DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

November 15, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #48

For

Participating Drug Manufacturers

INCORRECT CPI-U FOR CALENDAR YEAR 2000

In early October we were informed that all CPI-U values for calendar 2000 had been incorrectly calculated. A new list of monthly values was supplied to us immediately. The bad news is that about 4,000 NDCs were sent to states with incorrect Unit Rebate Amounts (URAs) for 2q00. The good news is that **ONLY** 2q00 processing was affected. Some labelers that calculate their own URA call us for the CPI-U information. Others pull it directly from the Department of Labor web site. Those that went to the web site apparently got the correct value. This only adds to the confusion of who calculated the URA correctly and who didn't.

We will be re-calculating the 2q00 URAs for the affected NDCs and include Prior Period Adjustments on the 3q00 URA tape to the states. Attached, please find a chart showing BOTH the incorrect and correct CPI-U values for 2000. Also, in order to keep confusion to a minimum, we have sent a report to affected labelers showing both old and new URA calculations. This will give them additional time to research for and create Prior Quarter Adjustment Statement forms to submit to affected states with the 3q00 payment.

Should you have any questions or comments, please contact Vince Powell on (410) 786-3314.

SELLING PRODUCTS TO ANOTHER LABELER

There seems to be continued confusion regarding the sale of products or product lines and just who is responsible for what, when, how long, etc. There are a couple of scenarios to be covered for this topic.

If a company buys a product but does not change the NDC, the company that holds title to the labeler code is ultimately responsible for reporting pricing and paying rebates. ANY company can send pricing data for ANY products and can pay states rebates on them. However, we have contact information on the labeler code of the product only and have only one source to go to if there is missing data or if rebates are not paid or paid in an untimely fashion. Also, history (Baseline information) doesn't change with the sale of this product. It follows the NDA/ANDA, NOT the NDC.

If a company buys a product and changes the NDC to be that of the new owner, the old owner is responsible to supply a termination date equal to the shelf life of the last lot sold under the old NDC and to supply pricing data for 4 quarters beyond the shelf life. The new company is responsible for supplying pricing data starting with the quarter the product is for sale under the new NDC. As in the previous example, product history stays with the product and is duplicated for the new NDC following that of the old NDC. History follows the NDA, NOT the NDC of the product. Also, as in the previous example, it doesn't matter who supplies pricing data for EITHER the old or new NDC, as long as it is supplied.

If a company buys a product, changes something (tablet to capsule, changes shape, makes a change in formulation, etc.) and applies for an ANDA, the NDC that reflects the product under the new ANDA has history start over for itself. Baseline information is to reflect dates, etc., of the product under the new ANDA, NOT under the old NDA/ANDA. The old company is responsible for supplying pricing data for the old NDC and for supplying Termination Date when the shelf life of the last batch sold is known. Pricing for 4 quarters beyond shelf life is required. New baseline and pricing data should be supplied by the new company.

REMEMBER TO REPORT ALL LABELER CODES

With all of the buying and selling of companies, sometimes we forget that when a drug company elects to come into the Medicaid Drug Rebate Program, ALL labeler codes owned by that company MUST be included; picking and choosing only select companies is not permitted. If your company holds title to one or more labeler codes

not as yet part of the program, please contact a member of the Operations staff for instructions on what to do.

TERMINATION DATES FOR PRODUCTS

Since the start of the Drug Rebate Program, product termination date has been one of the most misunderstood and incorrectly coded fields of the entire MDRI data base. Please remember the following:

- When a product (or a package size of a product) is no longer going to be produced or sold and the last lot shelf life is known, a termination date equaling the shelf life (last date it is allowed to be dispensed) should be reported to HCFA as a baseline update.
- When you stop selling this product, the calculated pricing from the last quarter of sales is to be reported, quarter after quarter, until and including 4 quarters past the termination date.
- The exception to this is when there are multiple package sizes of a product and not all package sizes are being terminated. In this case, continue to calculate the weighted AMP pricing and/or BP each quarter of all active package sizes. Report the calculated price on ALL (including terminated) sizes of the product.
- After the last quarter of reporting (4 quarters beyond termination date), stop reporting this pricing to HCFA..

Please review your data base and assure that accurate (and actual) termination dates are reported on your terminated products. Refer any questions to a member of the Operations staff.

UNIT REBATE AMOUNT ROUNDING - ONE MORE TIME

We continue to get questions (AND PRICING CHANGES) regarding the URA calculation and how and when it will become effective. In release **#46** dated April 18, 2000, there was a write-up about changing the way URAs will be calculated and that the change will occur beginning with **third quarter, 2000.** In release **#47** dated July 13, 2000, the timetable was **CHANGED.** We stated that the change would **NOT** take place until **FIRST QUARTER 2001,** which would be included on the state URA tape due out in May, 2001.

Also, due to inquiries, release #47 explained that there were **NO AMP/BP CHANGES TO BE MADE BY LABELERS. THE WAY YOU CALCULATE AND REPORT PRICES WAS TO REMAIN UNCHANGED**. We have had

several labelers submit third quarter, 2000 prices with their AMP/BP values calculated to the 5th position, rounded to the 4th and positions 5 and 6 padded with zeros.
PLEASE *DO NOT* CHANGE THE WAY YOU CALCULATE PRICES !!!
PLEASE *DO NOT* LOOK FOR URA CHANGES IN 3Q2000 !!!

If you still have any questions or comments, please call Vince Powell on (410) 786-3314 or Judy Allison on (410) 786-3330.

SEPARATE/SUPPLEMENTAL MEDICAID DRUG REBATE AGREEMENTS

In response to numerous requests from States and manufacturers , we are taking this opportunity to restate our policy and guidance that was provided in earlier releases regarding separate/supplemental Medicaid drug rebate agreements. Please note that the following information pertains to separate/supplemental *MEDICAID* drug rebate agreements and not to State-funded only drug rebate agreements. Solely State-funded drug rebate agreements and non-Medicaid State pharmaceutical assistance programs are not subject to HCFA review or approval.

1. Approval process for separate/supplemental Medicaid drug rebate agreements:

    - State submits agreement to appropriate HCFA Regional Office (RO).
    - HCFA RO sends agreement to HCFA Central Office,

      Attn: Michael Keogh.

    - HCFA CO reviews agreement, consults with RO, State and manufacturer(s), if necessary, then makes approval determination.
    - HCFA CO advises RO of approval determination.
    - HCFA RO advises State.
    - State advises manufacturer(s).

1. Effect on average manufacturer price (AMP) and best price:

    - Rebates paid under HCFA-approved, separate/supplemental Medicaid drug rebate agreements do not effect AMP or best price under the Medicaid program.

Note: Similarly, rebates received through State-funded only rebate agreements and/or State pharmaceutical assistance programs do not effect AMP or best price.

1. Rebate reporting and sharing:

    - Rebates received by the State under separate/supplemental Medicaid drug rebate agreements must be reported to and shared with the Federal government on the same percentage basis as rebates under the national rebate agreement.

If you have any questions on separate/supplemental Medicaid drug rebate agreements, please contact Mike Keogh at mkeogh1@hcfa.gov or (410) 786-5910.

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates for the period beginning June 7, 1999, are attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

Timothy M. Westmoreland

Director

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid