DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

7500 Security Boulevard

Baltimore, MD 21244-1850

March 30, 2001

SMDL# 01-018

Dear State Medicaid Directors:

This letter is to inform you that HCFA has received a rebate agreement from Danco Laboratories for participation in the Medicaid drug rebate program for Mifepristone (Mifeprex or RU-486). Under Federal law, States that choose to include outpatient drugs within their programs must cover, with a few limited statutory exceptions, Food and Drug Administration (FDA) approved drugs of all manufacturers that enter into this rebate agreement.

Mifepristone, when used in combination with misprostol, is used to terminate a pregnancy. Please note that the FDA and the manufacturer have placed restrictions on the distribution of mifepristone. Furthermore, the FDA has determined that a Medication Guide is necessary for women to use mifepristone safely. The FDA procedures include a requirement that the physician ask the woman to sign a Patient Agreement statement that she has decided to end her pregnancy. These restrictions may require changes in the usual billing and monitoring procedures as states apply these restrictions to Medicaid coverage.

Federal financial participation for mifepristone is available only when consistent with the applicable Hyde Amendment restrictions. The Hyde Amendment limits the use of federal funds for abortions to terminate a pregnancy resulting from an act of rape or incest or in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

The drug rebate law does not supercede state laws that set otherwise permissible limitations and protections, such as requirements for parental notification and informed consent.

Under the provisions of the drug rebate law, federal financial participation is available on January 22, 2001. Because of the restrictions placed on the

dispensing of the drug and the limitations of federal financial participation, we will consider several factors in determining a state's compliance with the drug rebate provisions in section 1927. In particular, these factors include a state's procedures to ensure compliance with the Hyde Amendment and its authority to place restrictions on coverage of drugs under Section 1927(d), its authority for drug use review under Section 1927(g), and its authority under other state laws.

Thank you for your attention to this matter. If you have any questions, please contact Cheryl Austein-Casnoff at 410-786-4196.

/s/

Penny R. Thompson

Acting Director

Center for Medicaid and State Operations

cc:

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