November 26, 1996

MEDICAID DRUG REBATE PROGRAM

Release Number 64

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

NOTE TO: All State Medicaid Directors

THERAPEUTIC EQUIVALENCY CODE

This year, the FDA issued a three-digit Therapeutic Equivalency (T.E.) Code to certain drugs that fall under the "AB" rating. These codes are used only in instances where more than one reference listed drug of the same strength has been designated under the same heading. When this occurs, rather than a rating of "AB", the rating will be "ABn" for all T.E. generic drugs where "n" is a numeric digit "1" through "9." Rather than increasing the size of this field from two to three positions and creating all the complex problems that accompany file conversions, we have decided that, IN THIS INSTANCE ONLY, the second position ("B") will be dropped and the numeric ("1" through "9") put in its place. Therefore, any labeler having a drug that requires this 3-digit T.E. designation will report it to HCFA as explained above. Any time you see this T.E. code on a quarterly tape we send to you, this is what it means. Please refer any questions or comments to Vince Powell on (410) 786-3314.

DESKTOP OPERATIONS TRAINING GUIDE

Hear Ye!! Hear Ye!! Believe it or not, we have finally been given permission to send the long-awaited desktop training guide to the printer!!!! We have been promised a completion by the first week of December (yes, 1996!!). It will be "in the mail" as soon as delivery is made to us. Expect this Christmas present to arrive at your desk sometime during mid-December.

Comments, corrections, etc. can be faxed to us at (410) 786-0390. Also, call Vince Powell at (410) 786-3314 or Sue Williams at (410) 786-3334.

ALLSCRIPS PHARMACEUTICALS, INC. (LABELER CODE 54569)

As mentioned in release number 61, Allscrips Pharmaceuticals did not enter into a drug rebate agreement and is not eligible to participate in the rebate program. The Food and Drug Administration reiterated that the labels used on their drug products do not conform to FDA specifications and, therefore, are out of compliance with acceptable standards. Additionally, we determined that this company fits the definition of a manufacturer and must enter into an agreement in order to have its drug products eligible for federal financial participation money. The legal representative for this drug labeler was informed of our decision in this matter. We believe your pharmacy communities should be cautioned to avoid filling Medicaid prescriptions with Allscrips drug products until such time as this company enters into a drug rebate agreement with the Secretary of the Department of Health and Human Services.

ANOTHER REMINDER ON REBATE/REIMBURSEMENT DISPUTES

Recently, a manufacturer requested clarification on a rebate issue involving a situation when a state Medicaid agency was not the primary payer for a particular drug. The manufacturer had withheld payment of rebates for the drug alleging that, since Medicaid did not fully reimburse for the drug, there is no rebate associated with the drug. Once again, we are reiterating that the level or amount of Medicaid reimbursement is irrelevant to rebate liability. If a Medicaid agency paid any portion of a drug claim, including the dispensing fee, then, for purposes of the rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug. Manufacturers that persist in withholding rebates based solely on the level of Medicaid reimbursement may be found in violation of the rebate agreement and risk termination from the program.

VITRASERT (OPTICAL IMPLANT WITH CYTOVENE) ASSIGNED A HCPCS CODE

Vitrasert, sold by Chiron Vision, contains the FDA-approved drug Cytovene/Gancyclovir. Vitrasert is a non-erodable polymer-based drug delivery system that is surgically placed in the posterior chamber of the eye. The FDA approved Vitrasert in March 1996 to treat CMV retinitis, a frequent complication in patients with HIV infection.

The National HCPCS Panel established a HCPCS code for this implant, effective 1/1/97; i.e., HCPCS: J7310 - Ganciclovir, 4.5 MG, Long-Acting Implant. The NDC code (61772-0002-01) will also be needed in order to receive the applicable rebates for the drug portion.

CPT code 67299 (unlisted procedure, surgery of the eye) has been recommended at this time for the implantation procedure.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on January 1, 1997:

Penederm Incorporated (Labeler Code 25074);
Genetics Institute, Inc. (Labeler Code 58394);
Orphan Medical, Inc. (Labeler Code 62161);
Bioglan Pharma, Inc. (Labeler Code 62436);
Bertek Pharmaceuticals, Inc. (Labeler Code 62794); and

Drug Emporium, Inc. (Labeler Code 62865).

DRUG LABELER REINSTATEMENT

Ion Labs, Inc. (Labeler Code 55532) has submitted missing drug prices for all quarters and signed a new rebate agreement. Their next period of participation in the drug rebate program will begin on January 1, 1997.

LABELER TERMINATIONS

The following labeler has requested to be terminated effective January 1, 1997:

Block Drug Company, Incorporated (Labeler Code 00021).

ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of May 6, 1996 through November 25, 1996 are attached.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 53.

/s/
Judith D. Moore
Acting Director
Medicaid Bureau

2 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid