

September 11, 1997

## **MEDICAID DRUG REBATE PROGRAM**

**Release Number 70**

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

**NOTE TO: All State Medicaid Directors**

### **DRUGDEX APPROVED AS A NEW COMPENDIUM**

The Balanced Budget Agreement of 1997 (BBA97), Pub. L. 105-33, revised the drug rebate provisions to include a reference to the DRUGDEX information system, a compendium produced by Micromedex, Inc. This change is effective after August 5, 1997. Under the BBA97, DRUGDEX has become part of the compendia under 1927(g)(1)(B), which applies to standards by which the drug use review (DUR) programs assess drug utilization information and to the medically accepted indications recognized under the drug rebate program. The addition of DRUGDEX also means that some additional indications would be considered "medically accepted indications" for purposes of 1927(k)(6). This will not effect coverage rules for non-FDA approved drugs (i.e., drugs that are international or investigational), nor over-the-counter (OTC) drugs. It would, however, require coverage of additional off-label uses of FDA approved drugs for the indications that are listed in the DRUGDEX monographs. As before, prior approval policies can be put in place, (e.g. to require another drug to be used first for that indication), but prior authorization cannot be used to simply deny the off-label DRUGDEX-identified indication for a drug.

The DRUGDEX compendium is described by Micromedex, Inc., as being based on independent reviews of literature and data gathered from drug centers worldwide. Once written, each monograph is reviewed by a combination of "in-house" and external consultants. These monographs include drugs and indications that are FDA-approved covered outpatient drugs, OTC, investigational and international. Micromedex says that the information can be cross-referenced by and about a drug's trade name, generic name, medical indication, adverse effects or disease state.

The compendium is available on CD-ROM and is updated quarterly. Micromedex has been contracting this service to hospitals for about a decade, but, as of this writing, does not have its policies in place for contracting with state Medicaid programs. The contact that we were given for purchasing information on DRUGDEX is Robert Jackson (1-800-525-9083 ext.6018).

If you have general questions about DRUGDEX, you can call Patricia Levy at (410) 786-5917. Questions pertaining to DUR should be referred to Christina Lyon at (410) 786-3332.

## **DRUG LABELERS**

### **New Labelers**

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

EM Pharma (Labeler Code 63254); and

Daiichi Pharmaceutical Corporation (Labeler Code 63395).

### **Terminations**

The following drug labelers are terminating effective October 1, 1997:

Aligen Independent Labs, Inc. (Labeler Code 00405);

Pasadena Research Laboratories, Inc. (Labeler Code 00418);

Horus Therapeutics (Labeler Code 59229); and

P.L. Development, Inc. (Labeler Code 59726).

## **NEW PHONE NUMBER FOR DIANE DUNSTAN**

Diane Dunstan, HCFA Denver Regional Office Drug Rebate Coordinator, has a new telephone number. That number is: **(303) 844-2121 x452**. Please make a note of Diane's new number. The telephone number for her facsimile machine remains unchanged at (303) 844-3753.

**OTHER ATTACHMENTS**

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period of December 30, 1996 through September 8, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide or in State release #53.

/s/

Sally K. Richardson  
Director  
Center for Medicaid and State Operations

2 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid