DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

June 27, 2001

MEDICAID DRUG REBATE PROGRAM RELEASE #107

For State Medicaid Directors

MDRI/FDA DATA MATCH

HCFA and the FDA have been working together for some time to develop a system of identifying non-drug products that erroneously have NDC numbers associated with them. To that end, we will be matching active records on the FDA listed and pending files to the active records on the Medicaid Drug Rebate Initiative (MDRI) file to identify any records that do not match and thus, do not meet the definition of "covered outpatient drug" established in section 1927 of the Social Security Act.

The process will work in the following manner and time frames:

- After we send the states the 2nd qtr/2001 Unit Rebate Amount (URA) tapes (about August 15th), we will perform a match between the FDA listed and pending files, updated through June 30, 2001 and the 2nd qtr/2001 MDRI master file. A report will be generated showing those NDCs on the MDRI that do NOT match the FDA files.

- Each labeler will receive that portion of the report pertaining to its labeler code, listed by NDC, with a letter explaining the report and stating that the labeler should provide information demonstrating that its drug product meets the definition of covered outpatient drug. Also, the letter will tell the labeler what needs to be done to make any corrections on those drug products that may be approved drugs but need a follow up notice to the FDA.

- The labeler will have 2 quarters to properly identify and list those drug products with the FDA. Information on how to do this will be included in the letter attached to the report.

- After we send states the 4th qtr/2001 URA tapes (about February 15th), we will perform this match again, using the updated FDA files through December 31st, 2001 and the 4th qtr/2001 MDRI master file.

- A report following the same format as mentioned above will be sent to each affected labeler, stating that these NDCs will be deleted from the MDRI master file and will not be covered by the drug rebate program effective April 1, 2002. These NDCs will, however, remain active on the MDRI file for Q1/2002.

- An electronic file of these non-matching NDCs (drugs not meeting the definition of covered outpatient drugs) will be sent to each state, on or about March 1, 2002. The states will be told to delete them from their drug rebate data bases and cease covering them under the drug rebate program effective April 1, 2002.

Beginning with the 2nd qtr/2002 state tape (due to states around August 20, 2002) and for every quarter thereafter, the first step in the URA calculation and tape creation process will be a match between new MDRI records and the FDA listed/pending files for that quarter. Every new record a labeler attempts to add to the MDRI that doesn't satisfy the definition of covered outpatient drug will be rejected and a record rejection report will be sent to the affected labeler with a message explaining that this record has been rejected.

This latest effort in cleaning up the MDRI files once again highlights the fact that no matter what data files or software states use for their "regular" Medicaid business, it is imperative that the MDRI master file be used when doing drug rebate processing. Using other files and other data may result in the state paying for but losing rebates for products not covered by the Medicaid Drug Rebate Program. Questions may be directed to any member of the drug rebate operations staff, as listed in section "O" of the Operations guide.

NDC DELETIONS FROM THE MDRI

Attached please find a list of NDCs from Dey Labs (labeler code 49502) that have been deleted from the MDRI master file. They are NOT covered outpatient drugs and should be removed from your file as well. These are not covered under the Drug Rebate Program and you should not submit utilization for rebates.

OVERPAYMENTS DUE TO AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS

As a result of recalculations of its AMPs and our review of those recalculations, The Hoffman-LaRoche Inc. (labeler codes 00004, 00033, 42987, 18393, and 53169) has submitted revised Baseline AMPs for the third quarter of 1990 and AMPs for the first quarter of 1991 through the first quarter of 1999, and will be recovering overpayments from States for excessive rebates paid during those quarters. These recalculations are necessary since the company had failed to properly compute AMP for pricing data prior to the first quarter 2000. In many States, these recalculations resulted in significant overpayments.

Beginning with second quarter 2001 invoices, and on a State-by-State basis, Roche will begin recoupment of the overpayments from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. Roche has indicated that it will contact each State representative to inform you of this action and has expressed a willingness

to work with individual States to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meanwhile, States should continue to invoice Roche for current quarters as usual.

If you have any questions on this particular issue, please call Kim Howell of the Drug Rebate staff on (410) 786-6762.

DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING

We are happy to announce that the next National DRP meeting will be held during the week of September 10 - 14, 2001 in Denver. This meeting is being coordinated by Diane Dunstan, our National DRP Regional Coordinator, and is a continuation of the highly successful meetings held in Denver since 1998. Attached is a form that MUST

be completed and faxed to Diane ASAP if you are planning to attend the September meeting.

These meetings are open to ALL states and manufacturers. Those of you that have attended any of our previous National meetings know about the overwhelming enthusiastic support given to this effort by the Denver Regional Office leadership. Overall, the meetings have been very successful in resolving millions of dollars of disputed rebates.

If you have any questions regarding the National DRP meetings in Denver, please contact Diane Dunstan at (303) 844.7040.

NEW LABELERS

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Pharmakon Labs. Inc. (Labeler Code 55422) 10/01/2001 05/08/2001

Optics Laboratory Inc. (Labeler Code 64108) 10/01/2001 05/24/2001

Sirius Laboratories, Inc. (Labeler Code 65880) 07/01/2001 04/16/2001

Healz-Plus, Inc. (Labeler Code 66073) 10/01/2001 05/21/2001

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

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TERMINATED LABELERS

The following labelers are being terminated effective October 1, 2001:

Camall Company (Labeler Code 00147);

The Ainsworth Corporation, DBA Dunhall Pharmaceuticals (Labeler Code 00217);

Jordan Pharmaceuticals, Inc. (Labeler Code 58196);

Sage Pharmaceuticals, Inc. (Labeler Code 59243); and

Neil Laboratories, Inc. (Labeler Code 60242).

The following labelers are being voluntarily terminated effective October 1, 2001:

UCB Pharma, Inc. (Labeler Code 58436);

Hamilton Pharma, Inc. (Labeler Code 60322); and

Peachtree Pharmaceuticals (Labeler Code 62793).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period January 3, 2000, 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.

David McNally, Deputy Director

Finance, Systems and Quality Group

5 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

Dey, L.P.
Labeler Code 49502
Sodium Chloride and Purified Water (Devices) NDC Listing

NDC1	NDC2	NDC3	FDA Name
49502	0030	03	DEY-VIAL SODIUM CHLORIDE
49502	0030	05	DEY-VIAL SODIUM CHLORIDE
49502	0030	10	DEY-VIAL SODIUM CHLORIDE
49502	0030	20	DEY-VIAL SODIUM CHLORIDE SOLUTION 0.9% 20ML
49502	0282	20	DEY-WASH SKIN WOUND CLEANSER (SODIUM CHLORIDE SOLN 0.9%
49502	0501	20	NEBU-SOL METERED DOSE DISPENSER SODIUM CHLORIDE SOLUTI
49502	0503	00	NEBUSOL MDD SODIUM C
49502	0610	03	DEY-PAK PURIFIED WATER USP 3ML
49502	0610	05	DEY-PAK PURIFIED WATER USP 5ML
49502	0620	03	DEY-PAK SODIUM CHLORIDE SOLUTION 0.45% 3ML
49502	0620	05	DEY-PAK SODIUM CHLORIDE SOLUTION 0.45% 5ML
49502	0630	01	DEY-PAK SODIUM CHLORIDE SOLUTION 0.9% 1ML
49502	0630	03	SODIUM CHLORIDE SOLUTION
49502	0630	05	DEY-PAK SODIUM CHLORIDE SOLUTION 0.9% 5ML
49502	0630	10	DEY-PAK SODIUM CHLORIDE SOLUTION 0.9% 10ML
49502	0630	15	DEY-PAK SODIUM CHLORIDE SOLUTION 0.9% 15ML
49502	0640	15	DEY-PAK SODIUM CHLORIDE SOLUTION 3% 15ML
49502	0641	15	DEY-PAK SODIUM CHLORIDE SOLUTION 10% 15ML
49502	0810	03	STERILE WATER FOR INHALATION USP
49502	0810	05	STERILE WATER FOR INHALATION USP
49502	0820	03	SODIUM CHLORIDE INHALATION SOLUTION USP .45%
49502	0820	05	SODIUM CHLORIDE INHALATION SOLUTION USP .45%
49502	0830	03	SODIUM CHLORIDE INHALATION SOLUTION USP 0.9%
49502	0830	05	SODIUM CHLORIDE INHALATION SOLUTION USP 0.9%
49502	0830	15	SODIUM CHLORIDE INHALATION SOLUTION USP 0.9%
49502	0830	50	CHLORIDE INHALATION SOLUTION USP 0.9%
49502	0831	03	SODIUM CHLORIDE INHALATION SOLUTION USP 0.9%
49502	0831	05	SODIUM CHLORIDE INHALATION SOLUTION USP 0.9%

All products on this list are now deleted from the Dey, L.P. MDRI database.