

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

July 13, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #47

For

Participating Drug Manufacturers

SEPTEMBER NATIONAL DISPUTE RESOLUTION (DRP) MEETING

This is a reminder that September is rapidly approaching and the time is NOW to get registered and to put in your requests for states/labelers you wish to visit with. If you haven't done so, please complete the attached form for the September DRP meeting and fax it ASAP to Diane Dunstan. Put together your list of whom you wish to meet with and pass it to Diane. The week is getting full quickly and you need to get on the list very soon in order to assure meeting with the maximum number of participants you wish to. The meeting dates are Monday, September 18 through Friday, September 22. Contact Diane regarding hotel reservations as well. They also are going quickly and, if you do not act soon, you may have to take accommodations outside of Denver and commute to the meetings. Please see the attachment for Diane's phone and fax numbers and her e-mail address, as well.

ROUNDING UNIT REBATE AMOUNT (URA)

In an earlier release, I explained a change that would be forthcoming to the way we report the URA to states. At that time, it was the plan to effect this change with the **3Q00 URA** file to the states due from HCFA around **November 15, 2000**. It has been brought to my attention that not all labelers and labeler support software companies will be able to have their systems changed in time for this effective date. Therefore, although this change will occur, it is being pushed back. We will now implement this change so that it is included in the **1Q01 URA** file due to the states around **May 15, 2001**.

Please remember that this update to the way the URA is reported **IN NO WAY** changes the way pricing is to be calculated and submitted to us from the labelers. Our system will still accept AMP/BP data with 6 decimal places. Only the URA will be calculated to the 5th decimal place, rounded to the 4th and have zeros pad positions 5 and 6. This change will be for all new URAs as well as any old URAs that are re-calculated due to corrections or baseline/market date/quarterly pricing changes.

Any questions regarding this change should be directed to Vince Powell on (410) 786-3314.

THE EFFECT OF SALES TO HEALTH MAINTENANCE ORGANIZATIONS (HMOs) AND TO OTHER ENTITIES PURCHASING DRUGS FOR DIRECT CONSUMER SALES OR DISTRIBUTION ON THE CALCULATION OF BEST PRICE

We were recently alerted to a situation where drug sales to an HMO are being omitted from a manufacturer=s best price calculation on the basis that the purchaser is a drug repackager.

Section 1927(c)(1)(C)(i) of the Social Security Act (the Act) specifies that best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States. Further, sections 1927(c)(1)(C)(i)(I)-(IV) and 1927(j) of the Act list specific exclusions from the best price calculation. Under these provisions, the sales to organized health care settings such as HMOs must be included in best price. While the entity may be engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, it is still an HMO and its sales are subject to inclusion in the best price calculation. The best price provisions in the statute contemplate the inclusion of sales to HMOs without regard to special packaging or labeling. Therefore, as required under the Medicaid Drug Rebate program, manufacturers should include all sales to any entity, such as HMOs, that purchase drugs for direct consumer sales or distribution in best price calculations except as excluded by section 1927 of the Act.

We are aware that the Office of Inspector General is currently reviewing this practice and is requesting information on sales to any repackager that was omitted from the best price calculations. Depending on the results of that review, we may address this issue in future policy statements.

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If specific questions arise concerning the best price provision, please contact Sue Gaston at

(410) 786-6918 or SGaston@hcfa.gov.

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates for the period beginning November 9, 1998, 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

Drug Rebate Program

Dispute Resolution Project (DRP)

2000 National September Meeting

Please check **if** you would like to attend the September 2000 National DRP meeting being held in Denver, Colorado. **Please FAX your completed form to Diane Dunstan at 303.844.3753.**

I would be interested in attending the September DRP meeting:

Date: Sept 18 to 22 _____

Name: _____ State or Manufacturer Name: _____

Phone: _____ Fax: _____ E-mail: _____

Mailing Address: _____

I would like to meet with the following States or Manufacturers:

If you have any questions please contact Diane Dunstan at 303.844.7040 or e-mail at ddunstan@hcfa.gov. Please print and fill out form completely.