

April 16, 2002

MEDICAID DRUG REBATE PROGRAM RELEASE #114

## For State Medicaid Directors

### **IMPROPER REBATE WITHHOLDING & INTEREST IMPLICATIONS FOR MANUFACTURERS**

It has come to our attention that several manufacturers are withholding current rebates from states' current invoices to recover amounts previously paid by the manufacturer but now determined by the manufacturer to not be due the states. In short, some manufacturers are automatically withholding amounts without initiating or reaching dispute resolution with the state. States have reported that some manufacturers have taken credit (that is, reduced or withheld current rebate payments) without first notifying the state and properly disputing past rebates.

CMS has consistently maintained that current rebates may not be reduced for "prior quarters" disputes until dispute resolution has occurred. Dispute resolution means that agreement between the state and manufacturer on disputed rebates has been reached. Absent this agreement, a determination by a manufacturer that amounts paid were not due and a subsequent withholding from current rebate payments without dispute resolution being achieved with the state may be considered violations of the rebate agreement.

The rebate agreement requires that current rebates owed and not properly disputed must be paid timely. It is also a requirement of the rebate agreement that manufacturers formally notify and work with states on disputes found in previously paid quarters. Manufacturers that withhold or reduce rebate payments from current quarters based on disputes they find in

previously paid quarters **without first reaching dispute resolution with states** will owe interest on the amount improperly withheld. Further, as stated earlier, we consider this practice a violation of the rebate agreement and manufacturers that do not cease this practice will be at risk for termination from the rebate program.

If you have any questions on this or any other dispute resolution issue, please continue to contact any of the regional office (RO) Dispute Resolution Program (DRP) Team staff, Diane Dunstan, Lead DRP RO Coordinator at [ddunstan@cms.hhs.gov](mailto:ddunstan@cms.hhs.gov), Tami Bruce, DRP CO Coordinator at [tbruce@cms.hhs.gov](mailto:tbruce@cms.hhs.gov) or Mike Keogh, DRP Team Leader at [mkeogh1@cms.hhs.gov](mailto:mkeogh1@cms.hhs.gov).

### **DOAK PHARMACEUTICALS, LABELER CODE 10337**

In Release #112, dated February 12, 2002, we notified you that Bradley Pharmaceuticals (Labeler Code 10337) was being terminated from the drug rebate program effective April 1, 2002. Note that Labeler Code 10337 in fact is owned by Doak Dermatologics, a division of Bradley. Over the past several months, Doak has submitted the pricing data we had not previously received. It has also documented extensive and ongoing efforts to pay outstanding rebates, including interest where applicable. The company has also submitted a new rebate agreement. Therefore, Doak (10337) is to be reinstated into the drug rebate program as of July 1, 2002. Note also that any state wishing to begin coverage of Doak products prior to July 1, 2002, may do so effective any time between the date of this Release and July 1. Questions may be directed to the Operations Staff, listed in section "O" of your Operations Guide.

### **TERMINATION CORRECTION (Name Only)**

In State Release #113 we notified you that Med-Tek Systems (Labeler Code 52349) was being voluntarily terminated. The labeler's name was reported incorrectly. The correct name of the labeler is Med-Tek Pharmaceuticals, Inc. We apologize for any inconvenience this may have caused.

### **NEW LABELERS**

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Gilbert Laboratories (Labeler Code 00535) 07/01/2002 03/29/2002

Questcor Pharmaceuticals, Inc. (Labeler Code 63004) 07/01/2002 04/11/2002

Scios, Inc. (Labeler Code 65847) 07/01/2002 03/14/2002

**NEW LABELERS (Con't)**

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Scientific Laboratories, Inc.

(Labeler Code 66239) 07/01/2002 04/02/2002

Xcel Pharmaceuticals, Inc. (Labeler Code 66490) 07/01/2002 04/02/2002

Rare Disease Therapeutics, Inc.

(Labeler Code 66607) 07/01/2002 03/27/2002

Regent Labs, Inc. (Labeler Code 66779) 07/01/2002 03/27/2002

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

**TERMINATED LABELER**

The following labeler is being voluntarily terminated as of July 1, 2002:

Summers Laboratories, Inc. (Labeler Code 11086).

**OTHER ATTACHMENTS**

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period July 31, 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

Center for Medicaid and State Operations

3 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators