September 9, 1994

#### MEDICAID DRUG REBATE PROGRAM

Release Number 43

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

NOTE TO: All State Medicaid Directors

### COVERAGE OF EXPERIMENTAL DRUGS

Several States have recently questioned whether Federal Financial Participation (FFP) dollars are available if a State chooses to cover experimental drugs. Experimental drugs include, for example, treatment investigational new drugs (INDs), group C cancer drugs and parallel track drugs.

States have the option to cover experimental drugs under their State Medicaid programs. Since section 1927 of the Social Security Act made no changes to a State's previous ability to cover these drugs, FFP continues to be available for these drugs. However, because they do not meet the definition of a covered outpatient drug in sections 1927(k)(2) through(4) of the Act, they are not covered under the drug rebate program and are not subject to a rebate.

Generally, States should indicate in their State Medicaid plans if experimental drugs are covered or if any restrictions are applied to these drugs.

### UNIT REBATE AMOUNT (URA) EDIT

Effective with the 3-94 calendar quarter, we are adding an edit which can cause the URA of a current quarter to be reported to the States as zero. This situation will occur when the URA for the current quarter is calculated as more than 50 percent different from the last quarter's URA for that drug product.

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Factors such as decimal misalignment, unit type changes without changing all quarterly prices and the quarterly AMP reflecting a package rather than unit price can cause this situation to occur.

We tested this edit using the 2-94 quarterly URAs. Each labeler that had at least one URA that would have been affected received a notice and listing of NDCs that failed the edit. All labelers will be notified of this edit in our next release to them.

## UNIT TYPE CHANGES AND PRIOR PERIOD ADJUSTMENTS

As drug labelers make unit type conversions to more accurately reflect how a drug product is packaged and marketed, we continue to notice selected problems being repeated. Most of the unit type conversions result in no change in the rebates already paid by the drug labeler and which have been considered closed items by both the States and drug labelers. However, several States are re-invoicing closed items because they are not converting their old unit types to the new unit types. This is creating unnecessary problems for the drug companies and will impede the processing of the rebate invoice by the affected drug labeler.

Additionally, we recommend that you compare the new NDC invoice amount due to the prior (settled) invoice amount due since these totals should be the same when unit type changes occur.

Please be sure that you are using the correct, converted unit types and that you check the converted dollar totals due to prevent erroneous prior period rebates being requested.

# GOLDLINE LABORATORIES (LABELER CODE 00182)

We were notified by Goldline personnel that they submitted erroneous termination dates for approximately 1700 NDCs. The problem is isolated to those NDCs that have 1994 as the year of termination. At their request, we deleted the termination dates for those affected NDCs, notified First DataBank and requested that First DataBank personnel inform MediSpan of our action.

We will not be sending a corrected 2-94 quarterly pricing tape to State Medicaid agencies. The changes affecting Goldline drug products will be reflected on the 3-94 quarterly pricing tape you receive in mid-November.

### UNIT TYPE CONVERSION EXCEPTION

We have encountered several exceptions when trying to convert a powder-filled vial (PFV) to an each (EA). Two examples involve the American Red Cross (labeler code 52769) and product codes 0470 and 0475 which have multiple package sizes.

Since each package size (PFV) contains a different amount of the drug product (and a different price), it is not possible to do a one-for-one conversion to an EA. The only way to correctly price these products is to do the weighting (and pricing) by gram (GM) and have the units per package size field reflect the correct number of grams in each PFV. Please ensure that these two drug products are maintained this way on your data bases and that you bill these two products as GMs.

### OTHER 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 September 6, 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:ABeachley, 63325, 09-08-94, HOTFAX43.WP