

February 27, 1998

**MEDICAID DRUG REBATE PROGRAM**

**RELEASE #76**

# **TODAY'S NEWS**

## **for State Medicaid Directors**

### **CALPHRON CONSIDERED A FOOD SUPPLEMENT**

Based on a decision from the Food and Drug Administration (FDA), the product CALPHRON, identified by National Drug Code 59528-0331-02, is considered a dietary supplement rather than a drug. Therefore, this product is no longer eligible for inclusion in the drug rebate program. The company was notified of this decision.

### **MEDEVA PHARMACEUTICALS - LABELER 53014 - DRUG CATEGORY CHANGE**

At the beginning of 1997, Medeva Pharmaceuticals purchased Adams Laboratories, maintaining the labeler code and all respective products. While perusing the history of their new data base, they discovered that several products, listed below, had been inadvertently reported to HCFA as Innovator (Drug category "I") drugs. Accordingly, the Drug Category of these products has been changed to Non-Innovator (Drug Category "N") effective for the 4Q97 reporting period.

Medeva realizes that this change would lower their Unit Rebates for 1997; however, the change WILL NOT be retroactive and they will maintain Innovator rebate responsibilities for all 1997 quarters prior to 4Q97. With the 4Q97 rebate data set,

therefore, please note that these products have been changed to "N" and that the 4Q97 URA for them reflects the 11% URA which will be lower than those of previous quarters. There are NO Prior Period Adjustment records for these records on this data set. The NDCs affected are:

0012-10 and -50    0015-10    0017-10 and -50

0030-10 and -50    0402-10

All fall under labeler code 53014. Any questions should be directed to Vince Powell on (410) 786-3314.

### **TRAINING GUIDE UPDATES**

Attached are the latest updates to the Medicaid Drug Rebate Operational Training Guide. These updates incorporate general revisions, HCFA's regional office consortia, and some additional millennium changes. Please share the updates with all staff involved in the program and replace these pages in your guide.

Please note that the staff directory section of the guide has been updated, and, in particular, now includes systems maintenance staff. In the future, any questions regarding the receipt or readability of the HCFA State tape should be directed to Kay Alexander. Kay's telephone number is listed on the revised page O2 of the staff telephone directory.

Also, be advised that although pages F20 and F22 are revised for the millennium, these revisions are not effective until January 1, 1999.

### **CREATION OF INVOICES WHERE DRUG LABELER HAS NO PRODUCTS**

There continue to be drug companies shown as active participants in the rebate program which used to have drug products on the market some years ago but currently have nothing for sale. In most cases, the companies have chosen to retain the drug labeler code assigned to them by the Food and Drug Administration in case they decide at some future time to market new drug products for those labeler codes.. No product or pricing data records for these companies appear on the quarterly HCFA tapes.

We are hearing from these companies that they receive form letter "zero" rebate requests every quarter from selected states despite having no products for sale. We suggest that the states implement system changes to halt this unnecessary generation of paper and mailing costs.

**MAILING ADDRESSES AND TELEPHONE NUMBERS**

Recently, several State drug programs moved to different physical locations or changed their telephone numbers and forgot to forward this information to HCFA or modify the invoice to reflect the change(s). It is extremely important that we have your **current** address, the names of the right people to contact and the telephone numbers where they can be reached. Additionally, you should ensure that you have given to us the correct facsimile machine telephone number. This information is shared with every participating drug company and is available on the HCFA website located at [www.hcfa.gov](http://www.hcfa.gov).

**NEW LABELERS**

The following labelers have entered into drug rebate agreements and are joining the rebate program effective January 1, 1998:

Warner Chilcott Laboratories (Labeler Code 00430); and  
Faulding Laboratories (Labeler Code 63857).

The following labelers have entered into drug rebate agreements and are joining the rebate program effective April 1, 1998:

Peachtree Pharmaceuticals (Labeler Code 62793); and  
Chain Drug Marketing Association, Inc. (Labeler Code 63868).

The following labeler has entered into a drug rebate agreement and is joining the rebate program effective July 1, 1998:

GM Pharmaceuticals, Inc. (Labeler Code 58809).

**TERMINATED LABELER**

The following labeler is being terminated effective April 1, 1998:

Huckaby Pharmaceutical, Inc. (Labeler Code 58407)

**OTHER ATTACHMENTS**

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period September 15, 1997 through February 23, 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.

/s/

Sally K. Richardson  
Director  
Center for Medicaid and State Operations

3 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid