DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

November 15, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #102

For State Medicaid Directors

INCORRECT CPI-U FOR CALENDAR YEAR 2000

In early October we were informed that all CPI-U values for calendar 2000 had been incorrectly calculated. A new list of monthly values was supplied to us immediately. The bad news is that about 4,000 NDCs were sent to states with incorrect Unit Rebate Amounts (URAs) for 2q00. The good news is that **ONLY** 2q00 processing was affected. Some labelers that calculate their own URA call us for the CPI-U information. Others pull it directly from the Department of Labor web site. Those that went to the web site apparently got the correct value. This only adds to the confusion of who calculated the URA correctly and who didn't.

We will be re-calculating the 2q00 URAs for the affected NDCs and include Prior Period Adjustments on the 3q00 URA tape to the states. Attached, please find a chart showing BOTH the incorrect and correct CPI-U values for 2000. Also, in order to keep confusion to a minimum, we have sent a report to affected labelers showing both old and new URA calculations. This will give them additional time to research for and create Prior Quarter Adjustment Statement forms to submit to affected states with the 3q00 payment.

Should you have any questions or comments, please contact Vince Powell on (410) 786-3314.

NEW PROCEDURE FOR LABELER "START" DATE

Since November, 1999, when labelers submit completed Drug Rebate agreements to HCFA, states no longer have to wait until the quarter that starts more than 60 days past the day the labeler signs the agreement to cover their products. Instead, once the agreement is received and reviewed for accuracy and completeness by HCFA, states have the option of covering their drugs immediately.

In order to comply with this requirement, the day the agreement is received and accepted by HCFA, each state technical contact receives a fax with the following information:

- Labeler Code
- Labeler Company Name
- Name/Address/Phone for each contact
- Optional Coverage Date
- Mandatory Coverage Date

As of the optional coverage date, each state may cover this company's products; however, please remember this means that ALL products for this company are covered, not just one or a few. Should your state wish to cover this company's products, you may do so anytime from the optional date up until the mandatory date. At that time, ALL states must cover the new company's products. Information regarding the status of labelers, new or old, MUST come from HCFA. Please do NOT attempt to get this information from other outside sources.

DHHS/OIG SPECIAL STUDY

There is a special study of Anti-Load Viral/AIDS drugs being performed by the Department of Health and Human Services/Office of the Inspector General that may require randomly-selected states to provide specific NDC utilization data. If so, you will be contacted by Madeline Carpinelli, HCFA/OIG office. Because the OIG has "blanket" coverage on all drug rebate program data, we ask that you please cooperate with Madeline. Any information requests can be completed without concern for privacy of data.

GOLDLINE OTC VITAMIN

After a question about a Goldline product, NDC 00182-4439-10 and whether it should be covered, we checked into the drug and found that this is an OTC Oyster shell

vitamin and is **NOT** covered by the Medicaid drug rebate program. Also, there is a second package size, that being -26. This is **not** covered either. We are IMMEDIATELY deleting these NDCs (00182-4439-10 and -26) from the MDRI master file. Even though they are included on the 3q00 URA tape, please remove these from your files. Also, the labeler will no longer cover them for rebates. We will continue our constant endeavor to clean up NDCs from our MDRI master file for products that do not belong there.

SEPARATE/SUPPLEMENTAL MEDICAID DRUG REBATE AGREEMENTS

In response to numerous requests from States and manufacturers , we are taking this opportunity to restate our policy and guidance that was provided in earlier releases regarding separate/supplemental Medicaid drug rebate agreements. Please note that the following information pertains to separate/supplemental *MEDICAID* drug rebate agreements and not to State-funded only drug rebate agreements. Solely State-funded drug rebate agreements and non-Medicaid State pharmaceutical assistance programs are not subject to HCFA review or approval.

1. Approval process for separate/supplemental Medicaid drug rebate agreements:

    - State submits agreement to appropriate HCFA Regional Office (RO).
    - HCFA RO sends agreement to HCFA Central Office,

      Attn: Michael Keogh.

    - HCFA CO reviews agreement, consults with RO, State and manufacturer(s), if necessary, then makes approval determination.
    - HCFA CO advises RO of approval determination.
    - HCFA RO advises State.
    - State advises manufacturer(s).

1. Effect on average manufacturer price (AMP) and best price:

    - Rebates paid under HCFA-approved, separate/supplemental Medicaid drug rebate agreements do not effect AMP or best price under the Medicaid program.

      Note: Similarly, rebates received through State-funded only rebate agreements and/or State pharmaceutical assistance programs do not effect AMP or best price.

1. Rebate reporting and sharing:

    - Rebates received by the State under separate/supplemental Medicaid drug rebate agreements must be reported to and shared with the Federal government on the same percentage basis as rebates under the national rebate agreement.

If you have any questions on separate/supplemental Medicaid drug rebate agreements, please contact Mike Keogh at mkeogh1@hcfa.gov or (410) 786-5910.

NEW LABELERS

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Layton BioScience, Inc. (Labeler Code 17205) 01/01/2001 09/14/2000

3M Pharmaceuticals (Labeler Code 17518) 01/01/2001 10/27/2000

3M Pharmaceuticals (Labeler Code 21200) 01/01/2001 10/27/2000

3M Pharmaceuticals (Labeler Code 51131) 01/01/2001 10/27/2000

Medefil, Inc. (Labeler Code 64253) 01/01/2001 10/23/2000

Cutis Pharma, Inc. (Labeler Code 65628) 01/01/2001 10/12/2000

Transkaryotic Therapies, Inc. 01/01/2001 10/20/2000

(Labeler Code 65757)

Lifecycle Ventures, Inc. (Labeler Code 65939) 01/01/2001 10/27/2000

TERMINATED LABELERS

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

Dupont Merck Pharmaceutical Co. (Labeler Codes 00060 and 00094);

AP Pharmaceuticals, Inc. (Labeler Code 00409);

Vital Signs, Inc. (Labeler Code 08166);

Mass Public Health (Labeler Code 14362);

Calgon Vestal Laboratories (Labeler Codes 08237 and 55559);

Apothecus Pharmaceutical Corporation (Labeler Code 52925);

Medline Industries, Inc. (Labeler Code 53329);

Parke-Davis, Div. of Warner-Lambert Co. (Labeler Code 53592);

Laboratorios Atral, S.A. (Labeler Code 53862);

Horizon Products Company (Labeler Code 54580);

Genderm (Labeler Code 57284);

Accumed (Labeler Code 60876);

Imiren Pharmaceuticals, Inc. (Labeler Code 61808); and

Unigen Pharmaceuticals, Inc. (Labeler Code 62305).

RETROACTIVELY TERMINATED LABELERS

The following labelers are being retroactively terminated as of January 1, 2000.

Pfizer Pharmaceuticals Group (Labeler Code 00995);

Novo Nordisk Pharmaceuticals, Inc. (Labeler Code 50445); and

Novartis Pharmaceuticals Corporation (Labeler Code 58345).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period June 7, 1999, 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