

April 30, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #130

For State Medicaid Directors

**INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS:
AMENDMENT UNDER THE MEDICARE PRESCRIPTION DRUG,
IMPROVEMENT, AND MODERNIZATION ACT OF 2003 ENACTED
DECEMBER 8, 2003**

Section 1002(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends section 1927(c)(1)(C)(i)(I) of the Social Security Act (the Act) to exempt inpatient prices charged to disproportionate share hospitals that participate in the 340B program from manufacturer's best price calculations. This exemption applies to drugs sold on or after December 8, 2003.

Section 1002(b) of the MMA amends section 1927(c)(1)(C) of the Act by including inpatient drugs in the provision that subjects these hospital drug purchases to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

The Health Resources and Services Administration (HRSA) maintains a public database of all hospitals that participate in the 340B program, and manufacturers should use this database to properly track sales for purposes of determining best price. The database is available on HRSA's website at <http://bphc.hrsa.gov/opa/download.htm>.

STATES ASKING FDB ABOUT CMS DATA

We have had several inquiries from First Data Bank (FDB) where states are asking why a data field on their (the states') CMS file does not match the FDB file. Once again, the CMS file is the one to use for ALL data when you are dealing with the drug rebate program. The data values reported to you by CMS are assumed to be correct unless we find otherwise and change it. However, until and unless it is changed, your rebates are covered as long as you follow the CMS file.

Also, data that is wrong on the CMS file will be corrected by CMS and reported to you on the next quarterly file. Please **DO NOT** ask FDB to correct CMS data. They cannot. Questions regarding drug rebate data should be directed to CMS, not to FDB.

QUARTERLY UTILIZATION FILE

After you send your quarterly invoices to all affected labelers, you are required to send a copy of all your invoice activity to CMS within 90 days after the end of each quarter. The file is to be sent once per quarter and is to contain all current quarterly billing plus any updates to previous quarters. Updates to previous quarters are **ONLY** to be done when a change has occurred to either 1) Total units billed, 2) Total number of scripts and 3) Total amount paid to pharmacies.

Apparently, some states are under the impression that update files are to be sent to us whenever one of these updates occurs. Please do **NOT** send more than one file per quarter and make sure that the one file contains **ALL** updates that occurred during that quarter plus that quarter's activities.

Also, please remember that only NDCs sent to you on the CMS quarterly URA file are to be billed to labelers and submitted to us on your quarterly utilization file. If an NDC that is not on the last CMS file you received is billed to you by a pharmacy, please check with CMS to assure that the NDC is valid and will be reported to you on the next URA file.

PERSONNEL CHANGE FOR DRUG REBATE OPERATIONS

Linda Sapperstein of the drug rebate operations staff retired as of April 2. Taking over Linda's responsibilities in the area of receiving and uploading labelers' diskettes and termination of labelers from the program is Karen Leshko. Karen's phone number is (410) 786-1291 and her e-mail address is kleshko@cms.hhs.gov. A revised page O2 of the Operational Training Guide is attached. Please replace this page in your guide. Also, reflected on this page is the deletion of drug rebate System Maintenance staff which is now replaced with their MDRtech@cms.hhs.gov e-mail. This e-mail address was discussed in release number 124 dated July 31, 2003.

REINSTATED LABELERS

The following labeler codes are being reinstated effective April 1, 2004:

Delta Pharmaceuticals, Inc. (Labeler Code 53706);
RIJ Pharmaceutical Corporation (Labeler Code 53807);
Amkas Laboratories, Inc. (Labeler Code 61073); and
Nnodum Corporation (Labeler Code 63044).

The following labeler code is being reinstated effective July 1, 2004:

Neil Laboratories, Inc. (Labeler Code 60242).

The above information was previously faxed to state Technical Contacts.

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Baxter Healthcare Corporation (Labeler code 60977)	07/01/2004	02/17/2004
Guilford Pharmaceuticals (Labeler code 61379)	07/01/2004	02/25/2004
Grifols Biologicals, Inc. (Labeler code 61953)	07/01/2004	03/15/2004
Synthon Pharmaceuticals Inc. (Labeler code 63672)	07/01/2004	02/13/2004
Purdue Products, L.P. (Labeler code 67618)	07/01/2004	02/27/2004
Vertical Pharmaceuticals, Inc. (Labeler code 68025)	07/01/2004	02/24/2004
Lupin Pharmaceuticals, Inc. (Labeler code 68180)	07/01/2004	03/02/2004
Vistakon Pharmaceuticals. LLC (Labeler Code 68669)	07/01/2004	04/08/2004

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

TERMINATED LABELERS

TERMINATED LABELER – REVISED EFFECTIVE DATE

In release number 129, dated February 19, 2004, Muro Pharmaceutical, Inc (Labeler Code 00451) was terminated effective July 1, 2004. The July 1 date was established in error. **The revised effective termination date for Muro Pharmaceutical, Inc. is April 1, 2004.** We apologize for any inconvenience this error may have caused.

The above information was faxed to state Technical Contacts on March 8, 2004.

The following labeler codes are being terminated effective July 1, 2004:

Schering Corporation (Labeler Code 00369);
DSC Laboratories Div Dsc Products, Inc. (Labeler Code 52316);
Nastech Pharmaceutical Company, Inc.(Labeler Code 57459);
AstraZeneca, LP (Labeler Code 61113); and
Reddy Pharmaceuticals (Labeler Code 67857).

The following labeler codes are being voluntarily terminated effective July 1, 2004:

Novartis Pharmaceuticals Corporation (Labeler Codes 00058, 57267 and 58887);
Scot-tussin Pharmacal Co., Inc. (Labeler Code 00372);
Bertek Pharmaceuticals, Inc. (Labeler Code 00514);
Heartland Services (Labeler Code 61392);
Gynetics (Labeler Code 63955); and
Women First Health Care (Labeler Code 64248).

OTHER ATTACHMENT

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period November 18, 2002, 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.

Edward C. Gendron
Director
Finance, Systems and Budget Group

3 Attachments

cc:

All State Drug Rebate Technical Contacts
All Regional Administrators

CMS DRUG REBATE PROGRAM

Area Code 410



OPERATIONS

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Chris Holmes	786-3328
Karen Leshko	786-1291
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Sue Williams	786-3334

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Carl Tepper	786-2137
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

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Tamara Bruce	786-1519
Diane Dunstan	303-844-7040



FAX

786-0390 – Operations/Systems
786-8534 - Policy

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

WEEKLY U.S. T-BILL DISCOUNT RATE

weekly 90-day treasury bill auction rates

Date of Auction	Discount Rate	Date of Auction	Discount Rate	Date of Auction	Discount Rate
11-18-02	1.227	06-16-03	0.854	01-12-04	0.887
11-25-02	1.228	06-23-03	0.830	01-20-04	0.891
12-02-02	1.231	06-30-03	0.903	01-26-04	0.907
12-09-02	1.215	07-07-03	0.907	02-02-04	0.939
12-16-02	1.219	07-14-03	0.895	02-09-04	0.939
12-23-02	1.207	07-21-03	0.911	02-17-04	0.931
12-30-02	1.207	07-28-03	0.964	02-23-04	0.947
01-06-03	1.207	08-04-03	0.964	03-01-04	0.957
01-13-03	1.199	08-11-03	0.960	03-08-04	0.945
01-21-03	1.179	08-18-03	0.964	03-15-04	0.961
01-27-03	1.159	08-25-03	0.997	03-22-04	0.945
02-03-03	1.175	09-02-03	0.988	03-29-04	0.961
02-10-03	1.171	09-08-03	0.951	04-05-04	0.945
02-18-03	1.179	09-15-03	0.947	04-12-04	0.929
02-24-03	1.195	09-22-03	0.953	04-19-04	0.949
03-03-03	1.198	09-29-03	0.953	04-26-04	0.985
03-10-03	1.077	10-06-03	0.939		
03-17-03	1.137	10-14-03	0.923		
03-24-03	1.174	10-20-03	0.939		
03-31-03	1.121	10-27-03	0.960		
04-07-03	1.158	11-03-03	0.960		
04-14-03	1.186	11-10-03	0.951		
04-21-03	1.182	11-17-03	0.951		
04-28-03	1.141	11-24-03	0.946		
05-05-03	1.117	12-01-03	0.943		
05-12-03	1.089	12-08-03	0.915		
05-20-03	1.040	12-15-03	0.903		
05-28-03	1.121	12-22-03	0.884		
06-02-03	1.133	12-29-03	0.901		
06-09-03	1.024	01-05-04	0.939		

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