide the required data on a timely basis can result in termination of your Rebate Agreement, in accordance with Section VIII of the Agreement. Section IV of the Agreement further provides for fiscal penalties for failure to provide timely information, such as AMPs, BPs, or Base Date AMPs. Your timely submission of quarterly data also is critical if HCFA is to provide States with a complete update file 45 days after the end of each quarter. The States in turn can use our updated file in preparing the utilization reports which are due to you no later than 60 days after the end of the quarter. The more complete and prompt your quarterly product and pricing data updates, the more comprehensive and accurate will be the current quarter update files we send to all States. The result will be smoother operation of the program, and fewer retroactive adjustments to your data and to rebates.

Discounts and Other Price Arrangements

We are taking this opportunity to highlight and discuss the subject of discounts or other price arrangements. As stated in paragraphs I(a) and I(d) of the rebate agreement, you must revise AMPs and/or BPs to reflect the impact of cumulative discounts or other arrangements on the prices actually realized in any quarter. The impact of such arrangements must be distributed appropriately across all quarters affected by them, rather than be assigned entirely to a single quarter.

For example, a discount applied at the end of a calendar year to sales made throughout that past year may not be assigned only to the fourth quarter of the year, and only that quarter's AMPs and/or BPs be revised. Rather, the retroactive discount must be distributed to the four quarters of the year to which it is applied, based upon units sold in each quarter. Revised AMPs and/or BPs for each of the four quarters should then be calculated and reported to HCFA on a timely basis, as specified in II(e) of the Rebate Agreement.

Modification of Unit Rebate Calculation

You will note that the attached July 22 letter includes a minor revision on page 3 of the unit rebate calculation. The revision is to specify that no additional rebate, due to an NDC price increase exceeding the rate of growth of the CPI-U, is to be calculated prior to the first full calendar quarter in which a new product is on the market. Our original unit rebate calculation methodology called for calculation of an additional rebate for the actual quarter in which the new drug entered the market.

Common Data Errors

Due to the many companies still encountering problems in determining the correct way to complete the Units Per Package Size (UPPS) field, use the following guidelines:

1. Enter a number other than "1" only where the package size that you sold contains the smallest dispensable number of units for that product identified by the NDC.

Example: The unit type is a tablet, the NDC is for a package size holding 20 tablets, and the pharmacist is expected to dispense the entire container, rather than dispensing a smaller number of tablets from it. The appropriate entry in the UPPS field is "20."

2. Where the number of units in the package size is such that the pharmacist is not expected routinely to dispense the entire package to the retail customer, the appropriate entry in the UPPS field is "l".

   Example: The unit type is a tablet, the package holds 500 tablets and the normal quantity prescribed by the doctor and dispensed by the pharmacist is fewer than 500 tablets. The UPPS entry should be "l".

Additionally, you should review the **Unit Type** field for each NDC to ensure that it is correct. We have seen numerous examples of liquid drug products with something other than "ML" or "CC" given as the Unit Type. While the strength of the drug product is shown by some manufacturers in the product name field, we expect the Unit Type for liquids to be "CC" or "ML." Corrections to baseline or pricing data for any drug product must be forwarded to HCFA as soon as possible.

Also, we are taking this opportunity to emphasize that, in accordance with FDA regulations, a drug form includes dosage form or strength. Therefore, a new product code in the NDC is required in any case when a drug is sold in a different form or strength. For example, it is inappropriate to use the same product code for both liquid and tablet forms of a drug. We expect manufacturers to take the necessary action regarding proper product code assignment.

We are receiving many inquiries from States questioning specific unit rebate amounts, all of which we calculated based on the AMPs/BPs you submitted to us. In many of the questioned cases, we find that the manufacturer calculated the AMPs/BPs based on package size rather than the unit type. Naturally, this results in our calculating greatly inflated unit rebate amounts for the affected NDCs, which in turn results in similarly inflated rebates being requested by the States. **Remember that HCFA relies on the individual manufacturers or labelers to furnish the correct information for each drug product.** If your review of State data indicates that specific NDC rebate amounts are in error because of incorrect data supplied to HCFA, rather than questionable State utilization data, you should:

1. Review the entire set of data elements supplied to HCFA for that drug product, and **prepare corrections for each drug product, as necessary;**

2. Prepare an explanation to the State and apply the correct data to compute the rebate amount owed to the State; and,

3. Notify HCFA by submitting the necessary drug product or pricing information corrections as soon as possible.

Parenteral/Enteral Products

We have information concerning parenteral/enteral nutritional products. This issue was discussed with the Food and Drug Administration (FDA). Their staff has informed us that only parenteral products given by the intravenous (IV) route of administration are approved as a drug under section 505 of the FDA Drug and Cosmetic Act. Therefore, only parenterals administered in this manner can be considered outpatient drugs and, therefore, covered by the drug rebate program.

Enteral nutritional products are not considered covered outpatient drugs. Therefore, enteral products are not covered by the drug rebate program, but can be covered by a State Medicaid program at its option. We recognize that certain nutritional products may serve as therapeutic agents for life and health maintenance. Typical services which could provide such nutritional components include outpatient hospital services, home health services (when the nutrients constitute a medical supply), clinic services, rural health clinic services, etc. While not covered under the drug rebate program, State coverage of enterals under Medicaid remains optional.

CPI-U Values

Finally, listed below are the CPI-U values used in our calculation of additional rebate amounts pursuant to Section II of the attached rebate calculation methodology:

September	l990	l32.7	January	l99l	l34.6	May	l99l	l35.6
October	l990	l33.5	February	l99l	l34.8	June	l99l	l36.0
November	l990	l33.8	March	l99l	l35.0			
December	l990	l33.8	April	l99l	l35.2			

The latest information on CPI-U is available by calling the Drug Rebate Hotline at (301) 966-3249.

Christine Nye
Director
Medicaid Bureau

Attachment

cc: State Medicaid Directors
All HCFA Regional Administrators
All HCFA Associate Regional Administrators
for Medicaid