DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

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

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
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	07/01/2007	04/11/2007

25682		
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

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
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)
Insmed, Inc. (Labeler Code 16249)
GlaxoSmithKline (Labeler Code 45800)
GlaxoSmithKline (Labeler Code 49692)
Blairex 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

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

Labeler Name: ANCHEN PHARMACEUTICALS, INC. **Effective Date:** 05/14/2007

NDC: 10370 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
JOHN MOONEY	DAN PIERGIES	DAN PIERGIES
ANCHEN PHARMACEUTICALS, INC.	ANCHEN PHARMACEUTICALS, INC.	ANCHEN PHARMACEUTICALS, INC.
9601 JERONIMO ROAD	N114 W18850 CLINTON DRIVE	N114 W18850 CLINTON DRIVE
IRVINE, CA 92618	GERMANTOWN, WI 53022	GERMANTOWN, WI 53022
(949) 282-8773	(262) 250-6229 x187	(262) 250-6229

Labeler Name: ROSEMONT PHARMACEUTICALS, LTD. **Effective Date:** 04/09/2007

NDC: 13632 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
WILLIAM THOMAS	THU DANG	EDWARD D. COLLINS
CYTOGEN CORPORATION	CYTOGEN CORPORATION	CYTOGEN CORPORATION
650 COLLEGE ROAD EAST	650 COLLEGE ROAD EAST	650 COLLEGE ROAD EAST
SUITE 3100	SUITE 3100	SUITE 3100
PRINCETON, NJ 08540-5308	PRINCETON, NJ 08540-5308	PRINCETON, NJ 08540-5308
(609) 750-8200 x8221	(609) 750-8200 x8207	(609) 750-8200 x8252

Labeler Name: IMARX THERAPEUTICS, INC. **Effective Date:** 04/26/2007

NDC: 24430 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
STEVE FRANCESCONI	STEVE FRANCESCONI	STEVE FRANCESCONI
IMARX THERAPEUTICS, INC.	IMARX THERAPEUTICS, INC.	IMARX THERAPEUTICS, INC.
323 ROLLING ROCK ROAD	323 ROLLING ROCK ROAD	323 ROLLING ROCK ROAD
MARIETTA, GA 30067	MARIETTA, GA 30067	MARIETTA, GA 30067
(770) 644-9215	(770) 644-9215	(770) 644-9215

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

Labeler Name: NEXTWAVE PHARMACEUTICALS, INC. **Effective Date:** 06/07/2007

NDC: 24478 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
CHRISTOPHER MONNING BURKE, WARREN, MACRAY & SERRITELLA, P.C. 22ND FLOOR 330 N. WABASH AVENUE CHICAGO, IL 60611 (312) 840-7010	IRENA KALIKA NEXTWAVE PHARMACEUTICALS, INC. 50 LAKEVIEW PARKWAY SUITE 134 VERNON HILLS, IL 60061 (847) 996-6200 x225	IRENA KALIKA NEXTWAVE PHARMACEUTICALS, INC. 50 LAKEVIEW PARKWAY SUITE 134 VERNON HILLS, IL 60061 (847) 996-6200 x225

Labeler Name: ALEXION PHARMACEUTICALS **Effective Date:** 04/11/2007

NDC: 25682 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
TOM DUBIN ALEXION PHARMACEUTICALS 352 KNOTTER DRIVE CHESIRE, CT 06410 (203) 271-8203	ANTHONY LANCIA ALEXION PHARMACEUTICALS 352 KNOTTER DRIVE CHESIRE, CT 06410 (203) 271-8208	ANTHONY LANCIA ALEXION PHARMACEUTICALS 352 KNOTTER DRIVE CHESIRE, 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	Invoice Information	Technical
VINITA GUPTA LUPIN PHARMACEUTICALS, INC. HARBORPLACE TOWER 111 S. CALVERT STREET 21ST FLOOR BALTIMORE, MD 21202 (410) 576-2000	RANDALL PERRY LUPIN PHARMACEUTICALS, INC. P.O. BOX 259 ACWORTH, GA 30101 (770) 975-7337	RANDALL PERRY LUPIN PHARMAEUTICALS, INC. P.O. BOX 259 ACWORTH, GA 30101 (770) 975-7337

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	Invoice Information	Technical
SHELLY KAPLAN NOSTRUM LABORATORIES, INC. 1800 N. TOPPING AVENUE KANSAS CITY, MO 64120 (732) 635-0036 x106	DAN PIERGIES NOSTRUM LABORATORIES, INC. C/O DDN PHARMACEUTICAL LOGISTICS N114 W18850 CLINTON DRIVE GERMANTOWN, WI 53022 (262) 250-6229	DAN PIERGIES NOSTRUM LABORATORIES, INC C/O DDN PHARMACEUTICAL LOGISTICS N114 W18850 CLINTON DRIVE GERMANTOWN, WI 53022 (262) 250-6229

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

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

Legal Information Information	Invoice Information	Technical
DANIELLE WOLFENDEN PHARMASCIENCE LABORATORIES, INC. 91 CATAMOUNT DRIVE P.O. BOX 15 MILTON, VT 05468-0015 (866) 341-2375 x203	DANIELLE WOLFENDEN PHARMASCIENCE LABORATORIES, INC. 91 CATAMOUNT DRIVE P.O. BOX 15 MILTON, VT 05468-0015 (866) 341-2375 x203	DANIELLE WOLFENDEN PHARMASCIENCE LABORATORIES, INC. 91 CATAMOUNT DRIVE 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	Invoice Information	Technical
JORDAN COOPER CEPHALON, INC. 41 MOORES ROAD PO BOX 4011 FRAZER, PA 19355 (610) 738-6415	EDWARD GALLAGHER CEPHALON, INC. 41 MOORES ROAD PO BOX 4011 FRAZER, PA 19355 (610) 738-6676	EDWARD GALLAGHER CEPHALON, INC. 41 MOORES ROAD PO BOX 4011 FRAZER, PA 19355 (610) 738-6676

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

Labeler Name: OCEANSIDE PHARMACEUTICALS **Effective Date:** 03/31/2007

NDC: 68682 **Transmission Option:** 2 **Termination Date:**

Legal Information Information	Invoice Information	Technical
AARON KIM	RANDALL PERRY	PATTI SEXSON
OCEANSIDE PHARMACEUTICALS PHARMACEUTICALS	OCEANSIDE PHARMACEUTICALS	OCEANSIDE
ONE ENTERPRISE BOULEVARD	P.O. BOX 259	10250 ELGIN
ALISO VIEJO, CA 92656	ACWORTH, GA 30101	SPRING HILL, FL 34608
(800) 548-5100	(770) 975-7337	(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		08-21-04	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

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