



6325 Security Boulevard
Baltimore, MD 21207

FEB 14 1992



MEDICAID DRUG REBATE PROGRAM

Release No. 18

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All State Medicaid Directors

LATE DATA SUBMISSIONS TO MANUFACTURERS AND HCFA

There are States which continue to be late in submitting their drug utilization data or invoices to drug labelers each quarter. We are aware of this situation since drug labelers are very quick to pinpoint those States which are tardy or have never billed the drug labelers. We urge you to make every effort to generate invoices to the drug labelers within 60 days after the end of each calendar quarter. The law is very clear on this point.

Finally, there are States which have never submitted invoices to drug labelers or utilization data to HCFA. HCFA staff will be contacting those States in this category to ascertain what problems are hindering this process, to render assistance, if requested, or take other actions as necessary.

NEW DRUG LABELER CODES

The following drug labeler code was just issued by the FDA and belongs to Winsor Pharmaceuticals which is a division of Whitby Pharmaceuticals. The effective date for this new drug labeler will be January 1, 1992. Personnel from Whitby Pharmaceutical stated that the drug products for this new drug labeler will enter the market in May.

- o Whitby Pharmaceuticals (Winsor Pharmaceuticals) (Labeler Code 59004. Contact information is attached.

The following drug labelers will be added to this program effective April 1, 1992:

- o Nephron Pharmaceuticals Corporation (Labeler Code 00487). Contact information is attached.
- o Scot-Tussin Pharmacal Company, Incorporated (Labeler Code 00372). Contact information is attached.

UTILIZATION DATA CORRECTIONS

Utilization data corrections for NDCs should be submitted whenever there are changes to fields other than the REBATE AMOUNT PER UNIT field. The utilization data are being used to prepare the required annual report to the Congress and must be, by necessity, as correct as possible. REMEMBER THAT THE CORRECTION FLAG FIELD SHOULD BE SET TO A "1" FOR EACH CORRECTION RECORD. A CORRECTION RECORD COMPLETELY OVERLAYS PREVIOUSLY REPORTED DATA.

UTILIZATION DATA PROBLEMS

Every utilization tape submitted to HCFA is screened for format and consistency compliance. Occasionally, we notice problems such as missing data fields, unusually small numbers of records and NDCs which are not in the HCFA data base. In our review of State-submitted utilization data, we noticed several instances where there were decimal values in the TOTAL UNITS REIMBURSED field where none should appear. We found that one labeler told HCFA that the UNIT TYPE for five drug products was "PAC" but many States ignored that unit type data given to them by HCFA. Instead, the States used unit types supplied by First DataBank or MediSpan. The incorrect decimal values occurred when converting State data to the values specified by HCFA. (For example, the product is a tablet sold as an unbreakable pack of 28. First DataBank shows the product as a tablet but the drug labeler tells HCFA that the product is marketed as a packet. In this instance, after any State conversion is done, the TOTAL UNITS REIMBURSED should be a whole number based on the number of "PACs" reimbursed. Remember that the UNIT REBATE AMOUNT is based on the UNIT TYPE sent to you by HCFA. Conversion errors can contribute to rebate disputes.

CONVERSION TO METRIC MEASUREMENTS AND ROUNDING

As you are aware, metric measurements were mandated for drug labeler use in the UNIT TYPE field. It appears that several trade groups and associations are advising their clients and State Medicaid agencies to "round up" whenever conversion to metric measurement results in a decimal value in the UNITS PER PACKAGE SIZE field. THAT ADVICE IS NOT CORRECT. Use the actual decimal value shown in the UNITS PER PACKAGE SIZE field.

Drug labelers converting a 4 ounce unbreakable bottle to milliliters must show 113.2 in the UNITS PER PACKAGE SIZE field, not 114.0. Since rebates are paid based on the TOTAL UNITS REIMBURSED field per NDC, the drug labelers expect invoices from States to reflect multiples of the values shown in the UNITS PER PACKAGE SIZE field. Deviations invite disputes and non-payment of invoices.

INCOMPLETE DATA ON DRUG LABELER INVOICES

There have been isolated instances where drug labelers did not receive complete information for their drug products. While a drug labeler must pay rebates based on receipt of an NDC and the number of units reimbursed, at a minimum, we are reminding you that the formats promulgated by HCFA for both paper and magnetic media invoices are mandatory; hence, the submission of complete NDC data is mandatory. If drug labelers are using the extra fields, NUMBER OF PRESCRIPTIONS REIMBURSED and TOTAL REIMBURSEMENT AMOUNT, to generate disputes, please notify us via the Drug Rebate hotline. We will contact the drug labelers to clarify their responsibilities under the rebate agreement.

DESI CHANGE FOR ALL DRUG PRODUCTS

Later this month, each drug labeler will receive a revised specification of values for the DESI DRUG INDICATOR field. You previously received from the Regional Office a copy of the new values and data definitions to reference when making decisions as to whether a drug product is LTE or IRS. We will be sending a slightly revised copy of this document in a future release; however, the values and definitions remain the same. The Food and Drug Administration (FDA) compiled a list of LTE drugs which we are sending to each affected drug labeler. This list will be compared with the data submitted by drug labelers. The FDA has agreed to share this list with HCFA quarterly. This DESI/IRS identification project must be completed by every drug labeler for every drug product with the data submitted to HCFA by March 31.

The schedule for this change is as follows:

- 03/31 - Ending date for drug labelers to complete this task and submit baseline DESI changes to HCFA.
- 05/15 - New DESI values sent to States on the regular quarterly pricing tapes/data cartridges.
- 08/15 - States begin using the DESI values in the Drug Rebate data to make LTE/IRS determinations.
- 10/15 - HCFA installs change to the utilization edits to check for LTE/IRS drugs being reimbursed by States.

We will keep you advised of the progress and any changes to this planned implementation.

DRUG LABELER INFORMATION CHANGES (Contact sheets attached.)

Labeler Code 00003, ER Squibb and Sons, Incorporated -change to financial and technical contacts.

Labeler Code 00006, Merck, Sharp and Dome - change to technical contact.

Labeler Code 00015, Mead Johnson and Company - change to financial and technical contacts.

Labeler Code 00056, DuPont Pharmaceuticals, change to legal, financial and technical contacts.

Labeler Code 00060, DuPont Pharmaceuticals, change to legal, financial and technical contacts.

Labeler Code 00072, Westwood Squibb Pharmaceuticals, change to financial and technical contacts.

Labeler Code 00074, Abbott Laboratories - change to technical contact.

Labeler Code 00085, Schering Corporation - change to technical contact.

Labeler Code 00087, Bristol-Myers Squibb Company - change to financial and technical contacts.

Labeler Code 00094, DuPont Pharmaceuticals - change to legal, financial and technical contacts.

Labeler Code 00126, Colgate-Hoyt Laboratories - change to financial and technical contacts.

Labeler Code 00186, Astra Pharmaceutical Products, Incorporated - change to financial contact.

Labeler Code 00264, McGaw, Incorporated - change to financial contact.

Labeler Code 00369, Schering Corporation - change to technical contact.

Labeler Code 00486, Beach Products, Incorporated - change to legal, financial and technical contacts.

Labeler Code 00590, DuPont Pharmaceuticals - change to legal, financial and technical contacts.

Labeler Code 00839, Moore Medical Corporation - change to financial contact.

Labeler Code 00944, Baxter Hyland Division - change to financial and technical contacts.

Labeler Code 10892, Lunsco, Incorporated - change to financial and technical contacts.

Labeler Code 19810, Bristol-Myers Squibb Company - change to financial and technical contacts.

Labeler Code 45985, Stewart-Jackson Pharmacal, Incorporated - change to legal, financial and technical contacts.

Labeler Code 54198, Liquipharm, Incorporated - change to legal, financial and technical contacts.

Labeler Code 55513, Amgen Incorporated - change to legal contact.

Labeler Code 57664, Caraco Pharmaceutical Laboratories, Limited - change to technical contact.

Labeler Code 57783, Bristol-Myers Squibb Company - change to financial and technical contacts.

DRUG PRODUCT DELETIONS

00046-0431-91 Inderal Tabs 90mg
00071-2401-17 Benylin DM Cough Syrup
00089-0355-80 Titralac Tablets
00378-0251-01 Trazodone 50mg Tabs
00378-0251-05 Trazodone 50mg Tabs
00378-0251-10 Trazodone 50mg Tabs
00378-0252-01 Trazodone 100mg Tabs
00378-0252-05 Trazodone 100mg Tabs
00378-0252-10 Trazodone 100mg Tabs
00601-0480-27 Novamine 15% 1000ml
49884-0019-01 Doxycycline 100mg
49884-0019-03
49884-0019-04
49884-0019-05
49884-0019-10
49884-0025-01 Isosorbide 40mg
49884-0025-05
49884-0025-10
49884-0030-01 ParDecon
49884-0030-05
49884-0030-10
49884-0036-01 Methocarbamol 500mg
49884-0036-05
49884-0036-10
49884-0037-01 Methocarbamol 750mg
49884-0037-05
49884-0037-10
49884-0139-01 Sulfamethoprim 400mg/80mg
49884-0139-05
49884-0139-10
49884-0159-01 Methylprednisolone 24mg
49884-0159-03
49884-0159-05
49884-0160-01 Methylprednisolone 32mg
49884-0160-03
49884-0160-05
49884-0213-01 Orphengesic
49884-0213-05
49884-0214-01 Orphengesic Forte
49884-0214-05
49884-0237-01 Leucovorin Calcium 5mg
49884-0237-11
49884-0238-01 Leucovorin Calcium 25mg
49884-0238-15

DRUG LABELER CONTACT INFORMATION

Because many new drug labelers were added since June 30 and many name and address changes occurred, we will be sending the complete file to you on 3-1/2" diskette before the end of February. Due to the growth in this file, we are furnishing the information to you in data format only.

In attempting to furnish the data in text format, it took 3 diskettes to contain the entire file. We are looking into several options such as compression to try to place the text file on one diskette. We will keep you advised of our progress in this area.

Please continue to contact us by using the Drug Rebate Hotline number at (410) 966-3249.



for
Christine Nye
Director
Medicaid Bureau

28 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid