DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

**Center for Medicaid and State Operations**

April 18, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #46

# For

# Participating Drug Manufacturers

## JUNE DISPUTE RESOLUTION PROJECT (DRP) MEETING

We have just recently concluded our first DRP national meeting for FY2000 in Denver. It was very successful, with 12 labelers and 17 states participating. Our next national meeting will be held in Denver during the week of June 5. If you have not, as yet, signed up for this week and would like to, please fill out the attached form and fax it to Diane Dunstan ASAP at (303) 844-3753. If you would like information regarding who is scheduled, so far, or to get information about hotel accommodations, please call Diane on (303) 844-7040.

## NEW LEGISLATION PROVIDING STATE OPTION OF USING DIFFERENT REBATE AGREEMENT EFFECTIVE DATES

Section 1927 (a)(1) of the Social Security Act (the Act) generally provides that in order for Federal Financial Participation to be made available for the drugs of a manufacturer, the manufacturer must enter into a drug rebate agreement with HCFA (or, if authorized by HCFA, with the States). Rebate agreements that were not in effect before March 1, 1991, became effective the first day of the calendar quarter that began more than 60 days after the date the agreement was entered into.

As a result of this section of the law, manufacturers that signed agreements less than 60 days before a quarter sometimes had to wait several months before their agreements became effective. In order to help eliminate this delay, Section 606 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 amended Section 1927 (a)(1) to give States the option of using different rebate agreement effective dates. Specifically, the law now states that rebate agreements that are entered into on or after November 29, 1999 may become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter up to the first day of the first quarter that begins more than 60 days after the agreement is entered into. As before, the date on which an agreement is entered into is the date on which it is postmarked.

A State has the flexibility to apply these new provisions for each manufacturer. The same, however, will not be true for individual drugs. When a manufacturer's agreement becomes effective in a State, all of its covered drugs must be included at that time. This change in effective date does not affect HCFA's policy regarding termination from the Medicaid drug rebate program, nor the subsequent delay before re-entry into the program.

In order to assure that States are promptly aware of the optional effective date as well as the mandatory effective date of a rebate agreement, we will fax that information to the State Technical Contacts on the day we receive the agreement. This information will also be provided in our releases to States.

**Please note** that as a result of this legislation, labelers must submit baseline AND pricing data for the quarter in which your agreement is postmarked in case any States wish to cover your products using the optional effective date.

## CLARIFICATION OF MANUFACTURER INTEREST CALCULATION

The following information is provided to clarify instances when it is appropriate for a manufacturer to apply interest on overpaid rebate amounts. In short, manufacturers can only charge interest on amounts that were previously paid, disputed, then resolved through dispute resolution with the state. The calculation of interest begins on the 38th day after the manufacturer notifies the state of the dispute until the date the state processes the adjustment and credits or repays the manufacturer.

These specific disputes occur when a manufacturer either pays the entire invoiced amount but provides written notification to the state that it is disputing specific units, or, makes a partial payment and provides written notification to the state that it is

disputing the remaining units. In these two scenarios, if the dispute is resolved in the manufacturer's favor, interest is charged from the 38th day after the manufacturer notified the state of the dispute until the date the state processes the adjustment and credits or repays the manufacturer.

However, it has come to our attention that a few manufacturers may be making unit adjustments for prior quarters and automatically taking interest credit on those related rebate payments without notifying the state of the dispute and resolving the dispute mutually through dispute resolution. This is an inappropriate application of the interest guidance we have provided through our informational releases. Those few manufacturers that have improperly taken unit adjustments or interest credits without the above notification and resolution steps being taken must immediately discontinue this practice. Further, we are requesting that those manufacturers promptly take corrective action for units improperly adjusted and any improperly credited interest. We will contact the states that have reported this situation to ensure that corrective actions are taken.

In another unrelated interest matter, when a manufacturer pays rebates that were formerly withheld or not paid timely, but fails to pay interest with that payment when required, the unpaid interest will be treated as principal due, and interest on that amount will begin accruing as of the date the manufacturer paid (that is, mailed) the original disputed or withheld amount. Similarly, interest stops accruing on the date the manufacturer mails the check to the state.

Any questions may be directed to Vince Powell at (410) 786-3314, Mike Keogh at (410) 786-5910 or Sue Gaston at (410) 786-6918.

## FLORIDA'S INVOICE FOR STATE HEALTH MAINTENANCE ORGANIZATION (HMO) MEDICAID REBATES

Recently, the State of Florida's Agency for Health Care Administration invoiced manufacturers for drug rebates on HMO Medicaid drug utilization. Manufacturers should be advised that according to Section 1927 (j) of the Act a state cannot require Medicaid drug rebates on drugs dispensed by managed care organizations (MCOs) where the State included such drugs in the capitated payment to such MCOs. Therefore, payment of these rebates is not mandated by the Act and is voluntary.

## NEW ROUNDING FOR UNIT REBATE AMOUNT (URA)

In the past, carrying the URA calculation "out to 7 positions, rounding back to 6" has caused many problems in trying to have every URA calculation from HCFA match the calculation from the labeler. To this end, we have instituted a new way to do the calculation. Beginning with ***3Q00 (the tape that will go to states in November, 2000)***, the URA will be calculated to 5 positions and rounded to 4. We will NOT change field or record length. What we will do is "pad" positions 5 and 6 with zeros. We will **NOT** go back and re-calculate all old URAs; however, when a change to an old NDC causes an old URA to be re-calculated, ***it will be done under the new method***.

We have made comparisons between the "carry to 7, round to 6" and "carry to 5, round to 4" calculations using state utilization data from quarters 2 and 3 from 1998. We found in each case that the TOTAL difference was less than $5,000 for the quarter, making a breakdown by NDC to be too small to make even a dollar difference. We, therefore, find this to be a very worthwhile, and, we believe, welcome change to the system.

**Please note** that we are instituting this change with a lead time of 2 quarters so that labelers that calculate their own URA or that use independent software to do so, will have time to change their systems. Any labelers or software companies having any problems regarding this lead time should call Vince Powell on (410) 786-3314 immediately.

## HRSA NOTICE PUBLISHED MARCH 15, 2000

This is to notify you that HRSA published a Notice in the Federal Register on March 15, 2000 that pertains to situations where State Medicaid agencies did not request rebates for drugs purchased by covered entities which participate in the 340B drug pricing program (and do not participate in the 340B program for Medicaid). Although we believe participating covered entities generally provide 340B drugs to Medicaid beneficiaries and bill the actual acquisition cost to the Medicaid agencies, some covered entities have elected to maintain a dual inventory, purchasing Medicaid drugs above the 340B price and billing the State Medicaid agency a non-340B price. For these drugs, the Medicaid agencies are entitled to a rebate. For these latter drugs, you may receive invoices from States requesting rebates retroactive to the quarter(s) in which covered entities did not participate in the 340B program for their Medicaid patients. Please contact Marge Lee at 410-786-4361 for further information on how to determine which covered entities participated in 340B for which quarters.

## STATE CONTACTS POSTED ON THE INTERNET

We have posted the technical, policy, and rebate contact information for states on the Internet at www.HCFA.GOV/MEDICAID/DRUGCON.HTM.

## 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 Meetings

Please check **EITHER** or **BOTH** of the remaining dates you would like to attend the 2000 National DRP meetings, which are held in Denver, Colorado. **Please FAX your completed form to Diane Dunstan at 303.844.3753.**

I would be interested in attending the DRP meetings during the following week(s):

Date: June 5 to 9 _____

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.