

June 23, 2003

MEDICAID DRUG REBATE PROGRAM

RELEASE #59

For Participating Drug Manufacturers

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IMPORTANT HIPAA/RX NEWS - STATUS OF PRESCRIPTION NUMBERS UNDER THE HIPAA PRIVACY RULE

Manufacturers have the right to dispute or audit state utilization information, and regularly request claims-level data from the states to help resolve Medicaid drug rebate disputes. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) we consulted with Health and Human Services' Office of Civil Rights on whether it is permissible for states to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors for claims validation in the Medicaid drug rebate program.

The HIPAA Privacy Rule permits state Medicaid agencies to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors that assist the pharmaceutical manufacturers, for purposes of validating claims under the Medicaid Drug Rebate program. This information is provided on the U.S. Department of Health and Human Services' web page and clearly states that claims-level data, specifically the prescription number, is appropriate to disclose as part of the state Medicaid agency's payment activities.

To view this information refer to <http://www.hhs.gov/ocr/>, click on "View Health Information Privacy Frequently Asked Questions (FAQs)" link. Go to page 10, click on #192.

STATE PHARMACY ASSISTANCE PROGRAMS – REVISED CRITERIA

We have received numerous inquires and comments on whether State only programs meet the criteria of a State pharmacy assistance program (SPAP) in order to be excluded from Best Price (BP) and Average Manufacturer Price (AMP), as was discussed in Labeler Release #57. As a result, we have revised the criteria described in Release #57. The new criteria should be applied prospectively as of the date of this release.

In order for a State only program to qualify as a State pharmacy assistance program, it should generally meet the following criteria:

- • The program is a State developed program specifically for disabled, indigent, low-income elderly or other financially vulnerable persons.
- • The program is funded by the State; that is, no Federal dollars are involved.
- • The program is set up such that payment is provided directly to providers.
- • The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefits or services.
- • The program does not allow for the diversion, resale or transfer of benefits reimbursed under the State pharmacy assistance program to individuals who are not beneficiaries of the State pharmacy assistance program.

Programs that reflect traditional state responsibilities, such as State employee benefit programs or medical programs for inmates or patients of State prisons or hospitals, do not meet these criteria. As a reminder, only the prices used under a State pharmacy assistance program can be excluded from the BP and AMP calculations; therefore, the prices of programs that do not meet these criteria should be included in BP and AMP calculations as appropriate.

In addition, as was mentioned in Release #57, we are aware of at least one state that is grouping several state-only programs together and sending manufacturers just one invoice for all the programs. It is possible that not all of these programs meet the above-mentioned criteria for a State pharmacy assistance program, and therefore, the prices used thereunder would not necessarily be excluded from BP and AMP. If a State sends out only one invoice for multiple programs and some of those programs do not qualify as State pharmacy assistance programs, it is the manufacturer's responsibility to determine the individual amounts that are being paid for each program and identify any instances where BP and AMP should be adjusted. To that end, it may be necessary to request separate invoices for the individual programs to ensure proper BP and AMP reporting.

DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING
SEPTEMBER 8 – 12, 2003

We are pleased to announce that the next National DRP meeting will be held September 8 – September 12, 2003 in Baltimore, Maryland. This meeting is a continuation of the highly successful meetings held in Denver. Many states and manufacturers have cited these meetings as essential to the resolution of outstanding rebate disputes.

While this meeting is open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. Since we are only having one National DRP meeting this fiscal year, we anticipate high attendance. Therefore, we may not be able to accommodate all states and manufacturers that wish to attend the September meeting. We are requesting that, if possible, states plan on arriving in Baltimore in time to attend a “States-only” meeting with the DRP Team Monday morning September 8th. We will provide details on that meeting later.

As in the past, prior planning is absolutely imperative to the success of these meetings so we are requesting that you register PROMPTLY by completing the registration form on our web page at <http://www.cms.hhs.gov/medicaid/drugs/drpmtdgs.asp> and return it as instructed to Diane Dunstan, Lead Regional Office (RO) DRP Coordinator. Whenever possible, priority scheduling will be afforded those who respond first. We will ensure that we provide adequate DRP staff to conduct the meeting based on your timely responses. In addition, you should begin planning now in order to obtain accommodations in Baltimore.

More detailed information on the meeting will be forthcoming on our web page, including a list of attendees. If you have any questions you may contact any of the DRP Team members:

Sue Gaston (410) 786-6918 or sgaston@cms.hhs.gov

Diane Dunstan (303) 844-7040 or ddunstan@cms.hhs.gov

Tami Bruce (410) 786-1519 or tbruce@cms.hhs.gov.

In addition, if at any time you should have any DRP related issues please contact the appropriate RO DRP Coordinator. A list of the RO DRP Coordinators may be found at: <http://www.cms.hhs.gov/medicaid/drugs/drpcoor.pdf>.

LABELER DATA REQUESTS

Because Medicaid drug rebate program data requests from labelers have increased over the past two years, CMS will no longer be able to accommodate requests to recreate databases. The data you request from CMS is a mirror image of the data you send to us each quarter, thus your database should serve as back up for the data requested.

Similarly, if a labeler merges with or purchases entire labeler codes or buys specific products from another labeler, the historical Medicaid data is to be supplied by the selling labeler as a condition of sale. CMS no longer has the resources to provide this often-requested data.

DISPUTE RESOLUTION PROGRAM WEB PAGE

We have established a web site for the Dispute Resolution Program (DRP). This site is intended to assist both new, as well as experienced CMS, state Medicaid program and manufacturer staff to navigate the often complex task of resolving Medicaid drug rebate disputes. This site provides background information on the DRP, historical information on the DRP and the Medicaid drug rebate program, the DRP national meetings and the DRP regional office (RO) coordinators contact list. The site may be found at: <http://www.cms.hhs.gov/medicaid/drugs/drphmpg.asp>

In the near future this site will contain DRP best practices, frequently asked questions and answers and a compilation based on our experiences and “lessons learned” through the DRP. It is intended to be a valuable resource for all participants in the program.

MEDICAID PRESCRIPTION REIMBURSEMENT INFORMATION WEBSITE

A website has been established for Medicaid Prescription Reimbursement Information. This chart outlines reimbursement methodologies by state that appear in their respective approved state plans - co-pay amounts, dispensing fees, AWP, WAC and if a MAC program is in place. This information will be updated quarterly. The site may be found at <http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp>.

PHARMACY PLUS DEMONSTRATIONS WEBPAGE

There is a new Pharmacy Plus Demonstrations webpage. This website includes the status of all Pharmacy Plus Demonstrations, a program summary, the template application for submitting a Pharmacy Plus Demonstration, instructions and worksheets for budget neutrality, and sample terms & conditions. The site may be found at www.cms.hhs.gov/medicaid/1115/pharmacyplus.asp.

OTHER ATTACHMENT

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period April 22, 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.

/s/

Wayne Smith
Acting Director
Finance, Systems and Budget Group

2 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

REGISTRATION FORM – FY 2003

Medicaid Drug Dispute Resolution Meeting
September 8 – 12, 2003
Baltimore, Maryland

Note: You may register electronically at:

<http://www.cms.hhs.gov/medicaid/drugs/drpmtdgs.asp>

Name:	Phone:
Manufacturer: (Labeler Code)	E-mail:
State:	Fax:

I would like to meet with the following Manufacturers/States:

The following staff may also be attending the meeting with me:

Name:

Phone:

E-mail:

FAX:

If you have issues with a Manufacturer/State that you think will take more time than a typical DRP meeting (30 minutes - 1 hour), please let us know ASAP so that we can try to accommodate you in our meeting plans.

Also, if there are new, complex or unusual program issues related to your dispute that the DRP Team can research before the meetings to better ensure efficient resolution, please call or email us with the issue(s) as soon as they are known.

If you have any questions please contact Diane Dunstan at (303) 844-7040 or email ddunstan@cms.hhs.gov. Please fax your completed form to Diane Dunstan at (303) 844-3753.

