DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

DEC 05 1993

NEWS

MEDICAID DRUG REBATE PROGRAM Release No. 9

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

OMNIBUS BUDGET RECONCILIATION ACT OF 1993 (OBRA'93)

On August 10, 1993, Congress enacted OBRA'93 (P.L. 103-66). The major changes which affect the drug rebate program and drug rebate policy in this area are described in the summary which is attached. Please pay particular attention to those sections in the summary which explain changes to the baseline Average Manufacturer Price (AMP) and the base Consumer Price Index - Urban (CPI-U) since they impact on the computation of the Unit Rebate Amount (URA) for drugs approved after October 1, 1990. A second attachment, DRUG REBATE CHANGES, describes how the OBRA'93 changes affect the computation of the URA.

UNIT TYPE CONVERSION DATE CHANGED

We are accelerating the unit type conversion process because we must make additional significant changes to comply with OBRA'93 requirements. Unit types that change from a milligram (MG) to a gram (GM) will result in the need to change the Average Manufacturer Prices (AMPs) and best prices (BPs) for all prior quarters. On page 6 of our release #7 dated April 29, we indicated that labelers would be responsible for computing and submitting the changes to AMP, BP and units per package size (UPPS).

**NOW, HCFA WILL ASSUME THAT RESPONSIBILITY AND WILL ELECTRONICALLY COMPUTE THE AMP, BP AND BASELINE AMP FOR UNIT TYPES BEING CONVERTED BY HCFA FROM MGs to GMs. PRIOR PERIOD ADJUSTMENTS WILL NOT BE ELECTRONICALLY GENERATED TO THE STATES FOR THESE CONVERTED UNIT TYPES.**

Currently, there are over 250 drug labelers that submit their quarterly prices on diskette. Since we do not want to release two different versions of the diskette program within a 60 day period, we are combining the unit type conversion and the OBRA'93 changes. Diskette users will receive converted master files on their diskettes and will not need to convert their unit types.

The new unit types will be effective for the calendar quarter ending December 31, 1993. Quarterly prices for all drug products will be due to us no later than January 30, 1994.

**NOTE: DISKETTE SUBMITTERS MUST USE THE NEW PROGRAM (Version 3.0) TO GENERATE THEIR 93-4 QUARTERLY PRICING FILES. YOUR CONVERTED FILE MUST BE UPLOADED AND THE NEW PROGRAM INSTALLED PRIOR TO KEYING YOUR PRICING DATA. PRICING FILES SUBMITTED USING OTHER THAN Version 3.0 OF THE DISKETTE PROGRAM WILL BE RETURNED AS INVALID SUBMISSIONS.**

Drug labelers that submit their prices via telecommunications or on paper can obtain a diskette copy of their converted master files by calling the drug rebate hotline at (410) 966-3249.

## MARKET DATE AND FDA APPROVAL DATE

During the past 30 days, you may have received up to three different notes relating to the Date Entered Market and FDA Approval Date data fields. These data fields are very important to implementing OBRA'93 changes. Missing or corrected information must be received by HCFA no later than Monday, December 20, 1993.

### Date Entered Market

This date must be the actual date that the drug entered the market. Prior to OBRA'93, our specifications asked for the first day of the first full month; OBRA'93 changed this requirement to be the actual date the drug entered the market.

### FDA Approval Date

OBRA'93 requires that this date be entered for all drugs approved after October 1, 1990.

## STATE REMITTANCE ADVICE CONTACTS

We are attaching the latest listing of State drug rebate personnel to be used when contacting State Medicaid agencies. At the suggestion of drug labeler personnel, the State Medicaid agencies have furnished the name, telephone number, facsimile number and address of the State contact to which all checks and remittance advice reports are to be sent.

## LATE SUBMISSION OF QUARTERLY PRICES

During the past year, we made a concerted effort to contact and explain the quarterly reporting requirement to any drug labeler that was tardy for more than one quarter in submitting their prices to us. This exercise resulted in 25 drug labelers having their agreements terminated.

For the quarter which ended on September 30th, it was necessary to contact more than 50 drug labelers that had not submitted their quarterly prices. We are finding it necessary to generate termination warning notices to about 18 drug labelers, which despite repeated telephone calls, have failed to submit timely pricing data in the correct formats. **Remember, your prices must be submitted to HCFA within 30 days after the end of each calendar quarter.**

## ADDING NEW PACKAGE SIZES TO EXISTING PRODUCTS

There has been a lot of confusion concerning what to send to HCFA on a quarterly update when adding a new package size of an existing product.

The pricing philosophy of the drug rebate program deals strictly with your "products" (NDC2) regardless of the number of different package sizes (NDC3). This is the reason you must develop an AMP which is weighted based on the sales of all package sizes for a product code and averaged so that all package sizes (of the same product) contain the same AMP (and best price for innovator drugs).

When adding a new package size to an already existing product, you must follow this procedure: 1) The new package size must be established as if it existed as long as the old package sizes;

2) The baseline data (including the BL/AMP and the Market Date) must be established with the same information as the existing or old sizes (this will keep the CPI-U value consistent for 'S' and 'I' drugs); and (3) Quarterly data must be included for all old quarters for as long as the original package sizes have been marketed. This is necessary because the HCFA automated system will begin generating notices requesting quarterly data for any prior quarter where the data are missing.

**EXAMPLE**

NDC 12345-6789-01 is a product that was in existence when the drug rebate program started. Baseline AMP = .123456 per ML and the Market Date = 10/01/90. On June 10, 1993, a new package size (NDC 12345-6789-02) was marketed.

When establishing this new package size with HCFA, the Baseline AMP would = .123456 and the Market Date would = 10/01/90. Quarterly pricing data (AMP & BP) must be submitted for all quarters, beginning with the 91-1 quarter and continuing to the present quarter. This pricing data must match the old package size(s) for each quarter.

Beginning with quarter 93-2, all sales for this new package size would be included in the calculation for the AMP, and the lowest price sold for any package size would be considered for the BP.

## WEEKLY U.S. TREASURY BILL DISCOUNT RATE

Included with this release is a listing of the 90 day treasury bill auction rates for the period January 7, 1991 through December 6, 1993.

## TOPIC INDEX

We have included a topic index for the information covered in all prior releases to you.

## STATE DELETION OF SPECIFIC LABELER CODES

At the request of a number of States and manufacturers, we have determined that it is allowable for a State to drop certain labeler codes whose drugs are definitely not marketed in that

particular State. These deletions may occur only after the State and manufacturer have entered into a written agreement which specifies that their products are not marketed in the State and that their labeler code will not be carried on the State's Medicaid data file. The State or manufacturer may cancel the agreement and restore those manufacturer's products to the file if it is found that, in fact, the manufacturer's drugs are being marketed in the State.

Please note any such agreement to drop labeler codes between a State and a Manufacturer has no effect on the Manufacturer's responsibilities to report pricing data to HCFA for all of their NDCs. A copy of each such agreement should be sent to HCFA at Post Office Box 26686, Baltimore, Maryland 21207.

## KEEPING THE DRUG COMPENDIA INFORMED

It is important for all Manufacturers to keep the drug compendia (Red Book, Blue Book, MediSpan, etc.) updated, on a routine basis, with their current drug file. The vast majority of States use one of these compendia to supply information for some or all of their drug data (except rebate pricing information). In an attempt to keep drug data uniform with the Medicaid Drug Rebate database, the reporting of events such as product deletions, terminations and additions is essential to HCFA and compendia sources.

## REBATE PAYMENTS

As a reminder, manufacturers must pay rebates on all undisputed data. If a manufacturer disputes specific utilization data, the manufacturer must identify, by individual NDC number, the utilization data in question and the methodology used for disputing data. Should a manufacturer believe any State utilization data to be overstated, the appropriate response is to pay a rebate for an amount or level of utilization considered reasonable, while disputing the balance. This will assist States in timely processing of disputes.

We actively encourage States and manufacturers to meet and review detailed utilization data in order to resolve backlogs of disputes and, hopefully, to develop workable approaches and dialogue that will result in fewer disputes in the future.

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

5 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators for Medicaid

ATTACHMENT 2

## OBRA'93 - DRUG REBATE CHANGES

The Omnibus Budget Reconciliation Act of 1993 (OBRA'93) includes changes in the Drug Rebate Program that affect values maintained for both Baseline Average Manufacturers' Price (BL/AMP) and Baseline Consumer Price Index-Urban (BL/CPI-U) for Single-Source ("S") and Innovator Multiple-Source ("I") category drugs approved by the FDA after 10-01-90. **Drugs approved (by the FDA) on or before 10-01-90 will not be affected by OBRA'93 changes and will continue to have their Unit Rebate Amounts (URAs) computed using the OBRA'90 calculation method. For Prior Period Adjustments (PPA) affecting quarters 91-1 thru 93-3, the OBRA'90 calculation will continue to be used.**

OBRA'93 states that BL/AMP is based on "the AMP for the first full Calendar quarter following the day on which the product is marketed." Likewise, the BL/CPI-U has been amended to equal "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed." Therefore, based on OBRA'93, for all products approved after 10-01-90, additional rebate calculations for all quarters beginning with 93-4 will have the following values:

- BL/AMP will be equal to the quarterly AMP for the first full calendar quarter after the product has been introduced on the market.
- BL/CPI-U will be equal to the value for the month preceding the first month of the first full calendar quarter the product is on the market.
- Market Date will be the actual date the product was introduced on the market.

### EXAMPLE 1

Product 12345-6789-01 is an "I" drug approved on 02-01-91 and first marketed on 02-20-91.

### FOR QUARTERS 91-1 THROUGH 93-3

- BL/AMP equals selling price on 03-01-91.
- BL/CPI-U equals 134.8 (Feb. '91).
- Market date equals 03-01-91.

### FOR QUARTERS 93-4 AND LATER

- BL/AMP equals AMP for quarter 91-2.
- BL/CPI-U equals 135.0 (Mar. '91).
- Market Date equals 02-20-91.

**EXAMPLE 2**

Product 12345-6789-01 is an "I" drug approved on 02-01-91 and first marketed on 03-05-91.

**FOR QUARTERS 91-2 THROUGH 93-3**

- BL/AMP equals selling price on 04-01-91.
- BL/CPI-U equals 135.0 (Mar. '91).
- Market date equals 04-01-91.

**FOR QUARTERS 93-4 AND LATER**

- BL/AMP equals AMP for quarter 91-2.
- BL/CPI-U equals 135.0 (Mar. '91).
- Market Date equals 03-05-91.

**EXAMPLE 3**

Product 12345-6789-01 is an "I" drug approved on 02-01-91 and first marketed on 04-02-91.

**FOR QUARTERS 91-2 THROUGH 93-3**

- BL/AMP equals selling price on 05-01-91.
- BL/CPI-U equals 135.2 (Apr. '91).
- Market date equals 05-01-91.

**FOR QUARTERS 93-4 AND LATER**

- BL/AMP equals AMP for quarter 91-3.
- BL/CPI-U equals 136.0 (Jun. '91).
- Market Date equals 04-02-91.

**EXAMPLE 4**

Product 12345-6789-01 is an "I" drug approved on 05-01-90 and first marketed on 10-01-93.

**FOR ALL QUARTERS 93-4 AND LATER**

- BL/AMP equals selling price on 10-01-93.
- BL/CPI-U equals 145.1 (Sep. '93).
- Market date equals 10-01-93.

Please note that, in this example, the Baseline record is set up exactly as those prior to OBRA'93. Likewise, the additional rebate calculation is performed using pre-OBRA'93 values. This is due to the **FDA APPROVAL DATE.**

OBRA'93 causes several changes in the way labelers report new drugs (drugs approved after 10-01-90 and marketed after 09-30-93) to HCFA. These changes include:

1. Use the actual date the product entered the market, not the first day of the first full month after introduction.

2. Put zeros in the BL/AMP, not the selling price on the first day of the first full month.

3. For those products introduced in the last month of a quarter, DO NOT hold until next quarter for reporting. Instead, follow steps 1 & 2 for submitting Baseline data for the quarter in which the product is introduced.

4. After the first full quarter the product is on the market, you must be able to adjust BL/AMP and BL/CPI-U to follow the directive in OBRA'93 for times that you are to perform the additional rebate calculation.

5. HCFA will maintain parallel BL/AMP and CPI-U values for all products having FDA approval after 10-01-90 and Market Dates that fall between 10-01-90 and 10-01-93. All products approved after 10-01-90 and entering the market after 09-30-93 will develop BL/AMP and CPI-U values under OBRA'93 rules.

*** * R E M I N D E R * ***

**THE ABOVE DOES NOT APPLY TO DRUGS THAT ARE APPROVED ON OR BEFORE 10-01-90. THESE DRUGS, EVEN IF MARKET DATES ARE AFTER 09-30-93, WILL STILL FOLLOW THE RULES ESTABLISHED UNDER OBRA'90. THEREFORE, WHEN REPORTING DRUGS UNDER THIS CONDITION, BL/AMP WILL STILL BE REQUIRED AND WILL EQUAL THE SELLING PRICE ON THE FIRST DAY OF THE FIRST FULL MONTH AFTER INTRODUCTION AND BL/CPI-U WILL EQUAL THE MONTH PRIOR TO THE FIRST FULL MONTH THE PRODUCT WAS MARKETED. LIKEWISE, ALL PRODUCTS APPROVED AFTER 10-01-90 THAT ENTERED THE MARKET PRIOR TO 10-01-93, ARE TO INCLUDE BL/AMP EQUAL TO THE SELLING PRICE ON THE FIRST DAY OF THE FIRST FULL MONTH THE PRODUCT WAS MARKETED. FOR THESE PRODUCTS, ALL OBRA'90 RULES FOR BL/AMP AND BL/CPI-U WILL PREVAIL FOR QUARTERS PRIOR TO 93-4.**