April 11, 1994

MEDICAID DRUG REBATE PROGRAM Release No. 11

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

BEST PRICE TO DISPROPORTINATE SHARE HOSPITAL (DSH) COVERED ENTITIES

On April 29, 1993, we issued the following statement in Manufacturer Release No. 7:

Manufacturers may only exclude from their best price calculation those prices charged for outpatient drugs sold to a DSH covered entity. All prices charged for inpatient drugs sold to a DSH must be included in a manufacturer's best price calculation.

Some hospitals and manufacturers have questioned this statement with regard to prices for inpatient drugs sold to a DSH. Specifically, some manufacturers claim that they cannot offer the Medicaid best price on inpatient drugs to these DSHs based on the language in Release No. 7. This interpretation is incorrect. Manufacturers can offer the DSH their current best price without setting a new best price specifically for that DSH (e.g., if the manufacturer is selling the drug for 10 cents per tablet to a health maintenance organization or other large-volume buyer, the manufacturer can offer that price to the DSH inpatient side.)

Please refer to **UPDATED** enclosure C (Manufacturer Data Dictionary) of the Drug Rebate contract included as an attachment to Manufacturer Release 10, dated February 14, 1994, for a complete definition of Best Price, including all exclusions to the calculation of it.

AVERAGE MANUFACTURER PRICE (AMP) CLARIFICATION FOR HEMOPHILIC DRUGS

We wish to clarify that sales of hemophilic drugs to home health care providers **MUST** be included in the calculation of AMP, and, if applicable, Best Price. If any manufacturer has incorrectly excluded these sales from the pricing calculations, please submit corrected pricing data for any and all affected quarters.

SEPARATE MEDICAID DRUG REBATE AGREEMENTS WITH STATES

At the request of several manufacturers, we are providing the following reminders regarding the effect of rebates paid to States under separate agreements on the calculation of best price. **Most importantly, all separate rebate agreements between states and manufacturers require HCFA approval.** If you and a State wish to enter into a separate agreement for Medicaid, the State must submit the agreement to the appropriate HCFA Regional Office (RO). The RO performs an initial review of the agreement and submits it, along with the RO recommendation of approval or disapproval, to the Medicaid Bureau. The Medicaid Bureau will then make a determination and notify the RO, which, in turn, will notify the State. The State should then notify you of our determination.

Upon approval of a separate Medicaid drug rebate agreement, the additional rebates paid to the State under the terms of the separate agreement must be excluded from the calculation of AMP and best price. This policy is consistent with the law and the rebate agreement which specify that any rebates under section 1927 of the Social Security Act are to be excluded from the pricing calculations by manufacturers.

We consider only rebates paid under HCFA-approved separate Medicaid drug rebate agreements to meet this requirement; thus, you should exclude these rebates from the pricing information submitted to HCFA. These exclusions from pricing calculations do not apply to agreements not approved (and thereby, not recognized) by HCFA.

If you have entered into a separate agreement with a State and have not been notified by the State that the agreement was approved by HCFA, you should contact the State to ascertain the status of the agreement. You may also contact the appropriate RO if unable to receive the information from the State.

DISPUTE RESOLUTION ISSUES

Due to continuing problems encountered regarding resolution of disputes with State Medicaid personnel, we are reiterating current HCFA guidelines regarding manufacturer and State responsibilities.

Our State Medicaid Director Release No. 19, dated May 18, 1992, contained most of the information detailed in this program release, with a few changes subsequently made on our part.

Unit Rebate Amount

As stated in the law and the rebate agreement, the manufacturer is responsible for calculating the correct amount of rebate per unit of drug. If the manufacturer calculates an amount that differs from the unit rebate amount HCFA calculated and provided to the State, the manufacturer must notify HCFA of the basis for its calculation. This type of disagreement is not subject to the dispute resolution process, which is used to resolve disputes between States and manufacturers.

Payment of Undisputed Amounts

Neither a State nor a manufacturer may request that the undisputed amount of the rebate not be paid until the disputed amount is resolved. The undisputed amount of the rebate must be paid within 38 days after postmark of State utilization data.

Minimum Rebate Tolerance

In any quarter, States should not invoice a manufacturer for rebate amounts that do not exceed their administrative costs associated with preparing the invoice. We consider rebate amount requests of $10 or less to meet this tolerance. States could set a smaller tolerance, but it should be greater than zero (if the unit rebate amount has not been filled in because the manufacturer failed to report pricing information timely, the rebate request will be zero; but, in this event the manufacturer must calculate the correct rebate amount and pay it to the states.

Steps in the Dispute Resolution

The following instructions are the steps that the dispute shall follow to reach a resolution.

1. Within 38 days after the postmark of State utilization data, the manufacturer must pay rebates on all undisputed data. Within the same timeframe, if a manufacturer disputes specific utilization data, the manufacturer must identify by individual national drug code (NDC) the utilization data in question, specific reasons why that data is in question, and notify the State in writing, also within 38 days of postmark of the data.

2. Within the 38-day period, we encourage the manufacturers to distinguish between data inconsistencies and legitimate disputes. For inconsistencies involving, for example, unit types and incorrect NDCs the manufacturers should contact the State as soon as possible to determine the proper

corrective action and attempt to resolve the dispute without further dispute resolution procedures. The disputed resolution timeframes and procedures apply, however, if informal negotiations do not resolve the problem.

3.The State must take steps to resolve the questionable data and may be asked by the manufacturer to provide zip-code level data which the manufacturer will compare with its records to identify discrepancies.

When pharmacy level data is requested, the State may submit its State pharmacy data for comparison with the manufacturer's pharmacy data or, if State confidentiality laws prohibit the release of such information, request that the manufacturer make its data available to the State for comparison. If requested by the manufacturer, a State may opt to conduct sampling of a particular drug's utilization data to detect and resolve problems.

Specific claims level data is not included in the information required to be reported by the State. A request for claims level data is an audit and is not necessary to resolve a dispute at this level. We encourage States and manufacturers to agree to mutually acceptable audit procedures, but the State is not obligated to provide specific claims level data. Manufacturers do retain the right to audit the Medicaid utilization information reported by the State apart from the dispute resolution process.

Note:If the manufacturer has already obtained such data from a third party, such as Market Measures, IMS, DDD or DataNiche, there should be no need to request the State to furnish the same data. Additionally, the analysis of 12 quarters of invoices should be enough to verify State purchase levels for most drug products.

4.The exchange of information between States and manufacturers is necessary to effectuate the drug rebate provisions and to resolve disputes in a timely manner. Both the State and the manufacturer must ensure that any exchange of data protects both the State and Federal confidentiality requirements. States must assure that any exchange of data protects the confidentiality requirements of Section 1927(b)(3)(D) of the Social Security Act. Under section VII(b) of the rebate agreement, data released to the manufacturer by the State shall also be held confidential by the manufacturer.

5. If the exchange of information fails to resolve the dispute, the state may choose to cease the process, if the disputed amount is **BOTH** under $10,000 per manufacturer and $1,000 per product code level. This tolerance is optional and states may continue to resolve disputes under these limits. If the state continues to the next step in the dispute process, the manufacturer is required to comply with the proceedings.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from the start of the program through
March 28, 1994.

NOTES FROM THE HOTLINE STAFF

At the end of every quarter, we receive a high volume of calls from participating drug labelers. Often, your calls are handled by an answering machine and then returned by one of three analysts. When leaving a message, please remember the following so that we may provide you with prompt and courteous service: (1) Speak as clearly as possible; (2) Leave your full name, the name of your company, your labeler code and your telephone number with the area code, and the best time to return your call; and (3) Provide us with information on the issue you want to discuss since any data questions require us to access our data base which can take several minutes. You may be assured that all calls are returned.

TERMINATION APPEAL PROCESS

Recently, HCFA held the first hearing involving a manufacturer which was terminated for continued failure to submit quarterly pricing data within 30 days after the end of a quarter. The right to request a hearing is specified in the Statute and national drug rebate agreement and was exercised by this manufacturer.

The manufacturer received the standard termination warning letter which specifies that unless the identified missing data is received by HCFA within 30 days of the date of the letter, they would be terminated from the drug rebate program, effective for the quarter that begins no earlier than 60 days from the data due date.

To prevent any confusion regarding manufacturer appeal rights, future termination letters will contain a notice which specifies that hearing requests must be filed with HCFA within 45 days after the date contained on the termination letter.

Termination warning letters are the final measure used by HCFA to have missing pricing data submitted. They are issued after repeated telephone requests are unheeded. Most tardy drug manufacturers come into compliance with reporting requirements. However, it has been necessary for HCFA to terminate 27 drug rebate agreements for failure to submit missing pricing data.

We recognize that the statute provides that a hearing shall not delay the effective date of any termination; however, we have provided additional lead time to give manufacturers an opportunity to file an appeal before any termination action. We expect that this additional time will permit us to conduct an informal hearing and give states adequate notification regarding any final termination. Once the States have been notified, the drug manufacturer will be required to remain out of the drug rebate program for (a minimum of) one calendar quarter unless the Secretary finds good cause for an earlier reinstatement of the rebate agreement.

POWDER-FILLED VIALS, AMPULES AND SYRINGES

We have received complaints from State Medicaid agencies (SMAs) that drug products marketed in powder-filled vials (PFVs) are causing conversion problems when they prepare invoice data relating to these items. As most of you are aware, the National Council for Prescription Drug Programs (NCPDP), First DataBank and MediSpan use the standard unit type of "each" (EA) for powder-filled vials, ampules or syringes (liquid-filled vials, ampules or syringes are to continue to be shown as milliliters (MLs)).

In 1993, HCFA agreed to use NCPDP standards, with few exceptions, and converted all PFVs to EAs effective with the 4-93 calendar quarter. Our review of selected drug products reveals that certain drug labelers continue to identify this type of drug as being sold in milligrams (MGs) which HCFA converted to grams (GMs). Since approximately 47 of the 51 SMAs are using unit types supplied by either First BataBank or MediSpan, they are encountering unnecessary conversion problems when preparing invoices for this type of drug product.

Therefore, we are requiring that: (1) The unit type for all powder-filled vials, ampules and syringes be converted to EA; (2) AMPs and BPs for these products are to be changed to reflect an EA price; and (3) This change is to be made by June 30, 1994 in order to be effective for the 2-94 calendar quarter.

PLEASE CONTACT THE DRUG REBATE OPERATIONS BRANCH USING THE HOTLINE NUMBER ((410) 966-3249) BEFORE MAKING ANY CHANGES. WE MUST CHANGE THE HCFA MDRI MASTER FILE (BY HAND) IN ORDER TO AVOID THE GENERATION OF ERRONEOUS PRIOR PERIOD ADJUSTMENTS (PPAs).

BEST PRICE--TennCare

Tennessee's request for waiver-only demonstration of its Medicaid program has been approved under the authority of section 1115 of the Social Security Act (the Act). The waiver, called TennCare, has been approved for the period January 1, 1994 through December 31, 1998. Because Medicaid beneficiaries will generally receive drugs through capitated managed care settings, a rebate under section 1927 of the Act will not be requested for these drugs.

These managed care entities are free to negotiate the purchase price for drugs in whatever manner they choose. However, it should be noted that these drug prices to TennCare managed care must be included in the best price calculation for the Medicaid drug rebate program. Under the definition of average manufacturer price (AMP) these prices will generally not be included in calculating AMP.

TOPIC INDEX

We have included a topic index for the information covered in all prior releases to you.

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 Regional Administrators

All Associate Regional Administrators Division of Medicaid