DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

February 15, 2000

MEDICAID DRUG REBATE PROGRAM RELEASE #97

For State Medicaid Directors

STATE OPTION OF USING DIFFERENT REBATE AGREEMENT EFFECTIVE DATES

Section 1927 (a)(1) of the Social Security Act (the Act) generally provides that in order for Federal Financial Participation to be made available for the drugs of a manufacturer, the manufacturer must enter into a drug rebate agreement with HCFA (or, if authorized by HCFA, with the States). Rebate agreements that were not in effect before March 1, 1991, became effective the first day of the calendar quarter that began more than 60 days after the date the agreement was entered into.

As a result of this section of the law, manufacturers that signed agreements less than 60 days before a quarter sometimes had to wait several months before their agreements became effective. In order to help eliminate this delay, Section 606 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 amended Section 1927 (a)(1) to give States the option of using different rebate agreement effective dates. Specifically, the law now states that rebate agreements that are entered into on or after November 29, 1999 may become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter up to the first day of the first quarter that begins more than 60 days after the agreement is entered into. As before, the date on which an agreement is entered into is the date on which it is postmarked.

A State has the flexibility to apply these new provisions for each manufacturer. The same, however, will not be true for individual drugs. When a manufacturer's agreement becomes effective in a State, all of its covered drugs must be included at that time. This change in effective date does not affect HCFA's policy regarding termination from the Medicaid drug rebate program, nor the subsequent delay before re-entry into the program.

OPERATIONAL AFFECTS OF THE ABOVE LEGISLATION

Because a State now has the option outlined above, we must notify you immediately when we receive a rebate agreement. Since our releases regarding this issue would not be received by you in a timely manner, on an ongoing basis we will fax all States the pertinent information concerning new labelers as soon as a rebate agreement is received in HCFA. However, in order to accomplish this, **we must have the most accurate contact information, including a fax number for the technical contact, in our system**. For your convenience, we are attaching the entire State contact listing as shown on our files. Please review ALL information for your State for accuracy. Also, attached are blank contact forms on which you can submit corrections.

Please complete the attached contact forms and return them to us **immediately** via fax at 410-786-0390. Failure to submit accurate information will prevent us from notifying you in a timely manner of new labelers and delay your option to make a labeler effective prior to the beginning of a quarter.

In addition to faxing new labeler information to you as soon as it is received, we will continue to include that information in our releases as usual.

MEDICAID COVERAGE OF XENICAL

On April 23, 1999, the Food and Drug Administration (FDA) approved Xenical (orlistat) for the treatment of obesity management, including weight loss and weight maintenance, when used in conjunction with a reduced calorie diet.

The Act specifically provides that States have the option to exclude or otherwise restrict from coverage drugs or classes of drugs that are used for weight loss. Thus, in accordance with the Act and the FDA-approved medically accepted indication, State Medicaid programs have the option of covering Xenical when used for weight loss. However, a compendium recognized in the Act does support a use for Xenical to reduce cholesterol not related to weight loss. Because States must generally cover

when prescribed for this indication, subject to a State's prior authorization program or drugs for reducing cholesterol, Xenical must be covered by a State Medicaid program other permissible restrictions.

LABELER NAME CHANGE

Galderma Laboratories, Inc., labeler code 00299, has changed its name effective January 1, 2000 to Galderma, L.T. Contact names, phone numbers, and addresses remain the same.

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Johnson & Johnson Medical (Labeler Code 56091)	04/01/2000	01/24/2000
Ameriderm Laboratories, Ltd. (Labeler Code 63921)	04/01/2000	12/07/1999
R&S Pharma, Inc. (Labeler Code 65162)	04/01/2000	12/17/1999
Virco Pharmaceuticals, Inc. (Labeler Code 65199)	04/01/2000	01/03/2000
American Pharmaceutical Partners, Inc. (Labeler Code 65219)	04/01/2000	12/29/1999

Contact information for new labelers is attached for your convenience.

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period November 9, 1998, is 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.

Timothy M. Westmoreland

Director

5 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid