

February 17, 2005

MEDICAID DRUG REBATE PROGRAM

RELEASE #136

For State Medicaid Directors

CMS-2175-F: REGULATION ISSUED NOVEMBER 26, 2004

On November 26, 2004, CMS issued the regulation entitled, Medicaid Program; Time Limitation on Recordkeeping Drug Rebate Program. This final rule makes permanent the temporary 10-year timeframe for pharmaceutical manufacturers to retain pricing records under the Medicaid drug rebate program. The final rule also finalizes the requirement that pharmaceutical manufacturers must retain records beyond the 10-year timeframe if the records are known by the pharmaceutical manufacturer to be the subject of an audit or a government investigation and if the audit findings or investigation related to the pricing records have not been resolved. The new regulation became effective January 1, 2005. The temporary recordkeeping requirement put in place January 2004 expired December 31, 2004.

HEPARIN FLUSH SYRINGES – COVERAGE ISSUES

In State Releases 132 and 134, we informed states about certain heparin flush syringes that are not drugs under the Medicaid Drug Rebate Program. The determination of covered outpatient drugs under the Medicaid Drug Rebate Program generally depends on whether the drug has been approved as a prescription drug by the FDA under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act. While the FDA approved certain heparin flush syringes as prescription drugs under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, others were issued device approvals. Those that were issued device approvals do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are therefore not eligible for Medicaid coverage under the Drug Rebate Program.

Those manufacturers participating in the Medicaid Drug Rebate Program that have received FDA approval under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act for their heparin syringes are:

- Hospira (labeler code 00409)
- Abbott (labeler code 00074)
- American Pharmaceutical Partners (labeler code 63323)
- Baxter Health Care (labeler code 00338 and 00641)

While a state may choose to cover the heparin flush syringes of other than the above manufacturers under other Medicaid services, those syringes are not subject to coverage as drugs under the Medicaid Drug Rebate Program. Questions regarding this issue can be directed to Operations staff (see Section O of the Operations Guide for contact information).

AKYMA PHARMACEUTICALS and DERMARITE INDUSTRIES, INC. – NDC DELETIONS

Attached are lists of products/NDCs being deleted from the MDR Master file of covered outpatient drugs as defined in Section 1927(k)(2) of the Social Security Act.

For labeler code 65162, Akyma Pharmaceuticals LLC, the NDCs will be deleted effective April 1, 2005. Akyma Pharmaceuticals will honor any utilization on these products through the first quarter of 2005 and will pay rebates as appropriate on that utilization.

For labeler code 61924, Dermalite Industries, Inc., the NDCs are deleted effective January 1, 2005.

UPDATES TO THE OPERATIONAL TRAINING GUIDE

Page O2 of the Operational Training Guide has been revised to add the e-mail addresses for the Operations/DRP staff and to delete some members of the Policy staff. Pages O5 through O7 are now deleted and replaced with a new page O5. Please replace the attached page O2 and O5 in your guide.

**DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING -
APRIL 11-15, 2005. Registration Due by March 28, 2005**

We are pleased to announce that the next National DRP Meeting will be held April 11-15, 2005 in Baltimore, Maryland at the Tremont Suite Hotel, 222 St. Paul Place. This meeting is a continuation of the highly successful DRP meetings held in Baltimore in recent years.

While this meeting is open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. As in the past, prior planning is absolutely imperative to the success of these meetings; therefore, we are requesting that you register PROMPTLY by completing the registration form on our web page at <http://www.cms.hhs.gov/medicaid/drugs/drpmtns.asp> and submitting it electronically. Whenever possible, priority scheduling will be afforded those who register earliest. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses.

If possible, states should plan on arriving in Baltimore in time to attend a "state-only" meeting with the DRP Team the morning of Monday, April 11th. Meeting details and hotel registration information is provided on our web page.

Feel free to contact any of the RO DRP Team members for any state specific DRP issues. Any non-state specific DRP questions or issues concerning the April meeting may be emailed to DRP@cms.hhs.gov.

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Patriot Pharmaceuticals, LLC (Labeler code 10147)	04/01/2005	01/13/2005
Perrigo Pharmaceuticals Company (Labeler code 10768)	04/01/2005	12/14/2004
Yamanouchi Pharma America, Inc. (Labeler code 51248)	04/01/2005	01/14/2005
Boudreaux's Butt Paste (Labeler code 62103)	04/01/2005	01/10/2005
JayMac Pharmaceuticals, LLC (Labeler code 64661)	04/01/2005	01/26/2005
Aurobindo Pharma Ltd. (Labeler code 65862)	04/01/2005	12/29/2004
Veracity Pharmaceuticals, Inc. (Labeler code 67887)	04/01/2005	01/25/2005
Glenmark Pharmaceuticals, Inc., USA (Labeler code 68462)	04/01/2005	01/27/2005

Contact information for new labelers is attached for your convenience.

TERMINATED LABELERS

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

Pharmascience Laboratories, Inc. (labeler code 51817; and
Effcon Laboratories, Inc. (labeler code 55806).

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

6 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

CMS DRUG REBATE PROGRAM

Area Code 410



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WEBSITE www.cms.hhs.gov/medicaid/drugs/drughmpg.asp

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Analysts	E-mail	Phone #	States
Region I – Boston Ray Porter	rporter@cms.hhs.gov	(617) 565-1260	Connecticut, New Hampshire, Maine, Massachusetts, Rhode Island, Vermont
Region II – N.Y. Robert Cochrane	rcochrane@cms.hhs.gov	(212) 264-3885	New York, New Jersey
Region III-Phil. Jennifer Quinn	jquinn@cms.hhs.gov	(215) 861-4174	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
Region IV - Atlanta Jessie Spillers Elaine Elmore	jspillers@cms.hhs.gov eelmore@cms.hhs.gov	(404) 562-7418 (404) 562-7408	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
Region V - Chicago *	Until further notice please contact RO VIII		Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
Region VI - Dallas Mike Jones	mjones7@cms.hhs.gov	(214) 767-6279	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
Region VII - Kansas City Frank Campbell	fcampbell@cms.hhs.gov	(816) 426-5925 x3310	Iowa, Kansas, Missouri, Nebraska
Region VIII – Denver *Diane Dunstan	ddunstan@cms.hhs.gov	(303) 844-7040	Colorado, Montana, North Dakota, South Dakota, Wyoming
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Region X - Seattle Maria Garza	mgarza@cms.hhs.gov	(206) 615-2542	Alaska, Idaho, Oregon, Washington

AKYMA PHARMACEUTICALS – NDC DELETIONS EFFECTIVE APRIL 1, 2005

Vitamin E (NDC 65162-0654-10)
Vitamin E (NDC 65162-0656-10)
Vitamin E (NDC 65162-0656-11)
Vitamin E (NDC 65162-0658-10)
Calcium Gluconate Tablets (NDC 65162-0388-11)
Formula Twenty-One Tablets (NDC 65162-0393-10)
Formula Twenty-One Tablets (NDC 65162-0393-11)
MI-C-T Tablets (NDC 65162-0412-10)
MI-C-T Tablets (NDC 65162-0412-11)
Multivitamin Chewable Tablets (NDC 65162-0022-10)
Multivitamin Tablets with Iron (NDC 65162-0113-10)
One Daily Tablets (NDC 65162-0398-10)
One Daily Tablets (NDC 65162-0398-11)
One Daily with Iron (NDC 65162-0400-10)
One Daily with Iron (NDC 65162-0400-11)
Thera Tabs (NDC 65162-0448-10)
Thera Tabs (NDC 65162-0448-11)
Thera-M Tabs (NDC 65162-0450-10)
Thera-M Tabs (NDC 65162-0450-11)
Vitamin B-1 Tablets (NDC 65162-0456-10)
Vitamin B-1 Tablets (NDC 65162-0456-11)
Vitamin B-1 Tablets (NDC 65162-0454-10)
Vitamin B-1 Tablets (NDC 65162-0454-11)
Vitamin B-6 Tablets (NDC 65162-0162-10)
Vitamin C Tablets (NDC 65162-0368-10)
Vitamin C Tablets (NDC 65162-0368-11)
Calcium Carbonate (NDC 65162-0389-06)
Ferrous Gluconate Tablets (NDC 65162-0404-11)
Glucosamine Chondroitin (NDC 65162-0099-06)
Niacin Tablets (NDC 65162-0420-10)
Niacin Tablets (NDC 65162-0420-11)
Niacin Tablets (NDC 65162-0418-10)
Niacin Tablets (NDC 65162-0418-11)
Oyster Shell with Vitamin D Tablets (NDC 65162-0435-10)
Oyster Shell with Vitamin D Tablets (NDC 65162-0435-11)
Oyster Shell Calcium (NDC 65162-0434-10)
Oyster Shell Calcium (NDC 65162-0434-11)
Vitamin B Complex with C (NDC 65162-0632-10)
Vitamin B Complex with C (NDC 65162-0632-11)
Vitamin B-12 Tablets (NDC 65162-0462-10)
Vitamin B-12 Tablets (NDC 65162-0464-10)
Vitamin B-6 Tablets (NDC 65162-0432-10)
Vitamin B-6 Tablets (NDC 65162-0432-11)
Vitamin B-6 Tablets (NDC 65162-0433-10)
Vitamin B-6 Tablets (NDC 65162-0433-11)
Vitamin C Tablets (NDC 65162-0377-10)
Vitamin C Tablets (NDC 65162-0377-11)
Vitamin C Tablets (NDC 65162-0366-10)
Vitamin C Tablets (NDC 65162-0366-11)
Vitamin E Softgels (NDC 65162-0650-10)
Niacin (NDC 65162-0421-10)
Ferrous Sulfate Tablets (NDC 65162-0406-11)
Ferrous Sulfate Tablets (NDC 65162-0406-60)

DERMARITE INDUSTRIES, INC., -- NDC DELETIONS EFFECTIVE JNAUARY 1, 2005

LubriSilk (NDC 61924-0166-16)

DermaCerin (NDC 61924-0178-04, 16)

DermaVantage (NDC 61924-0142-01, 02, 08, 34)

Alphabath (NDC 61924-0078-02, 08)

Dermasyn (NDC 61924-0248-03, 08)

Dermafilm (NDC 61924-0249-44)

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	11-22-04	2.197
10-06-03	0.939	05-03-04	1.001	11-29-04	2.380
10-14-03	0.923	05-10-04	1.078	12-06-04	2.253
10-20-03	0.939	05-17-04	1.058	12-13-04	2.243
10-27-03	0.960	05-24-04	1.066	12-20-04	2.223
11-03-03	0.960	05-31-04	1.150	12-27-04	2.269
11-10-03	0.951	06-07-04	1.251	01-03-05	2.320
11-17-03	0.951	06-14-04	1.413	01-10-05	2.376
11-24-03	0.946	06-21-04	1.336	01-18-05	2.407
12-01-03	0.943	06-28-04	1.381	01-24-05	2.366
12-08-03	0.915	07-05-04	1.344	01-31-05	2.525
12-15-03	0.903	07-12-04	1.336	02-07-05	2.530
12-22-03	0.884	07-19-04	1.352	02-14-05	2.592
12-29-03	0.901	07-26-04	1.449		
01-05-04	0.939	08-02-04	1.490		

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