DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

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MEDICAID DRUG REBATE PROGRAM **Release No. 80**

Bulletin

For
Participating Drug Manufacturers

REPORTING ZERO OR NEGATIVE AMP

If a calculated monthly AMP is zero or negative, we recommend that manufacturers report the most recent prior month's positive AMP. Please do not enter the value 99999.999999 or 0.000001 when you attempt to enter a value of zero for AMP. However, please note the actual calculated monthly AMP should be used to calculate the quarterly AMP. If the quarterly AMP is zero or negative, we recommend that manufacturers report the most recent positive AMP value. (Contact: DRARxPolicy@cms.hhs.gov)

GUIDANCE ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE (BP) METHODOLOGY RECALCULATIONS

This guidance responds to request we have from manufacturers to modify their methodology for calculating the Average Manufacturer Price (AMP) or best price (BP) under the Medicaid drug rebate program. In many cases these requests have been pending prior to the effective date of regulations that set the 12 quarter time limitation for the submission of this data. We have decided that manufacturers with pending recalculation requests may implement the revised pricing methodology for the specified periods without prior review and approval by the Centers for Medicare & Medicaid Services (CMS). Manufacturers may also proceed with changes to AMP or BP for a period not in excess of 12 quarters pending with us that were received after the 12 quarter limitation took effect.

Additionally, a manufacturer that needs to make future recalculations regarding AMP and/or BP methodology may do so without prior review and approval by CMS. However, we continue to request that manufacturers notify us of the change in the method used to calculate their AMP and/or BP, along with revised AMP and/or BP data to support the change 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. Manufacturers must report to CMS these revisions to

AMP and/or BP for a period not to exceed 12 quarters from the quarter in which the data were due.

Recognizing the financial impact that the recovery of these historical incorrect payments may have on some States, we suggest that each manufacturer work with all States to limit the recovery of overpayments so that no State is unduly burdened. Specifically, we suggest that manufacturers limit recoveries from each State to a maximum of 25 percent of the amount otherwise payable in one quarter.

Because of the recalculations at issue, manufacturers should contact MDROperations@cms.hhs.gov to obtain instructions regarding the data resubmission process.

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, BP or other pricing data by CMS, the Office of Inspector General, or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer is responsible for complying with that determination. Additionally, in accordance with Section 1927 and Federal regulations at 42 CFR § 447.510(f), 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 as to whether the revised pricing calculation is consistent with the methodology set forth in the statute and rebate agreement or the requirements of the Medicaid drug rebate program. CMS' receipt of revised pricing data, a recalculation request (or any acknowledgment of such receipt), or this Medicaid drug rebate program release is not, and may not be considered to be, CMS approval of the revised methodology or an advisory opinion under Section 1128D (b) of the Social Security Act. 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' receipt of a recalculation request (or any acknowledgement of such receipt), revised pricing data or this Medicaid drug rebate program release is not a release of any liability.
(Contact: DRARxPolicy@cms.hhs.gov)

CLARIFICATION ON POSTMARK DATE FOR WEB INVOICES

Recently, we have received questions from States that have decided to use a secured web site as the method of providing manufacturers their quarterly rebate invoices as to what constitutes a postmark date. Under section II(b) of the Medicaid Drug Rebate Agreement, it is stated that "the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at minimum, information on the number of units paid, by NDC." Therefore, we expect that when using electronic invoicing via email, States include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC. In this case, we view the postmark date as the date on which the email is sent. Please note that the date an email is sent with a link to an invoice web site does not qualify as a postmark date. If States choose to direct manufacturers to an invoice web site via a link in the email, then States need to include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC.
(Contact: DRARxPolicy@cms.hhs.gov)

CLARIFICATION ON STATE PHARMACEUTICAL ASSISTANCE PROGRAM (SPAP) BEST PRICE LIST

It has come to our attention that manufacturers are relying upon the Medicare SPAP List (Qualified State Pharmaceuticals Assistance Programs Under the MMA) to determine whether an SPAP can be excluded from the Medicaid Best Price. The Medicaid SPAP Best Price list and Medicare SPAP list are two separate and distinct lists. For the purposes of determining whether an SPAP is excluded from the Medicaid Best Price, manufacturers should refer to the Medicaid SPAP Best Price list which can be found at http://www.cms.hhs.gov/Reimbursement/19_SPAPBestPrice.asp.
(Contact: DRARxPolicy@cms.hhs.gov)

DRUG CATEGORY INCORRECTLY REPORTED TO CMS

We recently determined that drug products on the CMS' Drug Product Data file for second quarter of 2009 appear to have been incorrectly categorized when reported to CMS. We are requesting manufacturers to review the drug category of their reported products to ensure the accuracy of the data submitted to the CMS.

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).

We encourage manufacturers to check the FDA's NDC Directory to determine whether the correct application number has been reported to the FDA for the product or to identify the correct drug category for the product based on the application number assigned to the product. Manufacturers may search by NDC Number and search by Labeler Code Only to view the FDA's application number assigned to the NDC of the product.

Manufacturers may also access the FDA's Drugs@FDA to determine whether a product was approved under an NDA or ANDA. Under this option, manufacturers may need the FDA's application number retrieved from the FDA's NDC Directory. The Drug Details information on Drugs@FDA should identify the product brand name(s) and active ingredient(s) approved under the specific application number and what type of application it is approved under (NDA or ANDA).

If you determine that an incorrect drug category has been reported to CMS for a product, please email DRARxPolicy@cms.hhs.gov for assistance to change the drug category for the product.

If you determine that your product has been incorrectly listed with the FDA, please contact the FDA at eDRLS@fda.hhs.gov.
(Contact: DRARxPolicy@cms.hhs.gov)

FDA FEDERAL REGISTER NOTICES

When the FDA issues a Notice in the Federal Register that impacts a labeler's drug product data as reported to CMS (*e.g.*, product termination dates, DESI Code changes), it is that labeler's responsibility to submit updated data to CMS so that the data is accurate. In addition, if the action(s) described in a Notice requires that a labeler's product be removed from the Medicaid Drug Rebate Program, the labeler may send an email to CMS (mdroperations@cms.hhs.gov) requesting that the product be removed from the CMS Medicaid Drug Rebate database, citing the appropriate Notice in support of the requested deletion. FR Notices can be viewed online at http://www.gpoaccess.gov/fr/index.html.
(Contact: mdroperations@cms.hhs.gov)

IMPACT OF FDA NEW DRUG DETERMINATIONS ON THE MEDICAID DRUG REBATE PROGRAM (MDRP)

The FDA periodically issues Notices in the Federal Register to announce certain FDA-related compliance actions, such as a final determination that a drug is a new drug within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act. Drugs subject to such final new drug determinations generally require FDA approval by the date of the compliance action (e.g., the date of the Notice) in order to legally remain on the market.

In accordance with section 1927(k)(2) of the Social Security Act, those NDCs that have been subject to a final determination by the FDA that they are "new drugs" and for which the labeler has not received required FDA approval do not meet the definition of a covered outpatient drug. Therefore, when a final new drug determination is made, we expect affected labelers to notify CMS to update information submitted pursuant to section 1927. Labelers may send an email to CMS, including "Request for Deletion of Non-Rebate-Eligible NDC(s)" in the subject line and citing the appropriate FDA-issued FR Notice in support of the requested deletion in the body of the email.

When either the labeler or CMS has determined that an NDC is not a covered outpatient drug, CMS will work with labelers and states to ensure that all parties are notified that the NDC is no longer a covered outpatient drug under section 1927.

Please note that the national rebate agreement provides that labelers submit a list of all of those NDCs that meet the definition of a covered outpatient drug. In accordance with the statute, labelers that submit false information may be subject to civil monetary penalties and/or termination from the program.

T-BILL AUCTION RATES

Treasury bill (T-bill) auction rates will no longer be included in releases. T-bill rates are available via the Drug Data Reporting (DDR) application under the Documents tab, LookUp Tables, T-Bill Interest Rates and also on our website at:
http://www.cms.hhs.gov/MedicaidDrugRebateProgram/05_TresBillRates.asp .
(Contact: mdroperations@cms.hhs.gov)

Please direct your drug rebate data questions to mdroperations@cms.hhs.gov and your drug policy questions to the Division of Pharmacy at DRARxPolicy@cms.hhs.gov.

Edward C. Gendron
Director
Finance, Systems and Budget Group

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