

December 18, 2002

MEDICAID DRUG REBATE PROGRAM

RELEASE #57

For Participating Drug Manufacturers

MULTIPLE PACKAGE SIZES OF A PRODUCT

Over the course of the drug rebate program, in several releases, in the Operations Guide and in letters attached to reports showing differences, we have emphasized that multiple package sizes of a product **MUST ALL** contain the same information with the exception of:

- a) a) Units Per Package Size
- b) b) Termination Date
- c) c) Product Name

Earlier this year, we began testing a new software system for maintaining the MDRI Master file. We ran a full-system parallel test run this quarter and, based on the findings, will make any necessary corrections and conduct one final parallel run with the next quarterly cycle (4th qtr/2002). At the conclusion of that run, we will begin operation under the new system.

The major changes will be in the edit reports, where we have rewritten messages to make data errors more understandable. The biggest change to the processing, however, is in the acceptance of product/pricing data for multiple package sizes of a given product. ANY new package size of an already established product will be matched to the existing product record. Any fields, other than the 3 mentioned above not matching the existing record will be flagged as errors and must be changed by the labeler. Until the correction is made, we will use data from the oldest package size only. Likewise, if you submit pricing data for multiple package sizes where either the AMP or the BP for different package sizes are reported different, it will be rejected as an error. Until pricing corrections are made by the labeler, we will use the **HIGHEST AMP** and **LOWEST BP** in calculating URA for that product for that quarter; however, it is imperative that the labeler make corrections as soon as possible.

After we “shut down” the 4th qtr/2002 (around mid-February, 2003), we will generate reports showing differences you currently have in multiple package size products and what values will be used in the MDRI Master file. If you receive one of these reports, please review it carefully and make all field value corrections with the next quarterly pricing submission.

Any questions in this area should be directed to a member of the operations staff, per section “O” of the Operations Guide.

INVOICING FOR STATE PHARMACY ASSISTANCE PROGRAMS

Many states currently invoice manufacturers for rebates as part of their state-only programs, i.e., those in which no Federal Medicaid dollars are involved. As a reminder, only the prices used under a State pharmacy assistance program can be excluded from the Best Price (BP) and Average Manufacturer Price (AMP) calculations. In order for a state program to qualify as a State pharmacy assistance program, it should generally meet the following criteria:

- • The program must provide only prescription drugs and no other service or benefit
- • The program must be such that no Federal Medicaid dollars are involved

Any state program that does not meet these criteria should not be considered a State pharmacy assistance program and therefore, the prices used under such a program should be included in BP and AMP calculations.

We also note that at least one state 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 your 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.

**HHS OFFICE OF INSPECTOR GENERAL REVIEWING STATE
MEDICAID DRUG REBATE COLLECTIONS**

The HHS Office of Inspector General, Office of Audit Services (OAS) is currently conducting audits of the States' Medicaid Prescription Drug Rebate Programs (including supplemental rebate programs where they exist). Region VI and its Little Rock, Arkansas Field Office is the lead Region for the audits. The OAS plans to visit each of 49 States (Arizona is excluded) and the District of Columbia. The objectives of the audits are to (1) identify the amount of uncollected rebates as of June 30, 2002, (2) evaluate the States' internal controls over rebate funds, and (3) evaluate the States' procedures for resolving disputed rebate billings. The OAS will also review and report on state best practices in these areas. Most States will be contacted by the OIG early in calendar year 2003. Additionally, the CMS regional offices will be contacted.

ATTACHMENT

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period September 24, 2001, is attached

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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 Quality Group

Attachment

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

