April 13, 1995

MEDICAID DRUG REBATE PROGRAM

Release Number 51

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

NOTE TO: All State Medicaid Directors

PROPOSED STATE LEGISLATION ON EQUAL ACCESS TO DISCOUNTS FOR ALL PURCHASERS

Several States have recently introduced legislation which authorizes the State to deny reimbursement for medically necessary drugs if the manufacturers do not offer certain discounts to all purchasers within the State. Generally, the proposed legislation requires a drug manufacturer to give proportionately equal discounts on drugs to all purchasers within the State based on the discounts offered to the most favored purchaser or else Medicaid coverage of that manufacturer's drugs will be denied.

We have recently received several questions as to whether this type of legislation is inconsistent with HCFA's national rebate agreement and under what circumstances a manufacturer can be denied participation in the Medicaid program if it fails to offer the requisite discounts under the State legislation.

State legislation which denies Medicaid beneficiary access to medically necessary drugs of participating manufacturers conflicts with the mandatory coverage provisions of sections 1902(a)(54) and 1927 of the Social Security Act. Section 1902(a)(54) of the Social Security Act requires States to comply with the applicable requirements of section 1927. Section 1927 requires, among other things, that States permit coverage of medically necessary covered outpatient drugs of manufacturers

participating in the drug rebate program. Thus, State legislation conflicting with the mandatory coverage provisions of the drug rebate program would not supersede Federal law.

Except for those drugs which may be restricted or excluded under section 1927(d)(2), section 1927(d) provides that the State plan must permit coverage of any covered outpatient drug, regardless of its inclusion in the State formulary under section 1927(d)(4), pursuant to a prior authorization system. Section 1927(d) also provides that a covered outpatient drug must be included in the State formulary if it has a "significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical advantage" over other drugs in the formulary.

Therefore, States cannot impose legislation on manufacturers which denies coverage of their drugs under the Medicaid program contrary to the terms of the statute and the national rebate agreement. If the State legislation is drafted in a way which does not restrict Medicaid coverage of a manufacturer's drugs, then HCFA's rebate agreement would not apply to this type of situation.

ERRONEOUS UNIT REBATE AMOUNTS (URAs)

In State Medicaid Directors Release Number 44, dated October 18, 1994, we informed you of the new edit designed to prevent erroneous URAs from being sent to State Medicaid agencies. Briefly, 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.

It has come to our attention that some States interpret the zero URA on the quarterly pricing tape as a non-existent National Drug Code (NDC), and therefore do not send utilization data to the manufacturer for that NDC. Subsequently, this interpretation results in unnecessary adjustments in the following quarter's invoicing.

Please be reminded that URAs indicating zeroes for any NDC should NOT deter you from including utilization data for those NDCs along with all other utilization data on your invoices. The labeler is technically responsible for determining the correct rebate due to the State within 38 days of the postmark from your invoice using, at a minimum, information on the number of units paid by NDC number.

STATE INVOICES CONTAINING UNIVERSAL PRODUCT CODES (UPCs)

We received an example of an invoice where the UPC for lancets (52569-0379-58) was used to request a rebate from a drug labeler for a product that is not marketed by them. The drug company, Generamed, Incorporated, has received invoices from several States for this particular non-drug product. Please remind your pharmacy communities that UPCs are not used in the identification of drug products for the Medicaid rebate program, and that they cannot bill the drug rebate program for supplies or devices.

CORRECTIONS TO STATE UTILIZATION DATA RECORDS

In our review of utilization records for selected NDCs, we are finding many instances where States are submitting multiple supplemental data records to add to the original data record, rather than submitting an overlay correction record containing only the correct amount for an NDC. This practice results in the posting of the data on the latest record containing a correction flag of "1." For example, an original record contained 15,000 units, but the latest correction record contains 50. Consequently, the HCFA master utilization record now erroneously contains 50 units.

Correction records containing the correct amount should be submitted only where there is a change in the number of units, number of prescriptions, or the dollars reimbursed. **Changes to the unit rebate are not considered utilization corrections and should not result in the generation of a utilization correction record. Please refer to pages 3 and 4 of State Medicaid Directors Release Number 16 dated November 12, 1991 for a complete explanation of transmitting corrections to HCFA.**

NEW LABELERS

Bradley Pharmaceuticals, Incorporated has requested the addition of a new labeler code (10337 -- Doak Dermatologics Division) for inclusion in their Medicaid Drug Rebate Agreement. They will be joining the rebate program retroactive to April 1, 1995.

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

Lini, Incorporated (Labeler Code 58215); and

IYATA Pharmaceutical, Incorporated (Labeler Code 59291).

LABELER TERMINATIONS

The following labelers are being terminated effective July 1, 1995 for failure to submit pricing data:

Good Health (Labeler Code 33261);

T.E. Williams Pharmaceuticals, Incorporated (Labeler Code 51189);

Liquipharm, Incorporated (Labeler Code 54198);

National Vitamin Company, Incorporated (Labeler Code 54629); and

U.S. Trading Corporation (Labeler Codes 56126 and 58653).

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of July 5, 1994 through April 10, 1995 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

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State51.WP