MEDICAID DRUG REBATE PROGRAM RELEASE #52

For Participating Drug Manufacturers

*** IMPORTANT INFORMATION *** FDA/MDRI MATCH - RERUN

Several weeks ago many labelers received reports showing NDCs that were included on the MDRI master file, but not on the FDA master listed/pending files. Those affected labelers were instructed to contact the FDA in order to have those NDCs (on the report) that represented "drug" products properly listed (with the FDA) and to be prepared to have those NDCs (that were on the report) that represented "non-drug" products removed from the MDRI master file. Even though we did extensive testing of the FDA/MDRI master files, including a preliminary match, it was not until the reports were sent out that we discovered that there were, in fact, active, valid NDCs that were omitted from the FDA files. IF YOU HAVE ANY OF THESE REPORTS, PLEASE DISREGARD THEM.

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By the first week of October we intend to perform this match again using an updated set of files from the FDA. New reports (non-matches) will be generated and sent to all affected labelers. The same rules apply for this rerun as did for the original. All NDCs

included on this report are **NOT** on any of the FDA master files. If they are, in fact, "drugs," whether OTCs or RXs, whether one package size or a dozen, whether they are your drugs or you bought and repackaged them, they **MUST** be listed with the FDA **under the NDC shown** on the report in order for them to continue to be covered under the Drug Rebate Program. You will be given the phone number and address of the proper FDA contacts to update their files.

Originally, the second (follow-up) match was to be performed in February, 2002, using fourth quarter, 2001 data. Because of this re-run, the second (follow-up) match will not be performed until May, 2002, when the pricing for FIRST Quarter/2002 is completed. This will allow an additional quarter for drug companies to get their missing drug NDCs listed with the FDA before non-drugs are deleted from the MDRI master file.

If you have any questions or comments about this project, changes to it, new timeframes, etc., please direct them to a member of the operations staff.

OPERATIONAL TRAINING GUIDE

CMS's Medicaid Drug Rebate Operational Training Guide has been rewritten and printed. A copy of the September, 2001 issue is being mailed shortly and should be received by all technical contacts within the next two weeks. Please discard your old copy. If you receive a copy of the guide and you are not the technical contact for your company, please forward it to the appropriate person and have that person complete and submit pages M4 and M5 in the guide.

HCFA HAS A NEW NAME

Effective immediately, HCFA has changed its name to the Centers for Medicare & Medicaid Services (CMS). All current stock of letterhead, forms, etc., will be used before new stock is printed. If you have any forms which are generated electronically, e.g., ROSI, PQAS, please change HCFA to CMS on your system.

ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period January 3, 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

2 Attachments

cc:

All Regional Administrators All Associate Regional Administrators, Division of Medicaid