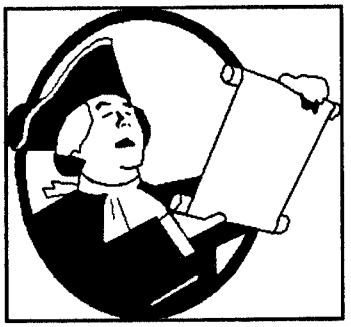
DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

JUN 14 1991

MEDICAID DRUG REBATE PROGRAM Release No. 9



NOTE TO: All State Medicaid Directors

* * * IMMEDIATE ATTENTION REQUIRED * * *

This notice is to inform you of one additional drug labeler code, 13143, that will be effective for the period beginning January 1, 1991. While we regret the lateness of this announcement, the delay was unavoidable. The rebate agreement was postmarked on April 30. Markings on the envelope indicate that it was misdirected to the Social Security Administration. It was not received by us until last week.

Labeler code 13143 belongs to:

New York Blood Center, Inc.
155 Duryea Road
Melville, New York 11747

The legal, financial and technical contact information for this drug labeler is on a separate sheet attached to this notice. We ask that you disseminate this information to the pharmacy community as soon as possible.

On June 10, we sent a notice to each drug labeler to inform them of the 60 day hold harmless period that was given to each State. With that notice, we included: 1) A copy of the names, addresses and telephone numbers of State technical and policy contacts; 2) A copy of the rebate calculation procedure used by HCFA; 3) Copies of the electronic and paper formats to be used by the States when transmitting data to drug labelers; and, 4) A one page information sheet on the Consumer Price Index to provide you with a better understanding of the rebate calculation. We have included the notice to the drug labelers plus this one page information sheet with this notice.

Our staff continue to receive corrected data plus new baseline and first quarter pricing data from drug labelers on a daily basis. At this point in time, our objective to mail a complete new data base to you by July 15 appears to be attainable.

Please continue to refer your questions to us by using the Drug Rebate Hotline number at (301) 966-3249.

Christine Nye
Director
Medicaid Bureau

Attachments: 3

cc:
All State Technical Contacts
All Regional Representatives
All Associate Regional Administrators for Medicaid

New York Blood Center, Incorporated
Labeler Code 13143

Legal Contact:

Miriam Sparrow
(212) 570-3009
310 East 67th Street
New York, New York 10021

Financial Contact:

Thomas J. O'Connell
(516) 752-7335
155 Duryea Road
Melville, New York 11747

Technical Contact:

George M. Agnew
(516) 752-8277
155 Duryea Road
Melville, New York 11747

Data Transmission Option: Diskette

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

JUN 10 1991

TO: All Participating Medicaid Drug Rebate Manufacturers

SUBJECT: Medicaid Drug Rebate Program

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

On May 31, we notified each Medicaid State Agency of our decision to hold States harmless, until July 30, 1991, from the statutory requirement to send their January - March quarterly drug utilization data to participating drug manufacturers by the end of May.

Due to delays in the development of reporting formats, receipt, verification and correction of data, as well as the need to discuss many of these issues with the States and selected manufacturers, we believe this decision is the most feasible to ensure better reporting.

In an effort to afford manufacturers, States and ourselves the opportunity to make the necessary data corrections, and thereby reduce anticipated problems concerning the amounts to be rebated, we are working with manufacturers and States to resolve specific data problems.

By mid-July, we will send to all States a revised data set so that they, at their option, can send to manufacturers by July 30 the utilization data for the first calendar quarter.

I emphasize that HCFA is permitting but not requiring States to delay until July 30 sending you the January-March utilization data. We are aware that some States have already sent manufacturers the first quarter data, and others may do so in the coming weeks, without waiting for HCFA's mid-July revised data set. The law requires you to calculate and make rebate payments within 30 days of receipt of the State's report of the number of units paid for in the subject quarter, by NDC.

If you believe a State's first utilization report may be preliminary, and subject to revision by the State after it receives our mid-July updated data, you must nonetheless make a rebate payment based upon the initial report unless the State, within the 30-day period and in writing, authorizes you to ignore its initial utilization report and await another that the State will send by the end of July.

Similarly, you must make rebate payments within 30 days of receipt of a State's utilization report, even though you may have recently sent corrected data to HCFA that will ultimately require revision of the States' utilization reports for that quarter.

Several manufacturers have asked what documentation HCFA expects you to send to States with the rebate payment. We plan no standardized requirements in this area, though clearly the rebate payment should be accompanied by an explanation of how it was calculated (unless the State included in its utilization report to you a total rebate amount claimed for all your products, and your rebate payment reflects your acceptance of that claim exactly as submitted).

Enclosed for your information are the following:

- A listing of the names, addresses and telephone numbers of the technical and policy contacts for each Medicaid State Agency for purposes of the drug rebate program.

- The methodology used by HCFA to calculate unit rebate amounts for each NDC. A copy of this methodology (not including the supplemental page on the Consumer Price Increase) was sent to all States on May 24.

- The magnetic media and hard copy data record formats HCFA requires States to use in sending utilization data to manufacturers and HCFA. These same formats were sent to all States on April 16, and to participating manufacturers with our April 25 letter.

We anticipate that most States will want to include a summary record with their quarterly utilization reports to manufacturers. In order to promote consistency in this area, we will shortly recommend to all States a standard way to modify the prescribed magnetic media data record format (enclosed) in order to use it as a summary record. HCFA will not require States to transmit a summary record or to use our approach if they prepare their own. We are merely providing a model for consideration.

If you have any questions regarding either the format or data associated with a State's utilization report, please contact the State directly (using the attached contact list of State representatives, if appropriate) to resolve such issues.

Finally, I ask that you review very carefully the rebate agreement and related instructions. While some problems are inevitable when a program of this size and complexity is implemented in a short timeframe, we are finding that a great many of the errors in manufacturer data submissions appear to reflect simply a failure to correctly apply HCFA's data reporting instructions. Again, should questions arise, please continue to contact us by calling the Medicaid Drug Hotline at (301) 966-3249.

Manufacturers representing over 340 labeler codes are participating in the Medicaid drug rebate program effective January 1, 1991. A number of additional manufacturers are due to start participating effective July 1. The overwhelming manufacturer response is highly gratifying, and we look forward to working with you and the States to make the operation of this program smooth and beneficial to all parties.

Sincerely yours,

Christine Nye
Director
Medicaid Bureau

3 Enclosures

CONSUMER PRICE INDEX INFORMATION

The following information is not included in the description of the rebate calculation but is general information that should enhance a better understanding of the rebate calculation.

Base Consumer Price Index-Urban - included in the Rebate Agreement in Section I, Definitions.

It is the CPI-U for September, 1990. For drugs approved by the FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed. The "month before in which the drug was first marketed" is the data element, "Date Entered Market."

In describing the use of CPI-U in the rebate calculation, the cover letter of February 11 specifies that:

> "An additional rebate must be paid on a drug-by-drug basis in the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990 to the month before the calendar quarter of the rebate."

The system assumes that the additional rebate is calculated from the Base CPI-U for each National Drug Code (NDC), which can be different depending on the Date Entered Market, to the CPI-U for the month before the beginning of the period covered. For instance, for the January - March 1991 quarter, the additional rebate amount was calculated using the increase from Base CPI-U of the NDC to the CPI-U for December, 1990.

The exact CPI-U values that were put into the system for the first quarter's calculations are:

September, 1990	132.7
October, 1990	133.5
November, 1990	133.8
December, 1990	133.8
January, 1991	134.6
February, 1991	134.8
March, 1991	135.0

These CPI-U values accounted for all available values from September 1990 to the date on which the rebate calculations were run. (Source: Bureau of Labor and Statistics)