

July 31, 2003

MEDICAID DRUG REBATE PROGRAM

RELEASE #124

## For State Medicaid Directors

### **INVALID LABELER CODE REPORTED IN RELEASE NO. 123**

In release no. 123, dated June 12, 2003, we reported a new labeler (Tyco Healthcare Group, LP, labeler code 08080) in the Drug Rebate Program. The manufacturer inadvertently gave CMS an incorrect labeler code. As shown below in the NEW LABELERS section of this release, the correct labeler code is 17474. *Please remove 08080 labeler code from your active files and note that labeler code 17474 has an optional coverage date of 04/29/2003 and a mandatory coverage date of 07/01/2003.* We apologize for any inconvenience this error has caused.

### **IMPORTANT HIPAA/RX NEWS - STATUS OF PRESCRIPTION NUMBERS UNDER THE HIPAA PRIVACY RULE**

Manufacturers have the right to dispute or audit state utilization information, and regularly request claims-level data from the states to help resolve Medicaid drug rebate disputes. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) we consulted with Health and Human Services' Office of Civil Rights on whether it is permissible for states to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors for claims validation in the Medicaid drug rebate program.

The HIPAA Privacy Rule permits state Medicaid agencies to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors that assist the pharmaceutical manufacturers, for purposes of validating claims under the Medicaid Drug Rebate program. This information is provided on the U.S. Department of Health and Human Services' web page and clearly states that claims-level data, specifically the prescription number, is appropriate to disclose as part of the state Medicaid agency's payment activities.

To view this information refer to <http://www.hhs.gov/ocr/>, click on "View Health Information Privacy Frequently Asked Questions (FAQs)" link. Go to page 10, click on #192.

### **STATE PHARMACY ASSISTANCE PROGRAMS – REVISED CRITERIA**

We have received numerous inquires and comments on whether State only programs meet the criteria of a State pharmacy assistance program (SPAP) in order to be excluded from Best Price (BP) and Average Manufacturer Price (AMP), as was discussed in Labeler Release #57. As a result, we have revised the criteria described in Release #57. The new criteria should be applied prospectively as of the date of this release.

In order for a State only program to qualify as a State pharmacy assistance program, it should generally meet the following criteria:

- The program is a State developed program specifically for disabled, indigent, low-income elderly or other financially vulnerable persons.
- The program is funded by the State; that is, no Federal dollars are involved.
- The program is set up such that payment is provided directly to providers.
- The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefits or services.
- The program does not allow for the diversion, resale or transfer of benefits reimbursed under the State pharmacy assistance program to individuals who are not beneficiaries of the State pharmacy assistance program.

Programs that reflect traditional state responsibilities, such as State employee benefit programs or medical programs for inmates or patients of State prisons or hospitals, do not meet these criteria. As a reminder, only the prices used under a State pharmacy assistance program can be excluded from the BP and AMP calculations; therefore, the prices of programs that do not meet these criteria should be included in BP and AMP calculations as appropriate.

In addition, as was mentioned in Release #57, we are aware of at least one state that is grouping several state-only programs together and sending manufacturers just one invoice for all the programs. It is possible that not all of these programs meet the above-mentioned criteria for a State pharmacy assistance program, and therefore, the prices used thereunder would not necessarily be excluded from BP and AMP. If a State sends out only one invoice for multiple programs and some of those programs do not qualify as State pharmacy assistance programs, it is the manufacturer's responsibility to determine the individual amounts that are being paid for each program and identify any instances where BP and AMP should be adjusted. To that end, it may be necessary to request separate invoices for the individual programs to ensure proper BP and AMP reporting.

### **PERSONNEL CHANGES**

Recently there have been a few personnel changes that are noteworthy.

Judy Allison, longtime member of the Operations staff, has retired. Judy's last day was June 28<sup>th</sup>. After more than 35 years of federal service, we all wish her the best for a long and happy retirement.

Taking over Judy's responsibilities in the area of receiving and uploading the diskettes is Linda Sapperstein. Linda's phone number is 410-786-3317. The responsibility for sending out rebate agreements, updating the system with contact changes, and alerting states, via FAX, about new labelers has been passed on to Karen Leshko. Karen is already a member of the Division of State Systems and, for the present, will be splitting her time between duties in the HIPAA area and learning the operations of the drug rebate program. Karen's phone number is (410) 786-1291 and can be reached via e-mail at [kleshko@cms.hhs.gov](mailto:kleshko@cms.hhs.gov).

After a 4-month hiatus having bilateral hip replacements, Vince Powell is once again on the scene and back at his duty station. Vince returned to "active" duty on June 30<sup>th</sup>.

Revised pages to section O of the Operational Training Guide which reflect the above changes are attached.

### **MDR TECHNICAL QUESTIONS E-MAIL ADDRESS**

CMSO has established an e-mail address for your use when technical questions arise. The e-mail address is: [MDRtech@cms.hhs.gov](mailto:MDRtech@cms.hhs.gov). Listed below are some examples of technical questions which can be answered via this e-mail address. Please use this new e-mail address to expedite your technical questions/requests.

- Request for an additional Rebate Tape
- Technical inquires regarding Rebate Tapes
- Utilization Tape submission errors or questions

**NEW LABELERS**

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Tyco Healthcare Group, LP (Labeler Code 17474)	07/01/2003	04/29/2003
Gil Pharmaceutical Corporation (Labeler Code 58552)	10/01/2003	06/12/2003
Abrika Pharmaceuticals, LLLP (Labeler Code 67767)	10/01/2003	06/27/2003
Corixa Corporation (Labeler Code 67800)	10/01/2003	06/27/2003
Larken Laboratories, Inc. (Labeler Code 68047)	10/01/2003	07/15/2003

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

**TERMINATED LABELERS**

RX Formulations Corporation (Labeler Code 11808) was terminated effective July 1, 2003. States were faxed this information on June 19.

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

Carlsbad Technology, Inc. (Labeler Code 61442);  
OraPharma, Inc. (Labeler Code 65976); and  
NuPharmx LLC (Labeler Code 66460).

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

D&K Healthcare Resources, Inc. (Labeler Code 31096);  
Biocodex Incorporated (Labeler Codes 04142 and 66825);  
Amkas Laboratories, Inc. (Labeler Code 61073);  
Am2Pat, Inc. (Formerly Emt-Rx) (Labeler Code 64054);  
Transkaryotic Therapies, Inc. (Labeler Code 65757);  
Scientific Laboratories, Inc. (Labeler Code 66239);  
Vistapharm, Inc. (Labeler Code 66689);  
Regent Labs, Inc. (Labeler Code 66779).

**OTHER ATTACHMENT**

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period April 22, 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/

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

3 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

# 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
Linda Sapperstein	786-3317
Sue Williams	786-3334

### POLICY

Christie Cahee	786-6614
Claire Hardwick	786-6777
Tammi Hessen	786-1025
Chris Hinds	786-4578
Kim Howell	786-6762
Christina Lyon	786-3332
Cindy Pelter	786-1176
Carl Tepper	786-2137
Marge Watchorn	786-4361
Larry Reed/Deirdre Duzor (Co-Directors)	786-3325/786-4626

### SYSTEM MAINTENANCE

Kay Alexander	786-0252
Dona Coffman (Technical Director)	786-0260

### 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.cms.hhs.gov/medicaid/drugs/drughmpg.asp](http://www.cms.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 Linda Sapperstein
CPI-U Values	Linda Sapperstein
Data Edit Reports	Linda Sapperstein Vince Powell
Data Submission (labelers)	Linda Sapperstein Vince Powell Kay Alexander
Data Submission (states)	Vince Powell
Diskette Installation/Problems	Kay Alexander
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, Tammi Hessen, Chris Hinds, Kim Howell, Christina Lyon, Cindy Pelter, Carl Tepper, 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	Kay Alexander
T-bill Rates	Linda Sapperstein
Training Guide	Sue Williams
VHCA/340B Drug Pricing	Marge Watchorn





**WEEKLY U.S. T-BILL DISCOUNT RATE**  
 weekly 90-day treasury bill auction rates

<b>Date of Auction</b>	<b>Discount Rate</b>	<b>Date of Auction</b>	<b>Discount Rate</b>	<b>Date of Auction</b>	<b>Discount Rate</b>
04-22-02	1.720	11-18-02	1.227	06-16-03	0.854
04-29-02	1.760	11-25-02	1.228	06-23-03	0.830
05-06-02	1.773	12-02-02	1.231	06-30-03	0.903
05-13-02	1.781	12-09-02	1.215	07-07-03	0.907
05-20-02	1.760	12-16-02	1.219	07-14-03	0.895
05-28-02	1.760	12-23-02	1.207	07-21-03	0.911
06-03-02	1.752	12-30-02	1.207	07-28-03	0.964
06-10-02	1.752	01-06-03	1.207		
06-17-02	1.732	01-13-03	1.199		
06-24-02	1.712	01-21-03	1.179		
07-01-02	1.719	01-27-03	1.159		
07-08-02	1.724	02-03-03	1.175		
07-15-02	1.712	02-10-03	1.171		
07-22-02	1.692	02-18-03	1.179		
07-29-02	1.712	02-24-03	1.195		
08-05-02	1.627	03-03-03	1.198		
08-12-02	1.659	03-10-03	1.077		
08-19-02	1.659	03-17-03	1.137		
08-26-02	1.661	03-24-03	1.174		
09-03-02	1.639	03-31-03	1.121		
09-09-02	1.676	04-07-03	1.158		
09-16-02	1.692	04-14-03	1.186		
09-23-02	1.639	04-21-03	1.182		
09-30-02	1.566	04-28-03	1.141		
10-07-02	1.615	05-05-03	1.117		
10-15-02	1.659	05-12-03	1.089		
10-21-02	1.696	05-20-03	1.040		
10-28-02	1.578	05-28-03	1.121		
11-04-02	1.433	06-02-03	1.133		
11-12-02	1.211	06-09-03	1.024		

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