



May 6, 2008

MEDICAID DRUG REBATE PROGRAM

Release No. 149



For State Medicaid Directors



AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS – WYETH PHARMACEUTICALS

As a result of modifications in its methodology for the calculation of AMP, Wyeth Pharmaceuticals has revised the AMPs for first quarter 1996 through fourth quarter 2003, and will be recovering overpayments from states for excessive rebates paid during those quarters.

In many cases the recalculation resulted in significant overpayments to the states. Wyeth will recoup overpayments on a State-by-State basis from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. Wyeth has indicated that it will contact each State representative to inform you of this action and has expressed a willingness to work with individual states to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meantime, states should continue to invoice Wyeth for current quarters as usual.

If you have any questions on this particular issue, please call Kim Howell at 410-786-6762.

AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS AND BEST PRICE (BP) – BAXTER HEALTHCARE CORPORATION

As a result of modifications in its methodology for the calculation of AMP and Best Price, Baxter Healthcare Corporation has revised the AMPs and Best Price for first quarter 1991 through second quarter 2001, and will be recovering overpayments from states for excessive rebates paid during those quarters.

In many cases the recalculation resulted in significant overpayments to the states. Baxter will recoup overpayments on a State-by-State basis from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. Baxter has indicated that it will contact each State representative to inform you of this action and has expressed a willingness to work with individual states to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meantime, states should continue to invoice Baxter for current quarters as usual.

If you have any questions on this particular issue, please call Kim Howell at 410-786-6762.

REMINDER--NEW STATE UTILIZATION DATA RECORD FORMAT

The revised state utilization record format went into effect on March 1, 2008. Any data submitted, regardless of whether it is for current or prior quarters, must now be in the new format, or it will be rejected. Rejected data will need to be resubmitted in the new format. Current data definitions and instructions for states on submitting utilization data to CMS were provided in State Release #147, which can be found at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp.

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Graceway Pharmaceuticals, LLC Labeler code 29336	01/01/2008	01/01/2008
International Labs, Inc. Labeler code 54458	07/01/2008	03/05/2008
Accord Healthcare Incorporated Labeler code 16729	07/01/2008	03/10/2008
TEC Laboratories, Inc. Labeler code 51879	07/01/2008	03/20/2008
Regeneron Pharmaceuticals, Inc. Labeler code 61755	07/01/2008	03/28/2008
Cardinal Health Singapore 225 PTE LTD Labeler code 42115	07/01/2008	04/23/2008

REINSTATED LABELERS

Carlsbad Technology, Inc.
Labeler code 61442

07/01/2008

04/30/2008

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

TERMINATED LABELERS

The following labeler codes are being terminated effective July 1, 2008:

Cangene Corporation	Labeler Code 60492
MGI GP dba MGI Pharma	Labeler Code 61379
Glaxosmithkline	Labeler Code 66203
Laser Pharmaceuticals, LLC	Labeler Code 68134

VOLUNTARILY TERMINATED LABELERS

The following labelers have requested voluntary termination effective April 1, 2008:

The Reese Chemical Company	Labeler Code 10956
Omnii Products	Labeler Code 48878
Johnson & Johnson Health Care	Labeler Code 56091
Oxford Pharmaceutical Services	Labeler Code 64803

The following labeler has requested voluntary termination effective July 1, 2008:

Faro Pharmaceuticals, Inc.	Labeler Code 60976
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NON-DRUG DELETIONS FROM MDR

The states were previously notified that the following products do not meet the definition of a covered outpatient drug and are not rebate-eligible. Therefore, they are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs:

00003	2910	NALOXONE HYDROCHLORIDE INJ
00015	3351	RUBEX
00067	0041	BENEFIBER
00067	0042	BENEFIBER
00245	0053	FERATAB
00590	5215	ACETYLCYSTEINE SOLUTION
24478	0101	MYKIDZ IRON
52747	0307	HEMOCYTE
58914	0010	ADEX'S
58914	0011	AQUADEKS
58914	0212	ADEK PEDIATRIC DROPS
58914	0214	AQUADEKS
63717	0037	SUPHERA CREAM
63717	0703	TRIAN'T HC
63717	0714	NARIZ HC SUSPENSION

63717	0710	DYTAN HC SUSPENSION
68453	0400	DURATUSS HD ELIXIR

NEW DRUG DETERMINATIONS--DELETIONS FROM MDR

The states were previously notified of the FDA's determination that the following active NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval as set forth in 21 CFR 310.502(a)(14). 72 Fed. Reg. 29517 (May 29, 2007). As a result, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, therefore, no longer eligible for inclusion in the rebate program. They are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs and should be deleted from state Medicaid Drug Rebate systems:

00095	0067	PNEUMOTUSSIN 2.5 COUGH SYRUP
00131	2055	GUAIMAX D TABLETS
00182	1042	GUAIFENESIN/DM TABLETS 600MG/30MG 100
00551	0189	GUA-SR TABLETS
00603	5543	Q-BID LA 250
00642	0421	TUSSO-HC
00642	0645	TUSSO-DMR
00677	1487	GUAIFENESIN 600MG/PSEUDOEPHEDRINE 60MG TAB 100
10914	0100	GUAIFENESIN 900 MG; PHENYLEPHRINE HYDROCHLORIDE 25 MG
10914	0200	GUAIFENESIN 1200MG; PHENYLEPHRINE HYDROCHLORIDE 25MG
10914	0300	PHENYLEPHRINE HCL 15 MG; GUAIFENESIN 600 MG
10914	0970	GUAIFENESIN 1200 MG. / DEXTROMETHORPHAN HBR 20 MG
14629	0203	EXTENDRYL HC
14629	0204	EXTENDRYL G
51674	0124	PROLEX D TABLETS
51674	0126	PROLEX
51674	0127	PROSET D TABLETS
51991	0428	GUAIFEN PE TABLETS
51991	0429	GUAIFEN DM TABLETS
51991	0461	GUAIFEN II DM
52152	0139	AMIBID DM TABS (100)
52152	0246	GUAIF. & DEXTROMETHORPHAN ER TABS
53489	0424	GUAIFENESIN 600MG / PSEUDOEPHEDRINE 120MG LONG ACTING
53489	0425	GUAIFENESIN 600MG / PSEUDOEPHEDRINE 60MG LONG ACTING
57664	0222	MIRAPHEN PSE (GUAIFENESIN/PSEUDOEPHEDRINE 600/120MG)
57664	0317	MIRAPHEN PE (GUAIFENESIN/PHENYLEPHRINE 300/20 MG)
57664	0355	GUAIFENESIN /DEXTROMETHORPHAN 600/30MG
58117	0214	GUAIFENEX PSE/60
58117	0373	GUAIFENEX GP EXTENDED-RELEASE TABLETS
58177	0019	BROMFENEX
58177	0020	BROMFENEX PD
58177	0208	GUAIFENEX PSE/120
58177	0213	GUAIFENEX DM
58177	0413	GUAIFENEX PSE-80 TABLETS
58177	0478	GUAIFENEX PSE 85 TABS 100'S

58177	0078	PHENAVENT CAPS
58177	0079	PHENAVENT PED
58177	0095	PHENAVENT LA CAPS 30's
58177	0444	PHENAVENT D 100:s
58605	0530	ALLFEN DM
58605	0613	ALLFEN
58605	0621	ALLFEN DM
58605	0630	ALLFEN DM
58605	0713	ALLFEN C
58605	0721	ALLFEN CX
58869	0411	TOURO DM
58869	0441	TOURO CC
58869	0445	TOURO CC-LD
58869	0581	TOURO HC
58869	0635	TOURO LA-LD
58869	0636	TOURO LA
59196	0112	SYMPAK COUGH/COLD BP
59196	0120	SYMPAK DM
59310	0120	MUCO-FEN 1200
59702	0191	SUDEX TABLETS
60258	0252	GFN 1200/DM 20/PE 40 TABLETS
60258	0256	GANIDIN NR LIQUID
60258	0263	GFN 1200/ DM 60 TABLETS
60258	0264	GFN 600/PSE60/DM30 TABLETS
60258	0266	GFN/PSE TABLETS
60258	0267	GFN 1000/ DM60 TABLETS
60258	0269	GFN 600/PHENYLEPHRINE 20 MG TABS
60258	0274	GFN 600/ PHENYLEPHRINE 40
60258	0275	GUAIFENESIN 400MG TABLETS
60258	0277	G/P 1200/75
60258	0284	GFN 1200/ PHENYLEPHRINE 40
60575	0078	RESPA DM
60575	0087	RESPA 1 ST
60575	0457	TRIKOF-D
60575	0786	RESPA BR
60575	0787	RESPA-PE
62022	0132	ENTEX PSE CAPSULES
62022	0333	ENTEX LA CAPSULES
62022	0334	ENTEX ER
62037	0827	GENERIC ENTEX LA 30/400 MG
63717	0240	XPECT-AT TABLETS
63717	0241	XPECT PE TABLETS
63717	0705	XPECT HC
64125	0126	GUAIFENESIN & DEXTROMETHARPHEN HBR 1200/60MG TABLETS
64376	0033	PSEUDO GG TR TABS
64376	0539	GUAIPHEN PD TR TAB
68025	0002	ZOTEX LA CAPLETS
68025	0005	ZOTEX GP CAPLETS
68025	0018	ZOTEX LAX CAPLETS

68025	0020	ZOTEX GPX CAPLETS
68025	0023	ZOTEX DMX
68453	0612	DURATUSS TABLETS
68453	0615	DURATUSS TABS
68453	0640	DURATUSS GP
68453	0645	DURATUSS GP TABS
68453	0750	DURATUSS A TABS
68453	0770	DURATUSS PE TABLETS
68453	0795	DURATUSS DA CAPSULES

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The following products were reported by the labeler as DESI code 2 (safe and effective or non-DESI drug). The FDA has determined that the drug is a DESI code 5 (less than effective/IRS drug).

02/09/1973, DESI 6514, 38-FR-4006 AND 05/29/2007, 72 FR 29517:

14629	0473	Zinx Cough Kit
28595	0602	Allres G
58809	0615	Carbatab-12
68032	0176	Carbetapentane Citrate 20 Phenylephrine HCl 15 Guaifenesin 100
68453	0550	Duratuss CS Tablets

01/03/1974, DESI 11114, 39-FR-841:

00603	8136	Proctosert HC
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12/09/1975, DESI 8076, 40-FR-57379:

00064	1070	Exactacain Aerosol Spray
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08/19/1977, DESI 7663, 42 FR 41921:

60258	0841	Aminobenzoate Potassium Envules
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09/18/1979, DESI 12283, 44-FR-54124:

50111	0364	Chlorthalidone Tablets 100mg
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09/25/1981, DESI 10367, 46-FR-47408:

58177	0803	Hydrocortisone and Idoquinol 1%
59366	2706	Hydrocortisone 1%-Iodoquinol 1% cream

05/25/1982, DESI 6514, 47-FR-22606:

10914	0960	Guaifenesin 600 MG/Carbetapentane Citrate 60 MG
51991	0083	Carbetaplex Liquid
51991	0163	Histacol DM Pediatric Syrup
58809	0303	Carba XP
58809	0535	Carbatuss
58809	0536	Carbatuss
58809	0707	Carbatuss

60258	0246	Chlordex GP
60258	0446	Bromhist DM Syrup
64376	0537	Phencarb GG Syrup
64376	0707	P Chlor GG Drops
64376	0723	Pediahist DM Syrup
66813	0179	Levall
67204	0210	Oratuss Liquid
67204	0273	Oratuss 12 Tablets
67336	0188	Respi-Tann G

05/06/1983, DESI 597, 48-FR-20495:

10267	2929	Phenazopyridine Plus Tablets
66663	0702	Pyrelle HB

07/01/1988, DESI 8656, 53 FR 25013:

66440	3767	Aero Otic HC TM
67887	0100	HC Pramoxime Rectal Cream
67887	0101	HC Pramoxime Topical 2.5% Cream
68047	0051	Oto-End 10 Drops
68047	0090	Ivderm

The following products were reported by the labeler as DESI code 3 (drug under review (no NOOH issued). The FDA has determined that the drug is a DESI code 5 (less than effective/IRS drug).

08/19/1977, DESI 7663, 42 FR 41921:

60267	0953	Aminobenzoate Potassium USP 0.5 GM Capsules
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07/01/1988, DESI 8656, 53 FR 25013:

00682	9090	Otomar Ear Drops
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The following products were reported by the labeler as DESI code 5 (less than effective/IRS drug). The FDA has determined that the drug is a DESI code 2 (safe and effective or non-DESI drug).

45802	0806	Salicylic Acid
45802	0818	Salicylic Acid

The following product was reported by the labeler as DESI code 6 (less than effective/IRS drug withdrawn from market). The FDA has determined that the drug is a DESI code 5 (less than effective/IRS drug).

09/18/1981, DESI 7337, 46 FR 46404:

52152	0190	Meperidine
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The following product was reported by the labeler as DESI code 5 (less than effective/IRS drug). The FDA has determined that the drug is a DESI code 6 (less than effective/IRS drug withdrawn from market).

Warning Letter Issued 02/26/2007:

11528 0200 Ergocaff PB

T-BILL AUCTION RATES

A copy of the current listing of the treasury bill auction rates beginning with the period December 4, 2006, is attached. Please note that the Treasury Department has changed the name of this listing from 91-Day to 13-Week.

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

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

WEEKLY U.S. T-BILL INVESTMENT RATE

Weekly 13-Week Treasury Bill Auction Rates
(Previously known as Weekly 91-day Treasury Bill Auction Rates)

Date of Auction	Invest. Rate	Date of Auction	Invest. Rate	Date of Auction	Invest. Rate
12-04-06	4.999	07-02-07	4.930	01-28-08	2.388
12-11-06	4.926	07-09-07	4.956	02-04-08	2.280
12-18-06	4.952	07-16-07	4.982	02-11-08	2.301
12-25-06	5.004	07-23-07	5.029	02-18-08	2.249
01-01-07	5.062	07-30-07	4.966	02-25-08	2.208
01-08-07	5.072	08-06-07	4.909	03-03-08	1.823
01-15-07	5.108	08-13-07	4.763	03-10-08	1.445
01-22-07	5.129	08-20-07	2.919	03-17-08	1.118
01-29-07	5.145	08-27-07	4.732	03-24-08	1.220
02-05-07	5.145	09-03-07	4.472	03-31-08	1.465
02-12-07	5.160	09-10-07	3.901	04-07-08	1.476
02-19-07	5.171	09-17-07	4.160	04-14-08	1.078
02-26-07	5.185	09-24-07	3.922	04-21-08	1.343
03-05-07	5.112	10-01-07	3.942	04-28-08	1.445
03-12-07	5.112	10-08-07	4.030	05-05-08	1.639
03-19-07	5.075	10-15-07	4.300		
03-25-07	5.070	10-22-07	4.004		
04-02-07	5.055	10-29-07	4.025		
04-09-07	5.023	11-05-07	3.642		
04-16-07	5.008	11-12-07	3.518		
04-23-07	4.976	11-19-07	3.476		
04-30-07	4.924	11-26-07	3.254		
05-07-07	4.898	12-03-07	3.104		
05-14-07	4.867	12-10-07	3.073		
05-21-07	4.914	12-17-07	3.073		
05-28-07	4.919	12-24-07	3.363		
06-04-07	4.846	12-31-07	3.394		
06-11-07	4.773	01-07-08	3.259		
06-18-07	4.617	01-14-08	3.156		
06-25-07	4.820	01-21-08	2.424		

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RELEASE #

MDRI Detailed Manufacturer Contact Information

Labeler Name: GRACEWAY PHARMACEUTICALS, LLC **Effective Date:** 01/01/2008
NDC: 29336

Legal Information

JOHN A. A. BELLAMY
GRACEWAY PHARM. LLC
340 MARTIN LUTHER KING JR. BLVD
SUITE 500
BRISTOL, TN 37620
(423) 274-2120

Invoice Information

JOHN BLISS
GRACEWAY PHARM., LLC
222 VALLEY CREEK BLVD.
SUITE 300
EXTON, PA 19341
(267) 948-0430

Technical Information

STEPHANIE L. KUPSKI
GRACEWAY PHARM., LLC
222 VALLEY CREEK BLVD.
SUITE 300
EXTON, PA 19341
(267) 948-0400 x20404

Labeler Name: INTERNATIONAL LABS, INC. **Effective Date:** 03/05/2008
NDC: 54458

Legal Information

FRED THOMPSON
INTERNATIONAL LABORATORIES, INC.
2701 75TH STREET NORTH
ST PETERSBURG, FL 33710
(727) 343-1548 x336

Invoice Information

DAN PIERGIES
DDN PHARMACEUTICAL LOGISTICS
N114 W18850 CLINTON DRIVE
GERMANTOWN, WI 53022
(262) 205-6229

Technical Information

DAN PIERGIES
DDN PHARM. LOGISTICS
N114 W18850 CLINTON DRIVE
GERMANTOWN, WI 53022
(262) 205-6229

Labeler Name: ACCORD HEALTHCARE INCORPORATED **Effective Date:** 03/10/2008
NDC: 16729

Legal Information

DR. SAMIR MEHTA
ACCORD HEALTHCARE INC.
8601 SIX FORKS ROAD
SUITE 400
RALEIGH, NC 27615
(919) 882-2060

Invoice Information

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ACCORD HEALTHCARE INC.
8601 SIX FORKS ROAD
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RALEIGH, NC 27615
(919) 882-2060

Technical Information

DR. SAMIR MEHTA
ACCORD HEALTHCARE INC.
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RALEIGH, NC 27615
(919) 882-2060

Labeler Name: TEC LABORATORIES, INC. **Effective Date:** 03/20/2008
NDC: 51879

Legal Information

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ALBANY, OR 97321
(541) 918-4138

Invoice Information

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ALBANY, OR 97321
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Technical Information

LISA LEVERICH
TEC LABORATORIES, INC.
7100 TEC LABS WAY SW
ALBANY, OR 97321
(541) 918-4156

Labeler Name: REGENERON PHARMACEUTICALS, INC. **Effective Date:** 03/28/2008
NDC: 61755

Legal Information

STUART KOLINSKI
REGENERON PHARM., INC.
777 OLD SAW MILL RIVER RD
TARRYTOWN, NY 10591-6707
(914) 345-7498

Invoice Information

DAN PIERGIES
DDN PHARMACEUTICAL LOGISTICS
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(262) 250-6229

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RELEASE #

Labeler Name: CARDINAL HEALTH SINGAPORE
NDC: 42115

Effective Date: 04/23/2008

Legal Information

ERIC CHRISTENSEN
CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017
(614) 757-3555

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CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017
(614) 757-7529

Technical Information

TRACEY O'HARRA
CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017
(614) 757-4543

Labeler Name: CARLSBAD TECHNOLOGY, INC.
NDC: 61442

Effective Date: 07/01/2008

Legal Information

(ANDY) HONGCHIN CHENG
CARLSBAD TECHNOLOGY, INC.
5923 BALFOUR COURT
CARLSBAD, CA 92008
(760) 431-8284 x150

Invoice Information

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