October 18, 1994

MEDICAID DRUG REBATE PROGRAM

Release Number 44

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

INVOICE WHEN THE UNIT REBATE AMOUNT (URA) IS ZERO

Beginning with the 3-94 quarter, HCFA is using a new edit designed to prevent erroneous Unit Rebate Amounts (URAs) from being sent to State Medicaid agencies (SMAs). This change was prompted by several instances where drug labelers submitted an erroneous Average Manufacturer Price (AMP) or Best Price (BP) which generated a huge URA and resulted in grossly inflated rebate invoices from SMAs.

If a computed URA deviates more than 50 percent from the prior quarter's URA, zeroes will be placed in the URA and a notification will be generated and mailed to the affected drug labeler. This should NOT deter you from including utilization data for this National Drug Code (NDC) along with all other utilization data on your rebate invoices. The labeler is technically responsible for determining the correct URA(s) to be used in calculating the total amount of rebate due each SMA.

Additionally, labelers complain that they are receiving rebate invoices for prior quarters that were never submitted to them in the proper quarter. In many cases, rebate requests for multiple quarters, for the same drug product submitted on the same invoice, cannot be processed by labeler automated systems. This results in delayed payment of the rebate. You should use either a separate invoice form or ensure that there is a distinct separation for each quarter being invoiced.

HCFA receives quarterly AMPs/BPs for approximately 91 to 94 percent of the records on the HCFA data base. Therefore, even with the new URA edit, the number of records you receive from HCFA containing zeroes in the URA should be very small.

TERMINATED/DELETED RECORDS

Drug labelers are responsible for submitting a drug product's prices for four quarters beyond the quarter in which the product is terminated. This allows States sufficient time to process old drug claims and prepare rebate invoices for them. Additionally, the HCFA system stops generating quarterly pricing records after these four quarters have elapsed.

Currently, HCFA deletes drug product records at the request of the drug labeler when the NDC was initially erroneous. This means that rebate invoices, for these specific NDCs, should never have been sent to the labelers. No special notification is given to States; rather, States must check the HCFA pricing file to ensure the continued presence of a drug product (identified by NDC). At the request of several State personnel, we are considering changing the HCFA system to alert the States when a particular NDC is deleted. Any decision in this area will be publicized well in advance of a target implementation date.

SUBMITTING UTILIZATION ADJUSTMENTS TO HCFA

In release number 42, we summarized the results of the survey conducted on dispute resolutions, and listed recommendations that were to be implemented. We indicated that State utilization adjustment records will need to be complete replacements for previously-submitted utilization data. This is not a new requirement; it has been a HCFA standard since States began submitting utilization adjustments.

However, there are States that continue to submit supplemental utilization records that are rejected. Therefore, we will continue to work with and encourage States to modify their systems in order to generate complete replacement records for utilization data.

RECALL OF ALBUTEROL SULFATE SOLUTION

Copley Pharmaceutical, Incorporated (Labeler Code 38245) issued a partial recall of Albuterol Sulfate Solution (NDC 38245-0640-09) in December of 1993 and a full recall of this product on January 5, 1994. All lots were to be returned and Copley reimbursed all pharmacies for their return. In those cases where the product was dispensed to Medicaid patients, it was the obligation of the pharmacy to pay or credit the State Medicaid agency for the full refund provided by the Copley company.

This issue arose after the Copley company began questioning why they were receiving rebate invoices for this product. All States should review their records for this product to determine whether they should pursue refunds from pharmacies and to ensure that they are not generating rebate invoices for a product which, ultimately, may not be eligible for rebates.

PUBLIC HEALTH SERVICE (PHS) DRUG PRICING PROGRAM

The PHS recently published a final notice in the Federal Register on September 19, 1994 regarding guidelines for including outpatient disproportionate share hospital (DSH) facilities in the PHS drug pricing program (59 CFR 47884).

Listed below is section C of the September 19, 1994 notice which describes the guidelines for including DSH outpatient facilities in the PHS drug pricing program. Please refer to 59 CFR 47884 for a detailed explanation of the comments relating to these guidelines.

"Set forth below are the final guidelines regarding the inclusion of DSH outpatient facilities: The outpatient facility is considered an integral part of the "hospital" and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report. For example, if a hospital with one Medicare provider number meets the disproportionate share criteria and this hospital has associated outpatient clinics whose costs are included in the Medicare cost report, these clinics would also be eligible for section 340B drug discounts. However, free-standing clinics of the hospital that submit their own cost reports using different Medicare numbers (not under the single hospital Medicare provider number) would not be eligible for this benefit.

A DSH, eligible for PHS pricing, must first request that the Office of Drug Pricing include in the PHS drug discount program the outpatient facilities that are included in its Medicare cost report. A list of these outpatient facilities along with Medicaid billing status information must be included with the request. Second, an appropriate official of the DSH must sign a statement that he/she is familiar with HCFA guidelines concerning Medicare certification of hospital components as one cost center, has examined the list of outpatient facilities, and certifies that the facilities are correctly included on the DSH's Medicare cost report.

When these facilities are added to the master list of eligible and participating covered entities, the off-site facilities will be able to access PHS discount pricing. On-site clinics that are not included on the Medicare cost report will not be eligible for PHS discount pricing.

This information will be posted on the Electronic Data Retrieval System (EDRS), maintained by the Office of Drug Pricing, on a quarterly basis. To access this information, call (301) 594-4992.

DSHs which have questions concerning this process, or manufacturers which have questions concerning the eligibility of certain DSH outpatient clinics, should contact Elizabeth Hickey (301-594-4353), at the Office of Drug Pricing."

These guidelines go into effect October 19, 1994. PHS recently sent a letter to DSHs regarding the steps they must take to add any qualifying outpatient facilities to the covered entity list for the PHS drug pricing program. Additions submitted to PHS will be effective with the quarter beginning January 1, 1995. For all drugs dispensed to Medicaid beneficiaries, participating outpatient clinics must bill the State Medicaid agencies at the actual acquisition cost of the drug purchased under the PHS drug pricing program.

Manufacturers must offer the required section 602 drug discounts to any qualified participating outpatient facilities. Prices given to these PHS covered entities are excluded from best price.

Manufacturers should retrieve the updated covered entity list every quarter from the PHS bulletin board to determine which covered entities are participating in the program. If a manufacturer is currently selling to covered entities which appeared on an older list but are not currently eligible or not participating on a current list, those sales to ineligible entities are subject to the best price calculation. Therefore, it is important that manufacturers maintain current information when selling to PHS covered entities.

States must include any additional participating covered entities in their provider exclusion file to prevent billing manufacturers for a rebate on those drugs sold at a discount and dispensed to Medicaid beneficiaries. HCFA provides States with the most current covered entity list on the quarterly tape containing the unit rebate amounts. If States are not able to retrieve this information from the tape, they must retrieve the latest covered entity list from the PHS bulletin board. The bulletin board number is (301) 594-4992. States must maintain current provider exclusion files so they do not violate the duplicate discount/rebate prohibition.

MEDICAID DRUG REBATE-STATE HEARING PROCESS

The National Rebate Agreement, section V, makes the State hearing mechanism available to Manufacturers under the Medicaid Program. A question arose whether a State can also use the State Hearing process.

While we recognize that the regulations pertain to "providers" participating in the Medicaid program, we consider the State hearing process as the appropriate mechanism to resolve State and Manufacturer disputes.

TOLERANCE THRESHOLD FOR ADJUSTMENTS TO REBATE AMOUNTS BECAUSE OF UTILIZATION CHANGES

At the request of many States, we are establishing a tolerance level for States to use in processing adjustments to rebate amounts due to changes in utilization data. Effective immediately, in any quarter, States may apply a $50 tolerance per labeler for adjustments due to utilization changes.

The application of this tolerance is optional for States; i.e., any State may choose to process any quarterly adjustment below the threshold. If a State applies the tolerance, however, there will be no risk of loss of Federal Financial Participation for those amounts. The State must maintain documentation which clearly identifies the applicable quarter, labeler, drugs (NDCs), and the amount to which the tolerance was applied.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on January 1, 1995:

LNK International, Incorporated (Labeler Code 50844);

Jordan Pharmaceuticals, Incorporated (Labeler Code 58196);

PRN Laboratories, Incorporated (Labeler Code 60459);

Respa Pharmaceutical, Incorporated (Labeler Code 60575);

Nard Laboratories, Incorporated (Labeler Code 61123); and

Circa Pharmaceuticals, Incorporated (Labeler Code 71114).

LABELER BANKRUPTCY

We are in receipt of a copy of a Chapter 7 bankruptcy filing in the State of Pennsylvania by Auro Pharmaceutics, Incorporated (Labeler Code 55829). It appears that this labeler is going out of business and will be terminated as a participating drug company in the near future.

ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 3, 1994 through October 17, 1994 are attached.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

FAB134:DMccarthy, 63314, 10-18-94,
state44.WP