DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

June 27, 2001

MEDICAID DRUG REBATE PROGRAM RELEASE #51

For

Participating Drug Manufacturers

MDRI/FDA DATA MATCH

HCFA and the FDA have been working together for some time to develop a system of identifying non-drug products that erroneously have NDC numbers associated with them. To that end, we will be matching active records on the FDA listed and pending files to the active records on the Medicaid Drug Rebate Initiative (MDRI) file to identify any records that do not match and thus, do not meet the definition of "covered outpatient drug" established in section 1927 of the Social Security Act.

The process will work in the following manner and time frames:

- After we send the states the 2nd qtr/2001 Unit Rebate Amount (URA) tapes (about August 15th), we will perform a match between the FDA listed and pending files, updated through June 30, 2001 and the 2nd qtr/2001 MDRI master file. A report will be generated showing those NDCs on the MDRI that do NOT match the FDA files.

- Each labeler will receive that portion of the report pertaining to its labeler code, listed by NDC, with a letter explaining the report and stating that the labeler should provide information demonstrating that its drug product meets the definition of covered outpatient drug. Also, the letter will tell the labeler what needs to be done to make any corrections on those drug products that may be approved drugs but need a follow up notice to the FDA.

- The labeler will have 2 quarters to properly identify and list those drug products with the FDA. Information on how to do this will be included in the letter attached to the report.

- After we send states the 4th qtr/2001 URA tapes (about February 15th), we will perform this match again, using the updated FDA files through December 31st, 2001 and the 4th qtr/2001 MDRI master file.

- A report following the same format as mentioned above will be sent to each affected labeler, stating that these NDCs will be deleted from the MDRI master file and will not be covered by the drug rebate program effective April 1, 2002. These NDCs will, however, remain active on the MDRI file for Q1/2002.

- An electronic file of these non-matching NDCs (drugs not meeting the definition of covered outpatient drugs) will be sent to each state, on or about March 1, 2002. The states will be told to delete them from their drug rebate data bases and cease covering them under the drug rebate program effective April 1, 2002.

Beginning with the 2nd qtr/2002 state tape (due to states around August 20, 2002) and for every quarter thereafter, the first step in the URA calculation and tape creation process will be a match between new MDRI records and the FDA listed/pending files for that quarter. Every new record a labeler attempts to add to the MDRI that doesn't satisfy the definition of covered outpatient drug will be rejected and a record rejection report will be sent to the affected labeler with a message explaining that this record has been rejected.

This latest effort in cleaning up the MDRI files once again highlights the fact that no matter what data files or software states use for their "regular" Medicaid business, it is imperative that the MDRI master file be used when doing drug rebate processing. Using other files and other data may result in the state paying for but losing rebates for products not covered by the Medicaid Drug Rebate Program. Questions may be directed to any member of the drug rebate operations staff, as listed in section "O" of the Operations guide.

UNIT REBATE AMOUNT ROUNDING

For several years now, both states and labelers have had problems with the rounding issue of the Unit Rebate Amount (URA). By calculating the URA to the 7th position and rounding to the 6th at the end of the calculation for any given quarter, the 5th and 6th positions of a URA calculated by the labeler for an NDC could have a different value than the URA calculated by HCFA for that same NDC depending on the calculator or computer used for the calculation. This meant that even though labelers and HCFA calculated the URA exactly the same using the exact same data, the URAs could (and most often would) be slightly different in value. Because of this, states (and labelers) have thousands of "open disputes" on their books even though there are no utilization issues pending on these NDCs.

In 2000, HCFA studied different ways of calculating the URA without changing the requirements of section 1927 of the Social Security Act. What turned out as the best solution was to change the last step of the (URA) calculation so that the final URA value

is calculated to the 5th position and rounded to the 4th position. Because we wanted to make this calculation correction as easy as possible for labelers, we did not want to change field size. Doing that would change record length and block size and would cause problems and confusion that would far outweigh what we were trying to fix; something we wanted to avoid at all possible costs. The answer would be to leave the URA field at the same length with 6 positions to the right of the decimal point and simply "complete" (decimal) positions 5 and 6 with zeros.

We ran simulation URA calculations using three quarters of data, side by side, comparing the final URA under the old method to the final URA under the new method. We computed total rebate dollars for all products for all three quarters and combined the quarterly rebates together. We then divided total rebate dollars by total rebate utilization and the total average difference worked out to less than .000001 cents per unit. Also, the calculation was done multiple times and showed different values under the old method (calculate to position 7 and round to 6) in about 64% of the products whereas the new method (calculate to position 5 and round to 4) done multiple times came up with the exact same values in more than 99% of the answers.

In labeler release #46, dated 04-18-2000, we laid out the new approach to the rounding issue and a timetable for implementation. In #47, dated 07-13-2000, we moved the implementation date 2 quarters because a few labelers that compute their own URAs and software companies that do the drug rebate systems work for labelers

could not get their program changes done in time for a 3Q/00 changeover. In #48, dated 11-15-2000, we once again reviewed the change and explained that there were NO changes to the AMP/BP calculations, only the URA calculation.

Now that the first quarter tape with this change has gone to the states, we have received several state reports where MORE THAN 20 (major) labelers have gotten invoices, **CHANGED the URAs BACK TO THE ORIGINAL CALCULATION,** and paid the states according to the OLD calculation. This is completely counter-productive to what we are trying to achieve. **We are asking labelers that are guilty of the above scenario to either change your URA calculation method with respect to URA rounding to match the "new" HCFA way or to pay states based on the URA they reported to you, unless you made a change since submitting quarterly pricing that would change the URA for a given product.** We don't want the same problems with the new calculation as with the old.

Questions may be directed to any member of the operations staff, as listed in section "O" of your operations guide.

REPORTING NEW PACKAGE SIZES

Since we changed the way we round the Unit Rebate Amount (URA), and do so only for new or Prior Period Adjustment (PPA) records, there have been some questions regarding how this will work when reporting new package sizes of old products. The new package size must have all quarters of pricing completed back to the Market Date of the oldest size. The question "Wouldn't that cause the new package size to have its old rebates calculated and, thus, have different values than the already existing package sizes?" has been asked on several occasions. The answer is "No, the new package size will have the same URA values as the existing package sizes."

When you submit information for a new package size, the system allows for specific information to be entered from your data, such as: NDC3, UPPS and Product Name. All other information is taken from the old package size. In a similar manner, all pricing *AND* URA information is copied from an old size to the new and flags to calculate the URA for this new package size are turned off. That means that the integrity of the URA from the old sizes is maintained by all new sizes. PPAs are NOT generated for two reasons; 1) Nothing changed, thus PPAs are not warranted and 2) There should never be any old utilization requests for this new size, as it didn't exist before this quarter.

BEST PRICE CALCULATION FOR PHARMACEUTICALS SOLD TO 340B COVERED ENTITIES

We are clarifying our policy on manufacturers offering discounts to covered entities participating in the 340B drug pricing program beyond the statutory ceiling price. The question of whether these additional discounts must be included in the calculation of best price depends on how the covered entity bills the Medicaid program for drugs dispensed to Medicaid patients. If a covered entity participates in the 340B program for their Medicaid patients and bills the State Medicaid agencies at the actual acquisition cost of the drug, then drugs sold at prices discounted below the 340B ceiling price may be excluded from best price. However, if a covered entity does not participate in the 340B program for their Medicaid patients and bills the State Medicaid agencies above the actual acquisition cost of the drug, then these drugs are not considered sold through the 340B programs and should be included in best price.

RE-USE OF NDCs AFTER FIVE YEARS

It has always been an FDA policy that an NDC can be reused after a product has been terminated for at least five (5) years. However, this creates a lot of problems for the drug rebate program as we must keep product and pricing data for ALL NDCs back to the start of the program. We have been informed that the FDA is about to change that policy and NEVER permit an NDC to be re-used.

With those two issues understood, HCFA is asking that, unless it is absolutely unavoidable (you have run out of possible product codes), please do NOT re-use an old NDC with a new product. This will make everyone's (HCFA, states and labelers) life just a little less complicated.

DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING

We are happy to announce that the next National DRP meeting will be held during the week of September 10 - 14, 2001 in Denver. This meeting is being coordinated by Diane Dunstan, our National DRP Regional Coordinator, and is a continuation of the highly successful meetings held in Denver since 1998. Attached is a form that MUST be completed and faxed to Diane ASAP if you are planning to attend the September meeting.

These meetings are open to ALL states and manufacturers. Those of you that have attended any of our previous National meetings know about the overwhelming enthusiastic support given to this effort by the Denver Regional Office leadership. Overall, the meetings have been very successful in resolving millions of dollars of disputed rebates.

If you have any questions regarding the National DRP meeting in Denver, please contact Diane Dunstan at (303) 844.7040.

OTHER 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

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

Registration Form

Medicaid Drug Rebate Dispute Resolution Program

September 10 - 14, 2001

Denver, Colorado

Name: _____ State: _____

Manufacturer: _____ Phone: _____

Fax: _____ E-Mail: _____

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

Name: _____ Phone: _____

Fax: _____ E-Mail: _____

Name: _____ Phone: _____

Fax: _____ E-Mail: _____

Name: _____ Phone: _____

Fax: _____ E-Mail: _____

Name: _____ Phone: _____

Fax: _____ E-Mail: _____

Please fax completed registration form to Diane Dunstan at 303.844.3753