

February 28, 2003

MEDICAID DRUG REBATE PROGRAM

RELEASE #121

For State Medicaid Directors

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TRANSFER OF DISPUTE RESOLUTION PROGRAM (DRP) FUNCTION

Organizational responsibility of the DRP was transferred from Policy Coordination and Planning Group to the Finance, Systems and Budget Group (FSBG), formerly the Finance, Systems and Quality Group (FSGQ).

In addition to this organizational change, we would like to inform you that Mike Keogh, former Team Leader for the DRP, will be retiring after 31 years of Government service. Sue Gaston has accepted a reassignment to FSBG and will be utilizing her knowledge related to the Medicaid Drug Rebate Program and pharmacy issues to take the lead on all aspects of the DRP. Tami Bruce, who will remain on the Drug Rebate Operations Team within CMSO, will continue to assist in the DRP. Also, Diane Dunstan remains our lead Regional Office DRP coordinator and will continue to assist Sue and Tami to further the DRP.

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As a reminder, all state specific DRP related issues should be directed to the Regional Office DRP Team members. Many of you are familiar with your RO DRP Team members; however, if you don't know who to contact in your region please call Diane Dunstan at (303) 844-7040. The DRP Team plans to have its own web page up and running in the near future that will contain DRP team contacts and other DRP related information. For non-state specific DRP questions please contact Sue Gaston at (410) 786-6918 or Tami Bruce at (410) 786-1519.

INTEREST CLARIFICATION WHEN PRIOR PERIOD ADJUSTMENTS (PPAs) ARE SUBMITTED

The purpose of this information is to provide clarification as to:

- When does interest apply when Prior Period Adjustments (PPAs) are submitted?
 - Interest applies to disputed or unpaid rebate amounts and late rebate payments.
 - Interest does not apply to PPAs of unit rebate amounts.
 - Interest does apply if the rebate amount due from the PPA is not paid timely.
- When does interest begin accruing on unpaid or disputed rebate payments that were generated due to PPAs?
 - Interest begins accruing 38 calendar days after the date the state receives the PPA/Unit Rebate Amounts (URAs), included on the current quarterly URA data file.

Interest is applied to disputed or unpaid rebate amounts and late rebate payments. Interest is **not** applied to PPAs of unit rebate amounts or to state utilization adjustments.

PPAs are unit rebate amount changes caused by a correction to a pricing record or a change to a baseline Average Manufacturer Price (AMP) or Market Date submitted by a manufacturer to CMS for Medicaid drug rebate update and inclusion on the next quarterly pricing/product file to the states. As noted, Manufacturer Program Release No.18, dated August 1995, the practice of states invoicing for PPAs is no longer allowed. This decision was made in keeping with the intent of the Federal statute requiring manufacturers to remit rebate payments based on accurate pricing data.

When a baseline AMP or Market Date changes or a pricing record is changed, which causes the recalculation of one or more URAs, the manufacturer may owe an additional rebate to states, which is considered a rebate amount due. Interest cannot be applied when the PPA is initially submitted by CMS to states. Interest may be applied if the rebate amount generated by the PPA is not paid timely. In such a case, it is considered a late rebate payment and interest will begin accruing.

Generally, interest starts accruing 38 calendar days from the date the state mails the state invoice to the manufacturers. Since states can't invoice for PPAs, some states have asked when interest would start accruing if a rebate payment, resulting from a PPA, was not paid timely. Interest accrual may be determined based on the postmarked date the state receives the PPA/URAs, which is the same time they receive the current quarterly URAs.

Note: An overview of the interest provisions of the Medicaid drug rebate program may be found in State Program Release No. 6 & 29 and Manufacturer Program Release No. 7.

NEW LABELERS

| <u>Labeler Name/Labeler Code</u> | <u>Mandatory Coverage Date</u> | <u>Optional Coverage Date</u> |
|---|--------------------------------|-------------------------------|
| PharmaDerm (Labeler Code 00462) | 07/01/2003 | 02/06/2003 |
| Schering Plough HealthCare Products, Inc. (Labeler Code 11523) | 04/01/2003 | 01/17/2003 |
| Nastech Pharmaceutical Co. (Labeler Code 57459) | 04/01/2003 | 12/20/2002 |
| Novo Nordisk Pharmaceuticals Inc. (Labeler Code 59060) | 01/01/2003 | 12/09/2002 |
| Millennium Pharmaceuticals, Inc. (Labeler Code 63020) | 07/01/2003 | 02/21/2003 |
| STADA Pharmaceuticals, Inc. (Labeler Code 64860) | 01/01/2003 | 12/10/2002 |
| Fairview Health Services (Labeler Code 65779) | 04/01/2003 | 12/17/2002 |
| Three Rivers Pharmaceuticals, LLC (Labeler Code 66435) | 07/01/2003 | 02/11/2003 |
| Inkin Pharmaceuticals (Labeler Code 66934) | 07/01/2003 | 02/11/2003 |
| Medecor Pharma, LLC (Labeler Code 67112) | 04/01/2003 | 11/25/2002 |
| Romark Pharmaceuticals, L.C. (Labeler Code 67546) | 04/01/2003 | 12/16/2002 |

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

TERMINATED LABELERS

The following labeler codes are being terminated effective April 1, 2003:

Hyrex Pharmaceuticals (Labeler Code 00314);
 Gemini Pharmaceuticals, Inc. (Labeler Code 51645);
 Pharmakon Labs, Inc. (Labeler Code 55422); and
 Healz-Plus, Inc. (Labeler Code 66073).

TERMINATED LABELERS (Con't.)

The following labeler codes are being voluntarily terminated effective April 1, 2003:

Celltech Pharmaceuticals, Inc. (Labeler Codes 19650 and 43567);
Roche Laboratories, Inc. (Labeler Code 53169);
Kerry Company, Inc. (Labeler Code 60475);
Amerx Health Care, Corp. (Labeler Code 61470); and
Graben Pharma, Inc. (Labeler Code 67445).

OTHER ATTACHMENT

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period September 24, 2001, 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.

Wayne Smith
Acting Director
Finance, Systems and Budget Group
Center for Medicaid and State Operations

2 Attachments

cc:

All State Drug Rebate Technical Contacts
All Regional Administrators