October 6, 1994

MEDICAID DRUG REBATE PROGRAM Release No. 13

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

BASELINE CHANGE RESULTING FROM OMNIBUS BUDGET RECONCILIATION ACT OF 1993 (OBRA93)

There is a significant change in the way the additional rebate calculation is performed for reporting quarters 4-93 and later.

The change involves using the calculated Average Manufacturer Price (AMP) from the first full quarter a drug product is marketed as the new baseline AMP, instead of continued use of the originally submitted baseline AMP. No actions are necessary by drug labelers to change the baseline AMP. This is accomplished by the HCFA system. Do not submit correction records to change the old baseline AMP to a new baseline AMP. The HCFA system retains both baseline AMPs in order to correctly calculate prior period unit rebate amounts (URAs) when labelers submit changes to the AMP and/or best price (BP) for calendar quarters prior to 4-93.

NEW HCFA EDIT REJECTING POTENTIALLY DEVIANT UNIT REBATE AMOUNTS

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 AMP or BP which resulted in a huge URA being generated and grossly inflated accounts receivables for 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 affected drug labelers. The data on the listing will include enough information from both quarters in question for you to analyze what caused this difference to occur. If you agree that the generated URA was the result of a data reporting problem (decimal

alignment, unit type change, incomplete quarterly pricing changes, etc.), please submit whatever changes are necessary to permit a correct URA to be generated.

If, however, your submitted prices are correct, do not submit any changes. When the next quarterly pricing file is generated by HCFA and sent to the SMAs, it will contain the calculated URA that would have been sent the previous quarter. A sample of the letter and listing are attached.

CHANGING THE UNIT TYPE TO EACH (EA)

If you are changing an existing unit type to an EA, please call HCFA at the drug rebate hotline BEFORE submitting the change.

If the unit type change is being done to comply with the new unit type requirements and should not result in adjusted rebates being paid for prior periods, HCFA personnel need to stop prior period adjustments from being sent to SMAs. Otherwise, you will probably receive 40 - 50 additional invoice requests for all prior calendar quarters. The erroneous generation of prior period adjustments has caused much confusion and we are attempting to minimize problems in this area.

If you submit the unit type changes on paper or diskette, please include a note in your mailing to alert us to unit type changes being included in your quarterly submission. Drug labelers using ORDERNET should mail or send a facsimile note to us at the same time you submit your data.

RESULTS OF THE DISPUTE RESOLUTION WORKGROUP SURVEY

As you are aware, HCFA has been working with States, drug labelers and drug industry associations in an effort to seek solutions to eliminate many of the problems that result in disputes occurring between States and drug labelers. To that end, HCFA made several changes which included but were not limited to clarifying data submission procedures, revising the number of unit types to more closely conform to NCPDP standards, and asking States to share claims data if requested by drug labelers.

Additionally, HCFA developed a survey document in order to ascertain State/drug labeler preferences for suggested program changes. The survey document was sent to all States and participating drug labelers on February 8, with a request for answers to be returned by the end of February. Responses were received from all State Medicaid agencies and approximately 40 percent of the participating drug labelers.

HCFA formed a survey analysis committee to review the answers provided by both States and drug labelers. On August 4, the committee presented its findings to a dispute resolution workgroup which included representatives of State Medicaid agencies, drug labelers, PhRMA, GPIA, APWA, and pharmacy associations such as NARD, NACDS, NPA, and NAPM.

Based on the results of the survey plus staff recommendations, HCFA is recommending that the following items be adopted as part of the drug rebate program operations:

1. HCFA will strongly encourage the States to work with drug labelers in an effort to provide third party liability data to those manufacturers that are interested in reviewing that data.

2. The use of a modified version of the proposed remittance advice report (RAR) to be a requirement for all drug labelers. Electronic and paper formats will be provided along with sufficient lead time to implement this new requirement. The following changes will be made to the draft RAR:

    a. Language will be added to adjustment code number 5 on the RAR to require the reporting of the actual dollar amount of interest included in the rebate; and

    b. An additional item will be added to the dispute codes on the RAR to reflect a close-out indicator to be used when disputes are resolved.

3. When States submit utilization adjustments to HCFA, a total replacement of previous utilization data will be required. HCFA will provide lead time to implement this item.

4. When responding to the labelers, States are to use their invoice form to make adjustments to data previously submitted to drug labelers.

Responses to other items in the survey show that there is no widespread problem regarding rounding of utilization data by States or pharmacies. Neither is there a need for a single turnaround document, since there are sufficient adjustment codes available on the RAR to explain disputes and adjustments.

PUBLIC HEALTH SERVICE (PHS) DRUG PRICING PROGRAM

The Public Health Service 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 FR 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 FR 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 procedures for adding 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 in order 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 which 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. 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 mechanism as the appropriate mechanism to resolve State and Manufacturer disputes.

PROCEDURES FOR MANUFACTURERS TO ADD LABELER CODES

The rebate agreement requires that every participating manufacturer report pricing information to HCFA for all its covered outpatient drugs. We have maintained that this requirement applies to all drugs bearing any of the manufacturer's labeler codes, including newly added labelers, newly formed subsidiaries, and labelers previously omitted from the original rebate agreement.

The proper procedure for manufacturers to add labeler codes is the submission of a revised, signed, and dated Page 12 of the rebate agreement which includes all "old" plus any "new" code(s). Manufacturers must also provide attachments indicating the contacts for legal, rebate, or technical questions. The effective date of labelers added in this fashion may be retroactive to either the beginning of the quarter in which the amended Page 12 was received, or to the effective date of the original agreement, at HCFA's discretion. We advise States and manufacturers of the effective date through our informational releases.

However, if a manufacturer asserts that the new labeler code(s) should not be included under the original rebate agreement and HCFA agrees with that assertion, an entirely separate rebate agreement must be entered into for the additional code(s). This is necessary in order for the drugs to be covered under Medicaid, and for the States to receive Federal financial participation for paying for those drugs which bear the new labeler codes. The effective date for the agreement will be determined in a similar manner as the effective date of any other new agreement; that is, the effective date will be the first day of the calendar quarter that begins more than 60 days after the date of the postmark of the signed rebate agreement.

STATE CONTACT LISTING

Attached is an updated listing of the technical, policy, and rebate contacts identified by each SMA. Additionally, we have included a facsimile telephone number when it was reported to HCFA.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1994 through October 3, 1994. By law, these rates are to be used to calculate interest owed States on overdue rebates.

TOPIC INDEX

For your convenience, also attached is a topic index of all items covered in prior releases.

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

4 Attachments

cc:
All Regional Administrators

All Associate Regional Administrators Division of Medicaid