DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

April 18, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #98

For State Medicaid Directors

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.

WARRICK PHARMACEUTICALS – SODIUM CHLORIDE SOLUTION

Warrick has a 0.9% sodium chloride solution product (NDC 59930-1609 package sizes -01 and -02) that states are attempting to include on their invoices for rebate. After checking with our contact at the Food and Drug Administration, it was determined that this is not a drug and, therefore, not eligible for rebate. **Please do not invoice Warrick for this product**.

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.

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.

TAPE/CARTRIDGE SPECIFICATIONS

Release Number 72, dated December 9, 1997, contained new utilization record specifications effective for utilization data submitted to HCFA on January 1, 1999 or later. Some States are still submitting the old record format. In addition, proper naming conventions for utilization tapes and cartridges are not being used. Because the standards for tape/cartridge submittal will be strictly enforced by HCFA, States are asked to review the utilization reporting instructions located on pages F20-F25 of the Medicaid Drug Rebate Operational Training Guide. Adherence to these standards will avoid future problems.

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 invoice the manufacturers for the drugs, 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.

NEW LABELERS

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Pharma-Tek Inc. (Labeler Code 39822) 07/01/2000 04/13/2000

Smith & Nephew, Inc. (Labeler Code 50484) 07/01/2000 04/03/2000

Watson Laboratories, Inc. (Labeler Code 62109) 07/01/2000 03/22/2000

Baxter Healthcare Corporation (Labeler Code 64193) 07/01/2000 03/24/2000 Prometheus Laboratories, Inc. (Labeler Code 65483) 07/01/2000 04/17/2000

Contact information for these new labelers is attached for your convenience.

TERMINATED LABELERS

The following labelers are being terminated effective April 1, 2000:

Keene Pharmaceuticals, Inc. (Labeler Code 00588);

Vita Pharm Canada Limited (Labeler Code 58946);

Bio-Pharm, Incorporated (Labeler Code 59741);

Loramen, Inc. (Labeler Code 60412);

Edyn Corporation (Labeler Code 60619); and

SuperGen, Inc. (Labeler Code 62701).

The following labeler is being voluntarily terminated effective July 1, 1999:

Morton Grove Pharmaceuticals, Inc. (Labeler Code 00426).

The following labelers are being voluntarily terminated effective July 1, 2000:

Gebauer Company (Labeler Code 00386); and

Mediplex Pharmaceuticals (Labeler Code 59010).

OTHER ATTACHMENTS

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

4 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid