

March 12, 2002

MEDICAID DRUG REBATE PROGRAM RELEASE #113

For State Medicaid Directors

REBATES FOR DRUGS PURCHASED THROUGH THE FEDERAL SUPPLY SCHEDULE

It has come to our attention that certain Indian Health Service (IHS) facilities that are purchasing drugs from the Federal Supply Schedule (FSS) may be dispensing these drugs to their Medicaid patients and billing the State Medicaid agencies for these drugs. Staff with the Department of Veterans Affairs (DVA) have informed us that under the requirements of the FSS program, these drugs should not be billed to a third party payor, such as Medicaid. IHS facilities should maintain a separate inventory of drugs purchased at open market prices dispensed to Medicaid patients which can then be billed to Medicaid for Medicaid eligible patients.

Accordingly, all participating manufacturers are required to pay rebates on drugs billed by IHS facilities to State Medicaid agencies, provided that those facilities do not participate in the 340B drug pricing program for Medicaid. We do not view this as a revision to our earlier policy that rebates are not due on drugs purchased through the FSS. Our earlier position continues to be based on the understanding that IHS facilities are prohibited from billing their FSS-obtained drugs to the Medicaid program. Therefore, you are required to collect rebates on all drugs billed by IHS facilities, except when those facilities participate in the 340B drug pricing program for their Medicaid patients.

VITAMIN AND OTHER NON-DRUG COMPANIES

Several times each month we get calls from vitamin companies or other non-drug companies who are told by a state that they must contact the drug rebate program and become an active labeler. They are told by the state that unless they become active in our program the state will not reimburse for their products. We assure them that their products can, in fact, be covered by states without participating in the drug rebate program and that the information they received from the state is incorrect. Please remember that only products deemed as outpatient drugs by the FDA can be covered by and reimbursed under the drug rebate program.

REBATE/REIMBURSEMENT DISPUTES

Recently, a state Medicaid agency requested clarification of a rebate policy. In one scenario the agency indicated that there was no state Medicaid reimbursement to a pharmacy provider as a result of a primary payer payment and the beneficiaries' copayment requirement. However, the state Medicaid agency did pay its pharmacy processor for the associated claims processing fees in the Point-of-Sale System and performed drug utilization review on the claim. A manufacturer disputed the rebate for the drug arguing that since the state Medicaid agency did not reimburse the provider for the drug there was no rebate associated with the drug.

In this case, the manufacturer was correct to withhold payment of rebates for the drugs. As discussed in previous releases, if a state Medicaid agency paid **any** portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug. Although the state Medicaid agency may pay their respective claims processors for their services, these payments are not to be included in the provider reimbursement for costs of the drug. Therefore, in all instances where the state Medicaid agency's pharmacy reimbursement for the cost of the drug results in no payment to the provider, there are no rebates associated with those units of the drug.

DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETINGS

We are pleased to announce that the next National DRP meetings will be held during the week of June 24-27, 2002, in Denver. These meetings will be our first DRP meetings since September 2001, and are a continuation of the highly successful meetings held in Denver since 1998. Nearly \$1 billion in formerly disputed rebates have been resolved through the DRP and these meetings have been cited by many states and manufacturers as essential to the resolution of outstanding rebate disputes.

While these meetings are open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. Since it is unclear at this time because of budget and resource limitations as to whether we will be conducting other DRP meetings beyond these, it is profoundly important that you take advantage of the opportunity to attend these meetings in June. Further, we are requesting that, if possible, states plan on arriving in Denver in time to attend a "States-only" meeting with the DRP Team on Monday morning, June 24th. 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 PROMPTLY complete the attached registration form and return it as instructed to Diane Dunstan, the National DRP Regional Office (RO) Coordinator. Whenever possible, priority scheduling will be afforded those who respond first. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses. Equally important, you should begin planning now in order to obtain satisfactory accommodations in Denver.

Please feel free to contact any of the RO DRP Team members for any dispute-related issue and they will coordinate with Diane, the RO lead in Denver. Of course, you may contact Tami Bruce, the DRP Central Office (CO) Coordinator or Mike Keogh, the DRP Team Leader, on any rebate dispute matter. Tami may be reached at (410) 786-1519 or tbruce@cms.hhs.gov and Mike at (410) 786-5910 or mkeogh1@cms.hhs.gov.

If you have any specific questions regarding the National DRP meeting in Denver, please contact Diane Dunstan at (303) 844-7040 or ddunstan@cms.hhs.gov.

NEW--DRUG REBATE POLICY E-MAIL ADDRESS

Drug rebate policy questions may now be sent to the following email address:
DrugRebatePolicy@cms.hhs.gov

Your questions will be reviewed and forwarded to appropriate staff for a response. Please note that this is an email address for policy issues only and that inquiries on other areas of the Medicaid drug rebate program should continue to be communicated as before.

Please use this email address for informal inquiries only. Formal inquiries where you wish a formal response should continue to be addressed to the appropriate CMS official in the normal manner.

SEPARATE OR SUPPLEMENTAL MEDICAID DRUG REBATE AGREEMENTS

This is to reiterate that the approval process for separate or supplemental Medicaid drug rebate agreements as specified in Release #48 for Drug Manufacturers and Release #102 for State Medicaid Directors requires the State to submit the proposed agreement to the appropriate CMS Regional Office.

Please note that the CMS contact has changed. If you have any questions regarding separate or supplemental Medicaid drug rebate agreements please contact Kim Howell at khowell@cms.hhs.gov or (410) 786-6762.

NEW LABELERS

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Rx Holdings, LLC (dba RxElite)

(Labeler Code 08367) 07/01/2002 03/08/2002

Rx Holdings, LLC (dba RxElite)

(Labeler Code 66794) 07/01/2002 03/08/2002

AMBI Pharmaceuticals, Inc.

(Labeler Code 66870) 07/01/2002 03/08/2002

Contact information for the new labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler is being terminated effective April 1, 2002:

Superior Pharmaceutical Company (Labeler Code 00144).

The following labeler is being voluntarily terminated effective July 1, 2002:

MED-TEK SYSTEMS (Labeler Code 52349).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period July 31, 2000, 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.

David McNally, Deputy Director

Finance, Systems and Quality Group

Center for Medicaid and State Operations

4 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators