December 26, 1991

MEDICAID DRUG REBATE PROGRAM Release No. 3

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

NOTE TO: All Participating Drug Manufacturers

VA APPROPRIATIONS ACT

The Department of Veterans Affairs Appropriation Act (P.L. 102-139) was passed on October 28, 1991. P.L. 102-139 affects how best price is defined for the drug rebate program. This law was effective from October 28, 1991 and will continue until June 30, 1992, unless other legislation extends that date. The law specifies that prices for drugs paid by the Department of Veterans Affairs (DVA) and for contracts administered by the DVA will not be considered in the Medicaid drug rebate calculation.

Therefore, the definition of best price will exclude all prices for drugs paid by the DVA and for contracts administered by the DVA during the period October 28, 1991 through June 30, 1992. For purposes of this legislation, we consider all sales through the Federal Supply Schedule, which is administered by the DVA, to be excluded. These sales would be excluded from the calculation of best price regardless of the party that buys through the Federal Supply Schedule (e.g., Department of Defense, Public Health Service). Sales to the DVA prior to October 28, 1991 should be included in best price calculations for the fourth quarter of calendar year 1991.

POSTPONEMENT OF CHANGES TO THE REBATE AGREEMENT

Changes to the rebate agreement will be delayed beyond January 1, 1992. This delay will allow us to incorporate changes into the agreement resulting from legislation and public comments on the drug rebate regulation. We will continue to operate the drug rebate program under the current agreement. The agreements will automatically renew under the terms of the statute and section VIII of the agreement unless a manufacturer terminates the agreement in writing.

DEPOT PRICES

Under section §1927(c)(1)(c), depot prices of any agency of the Federal Government are excluded from a manufacturer's price. Depot prices mean prices available to any depot of the Federal Government for purchase of drugs from a manufacturer through the depot system of procurement.

For purposes of the drug rebate program, we are defining a "depot" as any warehousing and distribution arrangement whether:

- Government owned and operated;
- Government owned and privately operated; or
- Privately owned and operated.

Note that in such an arrangement the drugs must actually physically pass through an independent third party (e.g. a manufacturer cannot independently ship drugs to a Federal facility in order to qualify for the depot price exclusion).

QUARTERLY PRICING DATA

Recently, requests were sent to those drug labelers where one or more of their products were missing prices for either the first, second or third calendar quarter of 1991. We would appreciate your prompt submittal of prices for each of the identified drug products.

PAYMENT OF STATE REBATES

We are taking this opportunity to clarify the timeframe in which manufacturers must pay rebates to States. As required by the rebate legislation, and as specified in the rebate agreement, manufacturers must pay rebates to States within 30 days of receipt of State utilization data. For purposes of the rebate program, utilization data, at the minimum, are the number of units paid and identified by the unique NDC. Thus, the 30 day "clock" starts ticking on the date the manufacturer receives State utilization data.

CHANGES TO DRUG PRODUCT INFORMATION

Another issue of importance concerns the responsibility for taking appropriate actions whenever changes occur that affect prices, basic drug product or utilization data. In those situations where State rebates are calculated using prices other than those you submitted to HCFA, you are responsible for providing this same information to HCFA as soon as the price changes are known. Also, changes to basic drug product information can be submitted to HCFA at any time.

Conversely, when States adjust utilization data, they are required to notify HCFA and each manufacturer affected by the changes so that underpayments and/or overpayments can be resolved quickly.

CLARIFICATION ON AVERAGE MANUFACTURERS PRICE (AMP), BEST PRICE (BP) AND UNITS PER PACKAGE SIZE (UPPS)

There still appears to be a lot of confusion regarding the AMP, BP and UPPS. For clarification purposes, the following guidelines should be used:

- AMPIt is a weighted average based on sales when there is more than one package size code (NDC #3) for the same product code (NDC #2). Therefore, **ALL** package sizes of the same product code **MUST** have the **same AMP.**

- BPIt **IS NOT** weighted (like AMP); however, **ALL** package sizes of a product code **MUST** contain the same BP, which is the **LOWEST PRICE AT WHICH IT IS SOLD REGARDLESS OF PACKAGE SIZE.**

  It must be submitted for all "S" and "I" drugs.

  It is **not** submitted for "N" drugs.

- UPPSIt **MUST BE "1"** for all drugs that can be dispensed in amounts smaller than the total package size. (e.g. The drug is in tablet form and is packaged in bottles of 100 but the pharmacist can open the bottle and dispense smaller amounts.)

  When the pharmacist **must** dispense the drug as it is packaged (an unbreakable quantity), you **must** show the **UPPS** as the actual size of the container. (e.g. A 12- pack of vaginal suppositories [the standard dosage] must be dispensed as a 12-pack.)

ACTIVE SHELF LIFE OF DRUG PRODUCTS

When a drug product is no longer manufactured but can have a shelf life that extends beyond the last date of production, the shelf life expiration date must be shown in the TERMINATION DATE FIELD for each affected drug product. Many drug labelers are correctly receiving invoices from State Medicaid agencies for discontinued drug products that still have effective shelf lives.
Prices for these discontinued drug products should be given to HCFA for at least four calendar quarters after the effective shelf life expires. This will allow the State Medicaid agencies to re-process rejected claims within their systems that have dates of service prior to the drug expiration date.

MONTHLY CONSUMER PRICE INDEX (URBAN) (CPI-U)

The latest CPI-U values are as follows:

09/90	132.7	02/91	134.8	07/91	136.2
10/90	133.5	03/91	135.0	08/91	136.6
11/90	133.8	04/91	135.2	09/91	137.2
12/90	133.8	05/91	135.6	10/91	137.4
01/91	134.6	06/91	136.0	11/91	137.8

DESI INDICATOR CHANGE

During the first quarter of calendar year 1992, you will receive a revised specification for the **DESI Indicator Field.** A new set of values is being installed and will require that you change the value for that field for each of your drug products identified by individual NDCs.

The revised specification will be sent to the person identified as the technical contact for each labeler code. Drug labelers which utilize the diskette reporting system will receive a revised diskette program accompanying the specification. We are attaching a preliminary description of the change to enable you to prepare for this change which must be accomplished by the end of the first quarter of calendar 1992. We anticipate releasing the finalized version of the specification on or about March 1, 1992.

Please continue to refer your questions to us by calling the drug rebate hotline at (410) 966-3249.

Christine Nye
Director
Medicaid Bureau

Attachment

cc: Regional Administrators, HCFA

COVERAGE AND PAYMENT FOR DESI/IRS DRUGS

COVERAGE/REBATE/FFP REQUIREMENTS	DESI/IRS CODE				
	2	3	4	5	6
Mandatory Coverage Under Medicaid Drug Rebate Program	X		*		
May be Excluded or Restricted Under Medicaid Drug Rebate Program		X			
Optional Coverage under Medicaid		X	X	X	
Subject to Rebate Payments	X	X	*		
FFP Is Available	X	X	X		
FFP Not Available				X	X

GROUP DESCRIPTIONS:

Group 2 - DESI/IRS Drugs Determined to be Safe and Effective **or** drugs are non-DESI
Group 3 - DESI/IRS Drugs Under Review (No NOOH Issued)
Group 4 - LTE DESI/IRS Drugs for Some Indications

*If a drug in this group has an FDA-approved labeled indication for which a NOOH has not been issued, the drug is covered for that indication and other medically accepted indications, and the drug is subject to rebate.

Group 5 - LTE DESI/IRS Drugs for All Indications
Group 6 - LTE DESI/IRS Drugs Withdrawn from the Market