

November 18, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #134

For State Medicaid Directors

NON-DRUG PRODUCTS DELETED – AM2PAT (LABELER CODE 64054)

CMS notified State Technical Contacts by fax on October 29, 2004, that the following products are being terminated from the Medicaid Drug Rebate Program effective January 1, 2005:

NDC2

1000 HEPARIN 100 U/ML 1ML FILL IN 3 ML SYRINGE
1001 HEPARIN 10 U/ML 1ML FILL IN 3 ML SYRINGE
1002 HEPARIN 100 U/ML 2ML FILL IN 3 ML SYRINGE
1003 HEPARIN 10 U/ML 3 ML FILL IN 6 ML SYRINGE
1004 HEPARIN 100 U/ML 5 ML FILL IN 12 ML SYRINGE
1005 HEPARIN 10 U/ML 5 ML FILL IN 6ML SYRINGE
1009 HEPARIN 100 U/ML 10ML FILL IN 12ML SYRINGE
1010 HEPARIN 10U/ML 10ML FILL IN 12ML SYRINGE
3000 HEPARIN 100 U/ML 1ML IN 3 ML COMBINATION
3001 HEPARIN 10 U/ML 1ML IN 3ML COMINABION K
3002 HEPARI N 10 U/ML 2ML IN 3 ML COMBINATION P
3003 HEPARIN 10 U/ML 3ML IN 12 ML COMBINATION
3004 HEPARIN 100 U/ML 5 ML IN 6 ML COMBINATION
3005 HEPARIN 10 U/ML 5ML IN 12 ML COMBINATION
3009 HEPARIN 100 U/ML 10ML IN 12 ML COMBINATION
3010 HEPARIN 10 U/ML 10ML IN 12 ML COMBINATION

The heparin and saline-filled flush syringes listed above do not meet the definition of covered outpatient drugs under section 1927 (k) of the Social Security Act. We are currently searching the MDR database for heparin and saline-filled flush syringes and will notify states as soon as we become aware of other products which should be deleted from the database. If you are aware of such devices in the program, please notify CMS.

HEPARIN/SALINE FLUSH SYRINGES & OTHER NON-DRUG PRODUCTS

It has come to our attention that manufacturers continue to report non-drug products to CMS, such as certain heparin/saline flush syringes, for inclusion in the Medicaid Drug Rebate Program (the program), and that states continue to cover them. When CMS discovers a non-drug product, we contact the manufacturer to notify it of the product(s) deletion from the program, and we notify states of the deletion of the product from our Medicaid Drug Rebate database.

Non-drug products are not eligible for coverage under the Medicaid Drug Rebate Program. States that discover non-drug products in CMS's quarterly data file should contact the Operations Team (see Section O of the Operations Guide) so that we may confirm their status and remove them if appropriate.

Ortho-Evra®. (00062-1920) REPLACEMENT PATCH BY ORTHO PHARMACEUTICAL CORPORATION

Ortho Pharmaceutical Corporation (OPC) makes the birth control patch Ortho-Evra. The patch comes in a box of three, intended for 3 weeks of use. Another package size contains one replacement patch intended to be dispensed in the event that the user has a problem with the patch, such as adhesive failure. OPC has implemented a replacement patch program, which is available to state Medicaid programs, as long as the replacement patch is used for replacement purposes and not as an initial script. Questions regarding the program should be addressed to:

Bill Baxter
Director, Medicaid Market & Rebate Management
Phone: 908/218-6462 Fax: 908/203-8052

LABELER CONTACT FILE ON THE CMS STATE TAPE

Effective with the 4Q2004 CMS tape to be sent to you in February 2005, the labeler contact file will **no longer contain contact information for terminated labelers**. Any contact information you now have on terminated labelers should be maintained to assist in resolving outstanding/future rebates issues.

UPDATES TO OPERATIONAL TRAINING GUIDE

Attached is revised page M5 of the guide. The page is revised to include the labeler's technical contact e-mail address and fax number. Also, attached are revised pages O2 and O4 to reflect staff changes. Please replace these pages in your guide.

RETIREMENT OF KAY ALEXANDER

Over the past several years, many of you contacted Kay Alexander of our system support group for assistance. She was a great deal of help with the diskette system (labelers) and with the quarterly utilization files (states).

Kay has retired from Federal Service. We ask that you no longer attempt to contact her for help. If you have an operations or a policy issue, please see section "O" of your Operations Guide for assistance on who to contact. If your issue is system related, please submit your inquiry or problem to the system trouble-shooting e-mail address, MDRTECH@cms.hhs.gov. If you're not sure who should be contacted, call one of the Operations staff for assistance.

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Hospira, Inc. (Labeler Code 00409)	01/01/2005	10/28/2004
Affordable Pharmaceuticals, LLC (Labeler Code 10572)	01/01/2005	11/01/2004
Ranbaxy Laboratories Incorporated (Labeler Code 10631)	01/01/2005	10/14/2004
FEI Women's Health LLC (Labeler Code 50907)	01/01/2005	09/29/2004
Kiel Laboratories, Inc. (Labeler Code 59063)	01/01/2005	10/18/2004
Ista Pharmaceuticals (Labeler Code 67425)	01/01/2005	11/01/2004
Oscient Pharmaceuticals Corporation (Labeler Code 67707)	01/01/2005	10/28/2004
Santarus, Inc. (Labeler Code 68012)	01/01/2005	10/19/2004

REINSTATED LABELERS

Mayne Pharma (USA) Inc., labeler code 61703, has signed a new rebate agreement and is reinstated in the drug rebate program effective 01/01/2005.

Vistapharm, Inc., labeler code 66689, has signed a new rebate agreement and is reinstated in the drug rebate program effective 01/01/2005.

Contact information for new/reinstated labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler code was terminated effective **October 1, 2004**:

Amkas Laboratories, Inc., (Labeler Code 61073).

The following labeler code terminated voluntarily effective **January 1, 2005**:

Aber Pharmaceuticals, Inc. (Labeler Code 67523).

The following labeler codes are being terminated effective **January 1, 2005**:

Warner Chilcott Laboratories (Labeler Code 00047);
Halsey Drug Company (Labeler Code 00879);
Tyco Healthcare Group/Kendall Division (Labeler Code 17474);
Collagenex Pharmaceuticals, Inc. (Labeler Code 27280);
Healthpoint, Ltd. (Labeler Code 48017);
Propharma, Inc. (Labeler Code 50313);
Dayton Laboratories (Labeler Code 52041);
Geri-Care Pharmaceuticals Corp. (Labeler Code 57896);
Martin Ekwealor Pharmaceuticals, Inc. (Labeler Code 58607);
Respa Pharmaceutical, Inc. (Labeler Code 60575);
Imiren Pharmaceuticals, Inc. (Labeler Code 61808);
Chiron Corporation (Labeler Code 63430);
Medefil, Inc. (Labeler Code 64253);
MGP Apothecon (Labeler Code 64681);
Syntho Pharmaceuticals, Inc. (Labeler Code 66576), and;
Corban Pharmaceuticals, LLC (Labeler Code 68549).

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period June 16, 2003, 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

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
06-16-03	0.854	01-12-04	0.887	08-09-04	1.497
06-23-03	0.830	01-20-04	0.891	08-16-04	1.498
06-30-03	0.903	01-26-04	0.907	08-23-04	1.541
07-07-03	0.907	02-02-04	0.939	08-30-04	1.607
07-14-03	0.895	02-09-04	0.939	09-06-04	1.663
07-21-03	0.911	02-17-04	0.931	09-13-04	1.671
07-28-03	0.964	02-23-04	0.947	09-20-04	1.716
08-04-03	0.964	03-01-04	0.957	09-27-04	1.741
08-11-03	0.960	03-08-04	0.945	10-04-04	1.716
08-18-03	0.964	03-15-04	0.961	10-12-04	1.711
08-25-03	0.997	03-22-04	0.945	10-18-04	1.803
09-02-03	0.988	03-29-04	0.961	10-25-04	1.890
09-08-03	0.951	04-05-04	0.945	11-01-04	1.987
09-15-03	0.947	04-12-04	0.929	11-08-04	2.084
09-22-03	0.953	04-19-04	0.949	11-15-04	2.115
09-29-03	0.953	04-26-04	0.985		
10-06-03	0.939	05-03-04	1.001		
10-14-03	0.923	05-10-04	1.078		
10-20-03	0.939	05-17-04	1.058		
10-27-03	0.960	05-24-04	1.066		
11-03-03	0.960	05-31-04	1.150		
11-10-03	0.951	06-07-04	1.251		
11-17-03	0.951	06-14-04	1.413		
11-24-03	0.946	06-21-04	1.336		
12-01-03	0.943	06-28-04	1.381		
12-08-03	0.915	07-05-04	1.344		
12-15-03	0.903	07-12-04	1.336		
12-22-03	0.884	07-19-04	1.352		
12-29-03	0.901	07-26-04	1.449		
01-05-04	0.939	08-02-04	1.490		

**MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 2 OF 3)
SUPPLEMENTAL DATA SHEET**

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT – Person responsible for sending and receiving data

NAME OF CONTACT

AREA	PHONE NUMBER	EXTENSION
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FAX #:

EMAIL Address:

NAME OF CORPORATION

STREET ADDRESS

CITY

STATE

ZIP CODE

Note: If more than one labeler code, attach one sheet for each code.

CMS-367a (Exp. 08/31/06)
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Rev. 11/04

M5

CMS DRUG REBATE PROGRAM



Area Code 410

OPERATIONS

Cindy Bergin	786-1176
Tamara Bruce	786-1519
Chris Holmes	786-
3328	
Karen Leshko	786-1291
Vince Powell (Technical Director)	786-3314
Sue Williams	786-3334

POLICY

Claire Hardwick	786-6777
Chris Hinds	786-4578
Kim Howell	786-6762
Christina Lyon	786-3332
Katiuscia Potier	786-1947
Gail Sexton	786-4583
Maria (Cora) Tracy	786-3289
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.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
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
HIV/AIDS Drugs	Marge Watchorn
Interest Calculation	Vince Powell Tamara Bruce
Invoice	Sue Williams
Policy Issues (general)	Claire Hardwick, Chris Hinds, Kim Howell, Christina Lyon, Gail Sexton, Maria (Cora) Tracy, 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

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