

**STATE OF VERMONT
AGENCY OF HUMAN SERVICES**

OVHA

Office of Vermont Health Access

Bulletin NO: 08-03

FROM: Joshua Slen, Director
Office of Vermont Health Access

DATE: 9/10/2008

SUBJECT: Pharmaceutical Manufacturer Fee

CHANGES ADOPTED EFFECTIVE 11/1/08

INSTRUCTIONS

Maintain Manual - See instructions below.

Proposed Regulation - Retain bulletin and attachments until you receive Manual Maintenance Bulletin:

Information or Instructions - Retain until _____

MANUAL REFERENCE(S):

**7700 - TOC
7700
7701**

This bulletin introduces a new section in rule to establish a pharmaceutical manufacturer fee as imposed by 33 V.S.A. § 2004. This statute was enacted by the Vermont legislature in Act 80 of the 2007 session. This fee shall be used to create and maintain the evidence-based education and advertising fund as described in 33 V.S.A. § 2004a. The fee is based on the previous calendar year's spending for prescription drugs that are paid for by the Office of Vermont Health Access for individuals participating in Medicaid, the Vermont Health Access Plan (VHAP), Dr. Dynasaur, VPharm, VHAP-Pharmacy, VScript, or VScript Expanded. The fee shall be collected in November 2008 from pharmaceutical manufacturers and labelers. This initial fee will be based on calendar year 2007 spending. For successive years, the fee based on the previous calendar year spending shall be collected beginning in February in the following calendar year.

Comment Period

A public hearing was held on Monday, June 22, 2008 at 10:00 a.m., in the Large Conference Room at the Office of Vermont Health Access (OVHA), Williston, Vermont. No comments were made during this time.

OVHA received one set of comments from the Pharmaceutical Research and Manufacturers of America (PhRMA). Their comments are summarized below along with OVHA's responses.

Comment: Rule-making concerning the manufacturer fee is premature because PhRMA has challenged the constitutionality of the fee.

Response: It is our understanding that PhRMA is challenging only one use for the funds to be collected by the fee, not the imposition of the fee itself. Therefore, even assuming PhRMA prevailed on its challenge, rule-making is still necessary and must proceed with an eye towards the current effective date.

Comment: The bulletin conflicts with Medicaid statutory and regulatory requirements and the state must amend its state plan to include this change.

Response: The purpose and the function of the fee are totally unrelated to Medicaid. Contrary to PhRMA's suggestion, the fee does not function as a supplemental rebate. Therefore, amendment of the Medicaid plan is unnecessary.

Comment: The proposed regulations are insufficiently detailed because 33 V.S.A § 2004 (c) requires an explanation of how the evidence-based program will work.

Response: The statute merely requires the Secretary to promulgate rules to implement the collection of the fee, nothing more. The Secretary has done so in this bulletin.

To get more information about the Administrative Procedures Act and the Rules applicable to state rule making go to the website of the Office of the Vermont Secretary of State at:

<http://vermont-archives.org/aparules/index.htm> or call Louise Corliss at 828-2863

For information on upcoming hearings before the Legislative Committee on Administrative rules go to the website of the Vermont Legislature at:

<http://www.leg.state.vt.us/schedules/schedule2.cfm> or call 828-5760.

Vertical lines in the left margin indicate significant changes. Dotted lines at the left indicate changes to clarify, rearrange, correct references, etc., without changing content.

Manual Holders: Please maintain manuals assigned to you as follows.

Manual Maintenance

Medicaid Rules

	<u>Remove</u>		<u>Insert</u>	
<i>None</i>			<i>7700 TOC</i>	(08-03)
<i>None</i>			<i>7701</i>	(08-03)

11/1/08

Bulletin No.08-03

Table of Contents

7700 Pharmacy Administration

7701 Pharmaceutical Manufacturer Fee

11/1/08

Bulletin No. 08-03

7700

7700 Pharmacy Administration7701 Pharmaceutical Manufacturer Fee

Act 80, of the 2007 legislative session, an Act relating to increasing transparency of prescription drug pricing and information, established a manufacturer fee under 33 V.S.A. § 2004. A fee shall be collected annually by the Agency of Human Services from each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the Office of Vermont Health Access for individuals participating in Medicaid, the Vermont Health Access Plan (VHAP), Dr. Dynasaur, VPharm, VHAP-Pharmacy, VScript, or VScript Expanded. The fee shall be 0.5 percent of the previous calendar year's prescription drug spending by the office and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program. The fee shall be deposited in the evidence-based education and advertising fund established by 33 V.S.A. § 2004a. This fee shall fund activities, including the evidence-based education program, established by 18 V.S.A. § 4622.

The evidence-based education program will provide information and education on the therapeutic and cost-effective use of prescription drugs, as well as the collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, and analysis of drug data needed by the attorney general's office for enforcement activities concerning prescription drugs.

The OVHA shall annually provide the manufacturer or labeler with a written bill in the amount of 0.5 percent of the payments made on claims submitted during the previous calendar year regarding the manufacturer's or labeler's prescription drugs. This amount will be based on paid claims data (data used to reimburse pharmacies) under the state's programs. The manufacturer or labeler shall remit the invoiced amount according to instructions provided by OVHA.

In the event the manufacturer or labeler believes an error in billing has occurred, the manufacturer or labeler must notify the OVHA in writing within thirty days of the receipt of the bill. This notification must be accompanied by written materials setting forth the basis for the requested review. The billing data will be verified and adjusted if appropriate, which may include a credit as to the amount of the bill, or a refund of amounts paid.

The OVHA shall maintain electronic claims records for five quarters after the end of a billing calendar year that will permit the manufacturer labeler to verify through an audit process the billing invoices provided by the OVHA.