

June 22, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #132

For State Medicaid Directors

QUARTERLY URA FILE – REPORTING FIRST-TIME URAS

There has been a lot of confusion over how CMS sends URAs for “first time” quarters. When a pricing record is reported to CMS for the first time for a **PAST** quarter, the URA goes out on a “0” flag record. When a URA goes out that was **initially reported with a zero URA because of 50/50 editing**, the URA goes out on a “3” flag record (coupled with a “2” record containing zeros in the URA). **Many states bypass “0” records for prior quarters, assuming that, when the labeler submits the missing data, the URA will come on the “2/3” PPA records.**

Please assure that your system can recognize **BOTH “0”** flag records **AND “3”** flag records with “**first time**” URA values, the “0” record for **prior quarters** and the “3” record for **the last quarter only**. Current quarter URAs will continue to be reported on “0” records as in the past.

COVERAGE OF NON-DRUG PRODUCTS

Over the past month, we have been approached by two companies that make and sell saline & heparin filled syringes that asked to be included in the drug rebate program. According to the FDA, these syringes are not drugs and CMS has determined that they cannot be covered under the drug rebate program. These companies argued that other companies in the drug rebate program have their syringes covered. Some states are apparently unaware that these are non-drugs and not covered by the drug rebate program.

We are currently investigating labelers active in the drug rebate program that are reporting non-drugs, such as these syringes and, upon finding these NDCs, will remove them from the MDRI Master file and will report them to you to be immediately pulled from your files as well. Supplies, devices and all other non-drug products (by FDA standards) are not covered under the drug rebate program.

DELETED NON-DRUG PRODUCTS FOR ABBOTT LABORATORIES (LABELER CODE 00074)

Attached to this release is a list of non-drug products under labeler code 00074 which are being deleted from the MDRI file effective July 1, 2004. These products are not rebateable under the drug rebate program and should be deleted from your state files beginning with 3Q2004.

CHANGE TO T-BILL RATE HEADING

It has come to our attention that the U.S. Treasury has two T-bill rate headings on their website. Originally, there was one T-bill rate referred to as the Discount Investment Rate. There is now a Discount Rate and an Investment Rate. The drug rebate program uses the Investment Rate and therefore we are revising the heading on our T-bill rate attachment to reflect the appropriate title. Also, the 90-day rate is now a 91-day rate and we have reflected that change as well. **It is important to understand that the T-bill rates reported by CMS have not changed and no changes to past interest calculations are necessary.**

FUTURE DELETION OF TERMINATED LABELER CONTACT INFORMATION ON THE CMS STATE TAPE

In the near future, CMS will no longer include contact information for terminated labelers on the state tape. We will inform you of the exact quarter this becomes effective as soon as our system is able to accommodate the change.

DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING – September 13 - 17, 2004

We are pleased to announce that the next National DRP meeting will be held September 13-17, 2004 in Baltimore, Maryland. While this meeting is open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. As in the past, prior planning is absolutely imperative to the success of these meetings so we are requesting that you register PROMPTLY by completing the registration form on our web page at <http://www.cms.hhs.gov/medicaid/drugs/drpd/rpmtgs.asp> and submitting it electronically. Whenever possible, priority scheduling will be afforded those who respond first. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses.

We are requesting that, if possible, states plan on arriving in Baltimore in time to attend a "State-only" meeting with the DRP Team on Monday morning September 13th. Meeting details and hotel accommodations will be provided on our web page.

Feel free to contact any of the RO DRP Team members for any state specific DRP issues. Any non-state specific DRP questions or issues concerning the September meeting may be emailed to DRP@cms.hhs.gov.

Note: Meeting is contingent to CMS 2004 budget approval.

OPERATIONAL TRAINING GUIDE UPDATE

Page O2 has been updated to remove two names from the policy staff. Page O4 has been updated to transfer Linda Sapperstein's duties to Karen Leshko as outlined in Release No.130, dated April 30, 2004. Please share this information with the necessary staff and replace pages O2 and O4 in your guide.

NEW LABELERS (Please note Mandatory Coverage Date change below for Imclone)

| <u>Labeler Name/Labeler Code</u> | <u>Mandatory Coverage Date</u> | <u>Optional Coverage Date</u> |
|--|--------------------------------|-------------------------------|
| Marlex Pharmaceuticals, Inc. (Labeler Code 10135) | 07/01/2004 | 04/30/2004 |
| Imclone Systems, Inc. (Labeler Code 66733) | 01/01/2004 | 01/01/2004 |
| American Health Packaging (Labeler Code 68084) | 10/01/2004 | 06/02/2004 |
| Precision Dose, Inc. (Labeler Code 68094) | 10/01/2004 | 06/14/2004 |
| Biomarin Pharmaceuticals, Inc. (Labeler Code 68135) | 10/01/2004 | 05/24/2004 |
| Instituto Grifols (Labeler Code 68516) | 07/01/2004 | 04/30/2004 |

Contact information for new labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler codes are being terminated effective July 1, 2004:

RIJ Pharmaceutical Corporation (Labeler Code 53807); and
RSJ, Inc. (Western Research Laboratories) (Labeler Code 64727).

The following labeler code is being voluntarily terminated effective July 1, 2004:

Foxmeyer Drug Company (Health Mart) (Labeler Code 52297).

The following labeler codes are being terminated effective October 1, 2004:

C O Truxton, Inc. (Labeler Code 00463);
Select Brand Distributors (Labeler Code 15127);
Penederm, Inc. (Labeler Code 25074); and
Creighton Products Corp. (Labeler Code 50752).

The following labeler code is being voluntarily terminated effective October 1, 2004:

Radford (Labeler Code 63252).

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period November 18, 2002, 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.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

5 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

Abbott Laboratories, Inc. (Labeler Code 00074)
Products to be deleted effective July 1, 2004 *

| LABELER NDC2 | | PRODUCT NAME |
|--------------|------|---|
| 00074 | 0162 | REHYDRALYTE,8OZ BOTTLE ORAL ELECTROLYTE REHYDRATION SOLUTION |
| 00074 | 0240 | PEDIALYTE GRAPE FLAVORED 1LITER |
| 00074 | 0245 | PEDIALYTE FREEZER POPS |
| 00074 | 5175 | PEDIALYTE BUBBLE-GUM 1LITER |
| 00074 | 5498 | PEDIALYTE ORAL ELECTROLYTE MAINTENANCE SOLUTION |
| 00074 | 3492 | CECON SOLUTION VITAMIN C DROPS |
| 00074 | 3741 | DICAL-D TABS CALCIUM AND PHOSPHORUS VITAMIN D |
| 00074 | 3925 | DAYALETS FILMTAB MULTIVITAMIN SUPPLEMENT |
| 00074 | 4287 | OPTILETS -500 FILMTAB |
| 00074 | 4877 | SURBEX FT W/C VITAMIN B COMPLEX WITH C |
| 00074 | 4878 | SURBEX-T FT HIGH POTENCY VITAMIN B COMPLEX WITH VITAMIN C |
| 00074 | 7235 | IBERET-500FT CRC CONTROLLED RELEASE IRON VITAMIN B COMPLEX VITA |
| 00074 | 7238 | FERO-GRAD-500 CRC CONTROLLED RELEASE IRON WITH VITAMIN C |
| 00074 | 8152 | SURBEX-750 W/ZINC ZINC, VITAMIN B COMPLEX VITAMIN C AND E |

* All package sizes (active and terminated) of the above products are to be deleted.

CMS DRUG REBATE PROGRAM

Area Code 410



OPERATIONS

| | |
|-----------------------------------|----------|
| Tamara Bruce | 786-1519 |
| Chris Holmes | 786-3328 |
| Karen Leshko | 786-1291 |
| Vince Powell (Technical Director) | 786-3314 |
| Sue Williams | 786-3334 |

POLICY

| | |
|---|-------------------|
| Christie Cahee | 786-6614 |
| Claire Hardwick | 786-6777 |
| Chris Hinds | 786-4578 |
| Kim Howell | 786-6762 |
| Christina Lyon | 786-3332 |
| Cindy Pelter | 786-1176 |
| Marge Watchorn | 786-4361 |
| Larry Reed/Deirdre Duzor (Co-Directors) | 786-3325/786-4626 |

SYSTEM MAINTENANCE

E-mail inquiries to: MDRtech@cms.hhs.gov

DISPUTE RESOLUTION PROGRAM

| | |
|---------------|--------------|
| Sue Gaston | 786-6918 |
| Tamara Bruce | 786-1519 |
| Diane Dunstan | 303-844-7040 |



FAX

786-0390 – Operations/Systems
786-8534 - Policy

WEBSITE

www.hhs.gov/medicaid/drugs/drughmpg.asp

**CMS DRUG REBATE PROGRAM
PRIMARY FUNCTIONS/CONTACT PERSON**

| <u>Primary Function</u> | <u>Contact Person</u> |
|---------------------------------------|---|
| Contact Changes (labelers and states) | Karen Leshko |
| CPI-U Values | Karen Leshko |
| Data Edit Reports | Karen Leshko Vince Powell |
| Data Submission (labelers) | Karen Leshko Vince Powell |
| Data Submission (states) | Vince Powell |
| Diskette Installation/Problems | MDRtech@cms.hhs.gov |
| Dispute Resolution | Sue Gaston Tamara Bruce |
| Federal Upper Limits | Cindy Pelter Christie Cahee |
| HIV/AIDS Drugs | Marge Watchorn |
| Interest Calculation | Vince Powell Tamara Bruce |
| Invoice | Sue Williams |
| Policy Issues (general) | Christie Cahee, Claire Hardwick, Chris Hinds, Kim Howell, Christina Lyon, Cindy Pelter, Marge Watchorn |
| Prior Quarter Adjustment Statement | Sue Williams |
| Prior Period Adjustments | Vince Powell |
| Pricing Data/Product Elements | Vince Powell |
| Reconciliation of State Invoice | Sue Williams |
| State Tape | MDRtech@cms.hhs.gov |
| T-bill Rates | Karen Leshko |
| Training Guide | Sue Williams |
| VHCA/340B Drug Pricing | Marge Watchorn |

WEEKLY U.S. T-BILL INVESTMENT RATE
 weekly 91-day treasury bill auction rates

| Date of Auction | Invest. Rate | Date of Auction | Invest. Rate | Date of Auction | Invest. Rate |
|------------------------|---------------------|------------------------|---------------------|------------------------|---------------------|
| 11-18-02 | 1.227 | 06-16-03 | 0.854 | 01-12-04 | 0.887 |
| 11-25-02 | 1.228 | 06-23-03 | 0.830 | 01-20-04 | 0.891 |
| 12-02-02 | 1.231 | 06-30-03 | 0.903 | 01-26-04 | 0.907 |
| 12-09-02 | 1.215 | 07-07-03 | 0.907 | 02-02-04 | 0.939 |
| 12-16-02 | 1.219 | 07-14-03 | 0.895 | 02-09-04 | 0.939 |
| 12-23-02 | 1.207 | 07-21-03 | 0.911 | 02-17-04 | 0.931 |
| 12-30-02 | 1.207 | 07-28-03 | 0.964 | 02-23-04 | 0.947 |
| 01-06-03 | 1.207 | 08-04-03 | 0.964 | 03-01-04 | 0.957 |
| 01-13-03 | 1.199 | 08-11-03 | 0.960 | 03-08-04 | 0.945 |
| 01-21-03 | 1.179 | 08-18-03 | 0.964 | 03-15-04 | 0.961 |
| 01-27-03 | 1.159 | 08-25-03 | 0.997 | 03-22-04 | 0.945 |
| 02-03-03 | 1.175 | 09-02-03 | 0.988 | 03-29-04 | 0.961 |
| 02-10-03 | 1.171 | 09-08-03 | 0.951 | 04-05-04 | 0.945 |
| 02-18-03 | 1.179 | 09-15-03 | 0.947 | 04-12-04 | 0.929 |
| 02-24-03 | 1.195 | 09-22-03 | 0.953 | 04-19-04 | 0.949 |
| 03-03-03 | 1.198 | 09-29-03 | 0.953 | 04-26-04 | 0.985 |
| 03-10-03 | 1.077 | 10-06-03 | 0.939 | 05-03-04 | 1.001 |
| 03-17-03 | 1.137 | 10-14-03 | 0.923 | 05-10-04 | 1.078 |
| 03-24-03 | 1.174 | 10-20-03 | 0.939 | 05-17-04 | 1.058 |
| 03-31-03 | 1.121 | 10-27-03 | 0.960 | 05-24-04 | 1.066 |
| 04-07-03 | 1.158 | 11-03-03 | 0.960 | 05-31-04 | 1.150 |
| 04-14-03 | 1.186 | 11-10-03 | 0.951 | 06-07-04 | 1.251 |
| 04-21-03 | 1.182 | 11-17-03 | 0.951 | 06-14-04 | 1.413 |
| 04-28-03 | 1.141 | 11-24-03 | 0.946 | | |
| 05-05-03 | 1.117 | 12-01-03 | 0.943 | | |
| 05-12-03 | 1.089 | 12-08-03 | 0.915 | | |
| 05-20-03 | 1.040 | 12-15-03 | 0.903 | | |
| 05-28-03 | 1.121 | 12-22-03 | 0.884 | | |
| 06-02-03 | 1.133 | 12-29-03 | 0.901 | | |
| 06-09-03 | 1.024 | 01-05-04 | 0.939 | | |

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