



June 26, 2007

MEDICAID DRUG REBATE PROGRAM**Release No. 146****For State Medicaid Directors****GUIDANCE ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE (BP) METHODOLOGY RECALCULATIONS**

We have received requests from manufacturers with pending recalculation submissions that CMS authorize prospective changes in the methodology used, by the manufacturer to calculate Average Manufacturer Price (AMP) and/or best price. Effective immediately, a manufacturer with a pending recalculation request may implement the revised pricing methodology on a prospective basis beginning with the date it notified us of the recalculation.

Additionally, a manufacturer with a new recalculation request regarding AMP and/or best price (submitted to CMS after the date of this release) may proceed with implementing the revised pricing methodology on a prospective basis without further review by CMS. We continue to request that manufacturers notify CMS and receive authorization in advance of any retroactive change in the method used to calculate their AMP and/or best price, along with revised AMP and/or best price data for the drugs affected, the relevant 11-digit NDC numbers, the fiscal magnitude of the change, and a statement as to the reason for the change in methodology.

As in the case with all pricing data submitted under the Medicaid drug rebate program, if a subsequent review of a manufacturer's methodology for calculating AMP and/or best price or other pricing data by CMS, by the Office of Inspector General, or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer should comply with that determination. Additionally, in accordance with Section 1927 and Federal regulations at 42 CFR § 447.534, manufacturers must maintain records (written or electronic) for 10 years from the date the manufacturer reports data (or reports revised pricing data) to CMS for that rebate period, including the reported data, and any other materials from which the calculations of AMP and BP are derived, as well as any assumptions made in the calculations. A manufacturer must retain records beyond the 10-year

period if they are the subject of an unresolved audit or government investigation of which the manufacturer is aware relating to pricing data that are used in AMP or BP.

CMS is not expressing an opinion in advance of the prospective recalculation as to whether the revised pricing calculation is consistent with the methodology set forth in the statute and rebate agreement. CMS's receipt of revised pricing data or a recalculation request (or any acknowledgment of such receipt) is not, and may not be considered to be, an advisory opinion under Section 1128D (b) of the Social Security Act, since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, CMS's receipt of revised pricing data or a recalculation request is not a release of any liability.

COMING SOON: ADDITIONAL CHANGES TO THE STATE INVOICE/UTILIZATION DATA RECORD FORMAT

State Releases #143 and #145 previously announced some changes to the CMS Form R-144 (the state invoice). At that time, CMS also provided a copy of the revised record format for the state invoice/utilization data. Although the record format as previously provided contained the correct field names, we have become aware that it will need some additional updates in terms of the sizes and positions of each data field. In the near future, we will be issuing another release item with the revised record format (i.e., the new field sizes and positions) provided so that state systems can be updated accordingly in time for the fourth quarter 2007 implementation date for the revised CMS Form R-144.

NEW STATE DATA GUIDE WILL BE E-MAILED SOON

As noted in State Release #145, the Medicaid Drug Rebate Operational Training Guide is now obsolete. The new Medicaid Drug Rebate Data Guide for States will be e-mailed to all State Technical Contacts in the next few weeks. This guide was developed for and is intended for use by Medicaid Drug Rebate State Technical Contacts; therefore, Operations staff will respond to questions about the new guide from those parties.

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Anchen Pharmaceuticals, Inc. 10370	07/01/2007	05/14/2007
Rosemont Pharmaceuticals, LTD 13632	07/01/2007	04/09/2007
ImaRx Therapeutics, Inc. 24430	07/01/2007	04/26/2007
NextWave Pharmaceuticals, Inc. 24478	10/01/2007	06/07/2007

Alexion Pharmaceuticals 25682	07/01/2007	04/11/2007
Lupin Pharmaceuticals, Inc. 27437	04/01/2007	04/01/2007
Nostrum Laboratories 29033	07/01/2007	04/24/2007
CIMA Labs 55253	04/01/2007	04/01/2007
Oceanside Pharmaceuticals 68682	04/01/2007	04/01/2007

REINSTATED LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Pharmascience Laboratories, Inc. 51817	07/01/2007	04/11/2007

TERMINATED LABELERS

The following labeler codes are being terminated effective 07/01/2007:

Lederle Parenterals (Labeler Code 00205)
H.D. Smith Wholesale Drug Company (Labeler Code 00304)
Aventis Pharmaceuticals, Inc. (Labeler Code 00585)
Monte Sano Pharmaceuticals, Inc. (Labeler Code 12162)
Alpharma Inc (Labeler Code 23317)
Actavis (Labeler Code 50962)
Storz Instrument Company (Labeler Code 57706)
Esi Lederle, Inc. (Labeler Code 59911)
Ascent Pediatrics, Inc. (Labeler Code 59439)
Bausch & Lomb, Inc. (Labeler Code 61772)
Apothecon/Invamed (Labeler Code 62269)
Corixa Corporation (Labeler Code 67800)

The following labeler code is being terminated effective 10/01/2007:

Axiom Pharmaceutical Corporation (Labeler code 67870)

VOLUNTARILY TERMINATED LABELERS

The following labelers have requested voluntary termination effective 07/01/2007:

GlaxoSmithKline (Labeler Code 00766)
Insmmed, Inc. (Labeler Code 16249)
GlaxoSmithKline (Labeler Code 45800)
GlaxoSmithKline (Labeler Code 49692)
Blair Laboratories, Inc. (Labeler Code 50486)
GlaxoSmithKline (Labeler Code 53100)

The following labeler has requested voluntary termination effective 10/01/2007:

Delta Pharmaceuticals, Inc. (Labeler Code 53706)

NON-DRUG DELETIONS FROM MDR

The following products have been deleted from the Medicaid Drug Rebate master file of covered outpatient drugs:

00135	0026	GERITOL COMPLETE TABLETS
24385	0547	ELASTIC BANDAGE 3"
49348	0377	BANDAGE WATERSHIELD 1"
	0378	BANDAGE ANTI-BACTERIAL ASST.
	0408	ELASTIC BANDAGE W/CLIPS
	0412	ELASTIC BANDAGE SELF-ADHES 3"
	0413	ELASTIC BANDAGE W/CLIPS 4"
	0414	ELASTIC BANDAGE SELF-ADHES 4"
	0536	BANDAGE-FABRIC 1-SIZE 3/4 INCH
	0538	BANDAGE FOAM 1-SIZE 1 INCH
	0581	BANDAGE CLEAR ASST
	0664	LIQUID BANDAGE
	0708	STRONG STRIPS BANDAGES 1"
	0755	BANDAGES CLEAR WATERSHIELD
	0758	BANDAGES BUTTERFLY CLOSURES
52735	0874	BANDAGE SHEER STRIP
66591	0800	AQUASOL E DROPS

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The following products were reported by the labelers as DESI Code 2 (Safe and effective or non-DESI drug). The FDA has determined that the drugs are DESI Code 5 (Less than effective/IRS drug for all indications).

DESI Notice 8656 (53 FR 25013, 07/01/88, Docket No, 88N-0242)

00603 7495 ZOLENE HC
 00603 7496 ZOCORT HC AQUEOUS SOLN 10 ML
 00642 0011 CORTIC EAR DROPS
 00642 0012 CORTIC-ND EAR DROPS
 00813 0393 TRI-OTIC
 12830 0781 OTOZONE
 14508 0304 MIDRIN CAPSULES
 51674 0116 CORTANE B-OTIC
 51674 0117 CBO LOTION
 51674 0118 CBO AQUEOUS DROPS
 51991 0671 OTIRX SOLUTION
 60258 0451 CYOTIC DROPS

The following products were reported by the labelers as DESI Code 3 (Drug under review (No NOOH issued)). The FDA has determined that these drugs are DESI Code 5 (Less than effective/IRS drug for all indications).

DESI Notice 8656 (53 FR 25013, 07/01/88, Docket No, 88N-0242)

00682 9080 OTOMAR-HC EAR DROPS
 59630 0135 ZOTO-HC EAR DROPS

The following product was reported by the labeler as DESI Code 2 (Safe and effective or non-DESI drug). The FDA has determined that the drug is DESI Code 6 (Less than effective/IRS drug withdrawn from market).

51079 0621 GRANULEX 2 OZ (56.7 G)

Please be aware that these drugs are no longer eligible for rebate billing.

The following products were reported by the labelers as DESI Code 5 (Less than effective/IRS drug for all indications); however, the FDA has informed us that the drugs are DESI Code 2 (Safe and effective or non-DESI drug).

68462 0202 MORPHINE 15MG
 68462 0203 MORPHINE 30MG

OTHER ATTACHMENTS

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period October 3, 2005, is attached.

Please remember to direct your drug rebate data questions to MDROperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

3 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

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TOPIC **RELEASE #**

MDRI Detailed Manufacturer Contact Information
10/02/2007

Date Range: 03/07/2007 to

Labeler Name: ANCHEN PHARMACEUTICALS, INC. **Effective Date:** 05/14/2007
NDC: 10370 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

JOHN MOONEY
 ANCHEN PHARMACEUTICALS, INC.
 PHARMACEUTICALS, INC.
 9601 JERONIMO ROAD
 CLINTON DRIVE
 IRVINE, CA 92618
 53022
 (949) 282-8773

Invoice Information

DAN PIERGIES
 ANCHEN PHARMACEUTICALS, INC.

 N114 W18850 CLINTON DRIVE

 GERMANTOWN, WI 53022

 (262) 250-6229 x187

Technical

DAN PIERGIES
 ANCHEN

 N114 W18850

 GERMANTOWN, WI

 (262) 250-6229

Labeler Name: ROSEMONT PHARMACEUTICALS, LTD. **Effective Date:** 04/09/2007
NDC: 13632 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

WILLIAM THOMAS
 CYTOGEN CORPORATION
 CORPORATION
 650 COLLEGE ROAD EAST
 EAST
 SUITE 3100
 PRINCETON, NJ 08540-5308
 08540-5308
 (609) 750-8200 x8221

Invoice Information

THU DANG
 CYTOGEN CORPORATION

 650 COLLEGE ROAD EAST

 SUITE 3100
 PRINCETON, NJ 08540-5308

 (609) 750-8200 x8207

Technical

EDWARD D. COLLINS
 CYTOGEN

 650 COLLEGE ROAD

 SUITE 3100
 PRINCETON, NJ

 (609) 750-8200 x8252

Labeler Name: IMARX THERAPEUTICS, INC. **Effective Date:** 04/26/2007
NDC: 24430 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

STEVE FRANCESCONI
 FRANCESCONI
 IMARX THERAPEUTICS, INC.
 THERAPEUTICS, INC.
 323 ROLLING ROCK ROAD
 ROAD
 MARIETTA, GA 30067

 (770) 644-9215

Invoice Information

STEVE FRANCESCONI

 IMARX THERAPEUTICS, INC.

 323 ROLLING ROCK ROAD

 MARIETTA, GA 30067

 (770) 644-9215

Technical

STEVE

 IMARX

 323 ROLLING ROCK

 MARIETTA, GA 30067

 (770) 644-9215

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TOPIC **RELEASE #**

MDRI Detailed Manufacturer Contact Information
10/02/2007

Date Range: 03/07/2007 to

Labeler Name: NEXTWAVE PHARMACEUTICALS, INC.

Effective Date: 06/07/2007

NDC: 24478

Transmission Option: 2

Termination Date:

Legal Information
Information

CHRISTOPHER MONNING
BURKE, WARREN, MACRAY & SERRITELLA,
PHARMACEUTICALS, INC.
P.C.
PARKWAY
22ND FLOOR
330 N. WABASH AVENUE
60061
CHICAGO, IL 60611
(312) 840-7010

Invoice Information

IRENA KALIKA
NEXTWAVE PHARMACEUTICALS, INC.

50 LAKEVIEW PARKWAY

SUITE 134
VERNON HILLS, IL 60061

(847) 996-6200 x225

Technical

IRENA KALIKA
NEXTWAVE

50 LAKEVIEW

SUITE 134
VERNON HILLS, IL

(847) 996-6200 x225

Labeler Name: ALEXION PHARMACEUTICALS

Effective Date: 04/11/2007

NDC: 25682

Transmission Option: 2

Termination Date:

Legal Information
Information

TOM DUBIN
ALEXION PHARMACEUTICALS
PHARMACEUTICALS
352 KNOTTER DRIVE
CHESHIRE, CT 06410
(203) 271-8203

Invoice Information

ANTHONY LANCIA
ALEXION PHARMACEUTICALS

352 KNOTTER DRIVE
CHESHIRE, CT 06410
(203) 271-8208

Technical

ANTHONY LANCIA
ALEXION

352 KNOTTER DRIVE
CHESHIRE, CT 06410
(203) 271-8208

Labeler Name: LUPIN PHARMACEUTICALS, INC.

Effective Date: 04/01/2007

NDC: 27437

Transmission Option: 2

Termination Date:

Legal Information
Information

VINITA GUPTA
LUPIN PHARMACEUTICALS, INC.
PHARMAEUTICALS, INC.
HARBORPLACE TOWER
111 S. CALVERT STREET

21ST FLOOR
BALTIMORE, MD 21202
(410) 576-2000

Invoice Information

RANDALL PERRY
LUPIN PHARMACEUTICALS, INC.

P.O. BOX 259
ACWORTH, GA 30101

(770) 975-7337

Technical

RANDALL PERRY
LUPIN

P.O. BOX 259
ACWORTH, GA 30101

(770) 975-7337

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TOPIC **RELEASE #**

MDRI Detailed Manufacturer Contact Information **Date Range: 03/07/2007 to 10/02/2007**

Labeler Name: NOSTRUM LABORATORIES **Effective Date:** 04/24/2007

NDC: 29033 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

SHELLY KAPLAN
NOSTRUM LABORATORIES, INC.
LABORATORIES, INC
1800 N. TOPPING AVENUE
PHARMACEUTICAL LOGISTICS
KANSAS CITY, MO 64120
CLINTON DRIVE
(732) 635-0036 x106
53022

Invoice Information

DAN PIERGIES
NOSTRUM LABORATORIES, INC.

C/O DDN PHARMACEUTICAL LOGISTICS

N114 W18850 CLINTON DRIVE

GERMANTOWN, WI 53022

(262) 250-6229

Technical

DAN PIERGIES
NOSTRUM

C/O DDN

N114 W18850

GERMANTOWN, WI

(262) 250-6229

Labeler Name: PHARMASCIENCE LABORATORIES, INC. **Effective Date:** 07/01/2007

NDC: 51817 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

DANIELLE WOLFENDEN
WOLFENDEN
PHARMASCIENCE LABORATORIES, INC.
LABORATORIES, INC.
91 CATAMOUNT DRIVE
DRIVE
P.O. BOX 15
MILTON, VT 05468-0015
0015
(866) 341-2375 x203

Invoice Information

DANIELLE WOLFENDEN
PHARMASCIENCE LABORATORIES, INC.

91 CATAMOUNT DRIVE

P.O. BOX 15
MILTON, VT 05468-0015

(866) 341-2375 x203

Technical

DANIELLE
PHARMASCIENCE

91 CATAMOUNT

P.O. BOX 15
MILTON, VT 05468-
0015
(866) 341-2375 x203

Labeler Name: CIMA LABS **Effective Date:** 04/01/2007

NDC: 55253 **Transmission Option:** 2 **Termination Date:**

Legal Information
Information

JORDAN COOPER
GALLAGHER
CEPHALON, INC.
41 MOORES ROAD
PO BOX 4011
FRAZER, PA 19355
(610) 738-6415

Invoice Information

EDWARD GALLAGHER

CEPHALON, INC.
41 MOORES ROAD
PO BOX 4011
FRAZER, PA 19355
(610) 738-6676

Technical

EDWARD

CEPHALON, INC.
41 MOORES ROAD
PO BOX 4011
FRAZER, PA 19355
(610) 738-6676

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TOPIC

RELEASE #

**MDRI Detailed Manufacturer Contact Information
10/02/2007**

Date Range: 03/07/2007 to

Labeler Name: OCEANSIDE PHARMACEUTICALS

Effective Date: 03/31/2007

NDC: 68682

Transmission Option: 2

Termination Date:

Legal Information
Information

AARON KIM
OCEANSIDE PHARMACEUTICALS
PHARMACEUTICALS
ONE ENTERPRISE
BOULEVARD
ALISO VIEJO, CA 92656
34608
(800) 548-5100

Invoice Information

RANDALL PERRY
OCEANSIDE PHARMACEUTICALS

P.O. BOX 259

ACWORTH, GA 30101

(770) 975-7337

Technical

PATTI SEXSON
OCEANSIDE

10250 ELGIN

SPRING HILL, FL

(352) 688-3931

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
10-03-05	3.606	05-01-06	4.807	12-04-06	4.999
10-11-05	3.714	05-08-06	4.864	12-11-06	4.926
10-17-05	3.875	05-15-06	4.864	12-18-06	4.952
10-24-05	3.942	05-22-06	4.828	12-25-06	5.004
10-31-05	3.983	05-30-06	4.843	01-01-07	5.062
11-07-05	3.963	06-05-06	4.833	01-08-07	5.072
11-14-05	4.004	06-12-06	4.926	01-15-07	5.108
11-21-05	4.034	06-19-06	4.958	01-22-07	5.129
11-28-05	3.994	06-26-06	5.036	01-29-07	5.145
12-05-05	4.025	07-03-06	5.088	02-05-07	5.145
12-12-05	3.911	07-10-06	5.056	02-12-07	5.160
12-19-05	3.988	07-17-06	5.098	02-19-07	5.171
12-26-05	3.999	07-24-06	5.108	02-26-07	5.185
01-02-06	4.169	08-07-06	5.124	03-05-07	5.112
01-09-06	4.252	08-14-06	5.114	03-12-07	5.112
01-17-06	4.377	08-21-06	5.109	03-19-07	5.075
01-23-06	4.397	08-28-06	5.093	03-25-07	5.070
01-30-06	4.485	09-04-06	4.984	04-02-07	5.055
02-06-06	4.485	09-11-06	4.947	04-09-07	5.023
02-13-06	4.553	09-18-06	4.942	04-16-07	5.008
02-21-06	4.563	09-25-06	4.895	04-23-07	4.976
02-27-06	4.625	10-02-06	4.890	04-30-07	4.924
03-06-06	4.615	10-09-06	4.978	05-07-07	4.898
03-13-06	4.625	10-16-06	5.072	05-14-07	4.867
03-20-06	4.662	10-23-06	5.124	05-21-07	4.914
03-27-06	4.610	10-30-06	5.108	05-28-07	4.919
04-03-06	4.651	11-06-06	5.088	06-04-07	4.846
04-10-06	4.688	11-13-06	5.088	06-11-07	4.773
04-17-06	4.719	11-20-06	5.071	06-18-07	4.617
04-24-06	4.755	11-27-06	5.036	06-25-07	4.820