

Memo

To: Manufacturers of Prescribed Products

From: Wendy Morgan, Chief of the Public Protection Division
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Vermont Office of the Attorney General

Date: May 12, 2011

Subject: 2011 Legislation and Guide

Legislation: The Vermont legislature has passed legislation amending the law on prescribed products. The final version of the bill has not yet been posted, and has not yet been signed by the Governor, but appears in the Senate Journal for May 6, 2011, on pages [2080-2091](#).

The important changes, effective July 1, 2011, unless otherwise noted are:

- Reporting is moved to a **calendar year**; reports are due to the Attorney General by April 1; the Attorney General will report by October 1; with a transition six-month reporting period and \$250 fee for July 1, 2011 through December 31, 2011.
- Manufacturers whose prescribed products are **only certain Class I medical devices** do not fall within the law. 18 V.S.A. § 4631a(a)(9).
- Research, such as **marketing research** or surveys, which does not fall within the allowable expenditures for clinical trials and scientific research, §§ 4631a(a)(1)(C) and (D), is banned. § 4631a(c).
- **Patient assistance programs** (PAPs) are not within the definition of “sample,” § 4631a(a)(13), are a permitted gift, § 4631s(b)(2)(I), and need not be reported. § 4632(a)(1)(A)(vii).
- Expenses for manufacturers’ **employees health care** are allowed, § 4631a(a)(1)(G), and need not be reported. § 4632(a)(1)(A)(iv).
- **Delayed reporting for clinical trials** is extended to four years and for new uses of an FDA-approved prescribed product. § 4632(a)(1)(A)(iii).
- **Trial period for loans** of medical devices is extended to 120 days, and need not be reported in all circumstances. § 4631a(b)(2)(B); § 4632(a)(1)(A)(vi).
- Effective January 1, 2012, **over-the-counter** drugs and medical devices permitted by § 4631a(b)(2)(A) are to be reported; the Attorney General will not disclose the identity of individual recipients to the public. § 4632(a)(1)(B).

- Members of the Green Mountain Care board, established as part of Vermont's health care reform package, are treated similarly to health care providers for purposes of the gift ban and reporting. §§ 4631a(a)(5) and (b)(1); § 4632(a)(1).

Reporting of Distributions through Patient Assistance Programs: We will not require reporting of PAP for past years, including FY2011, even though the statutory provision eliminating PAP reporting does not go into effect until July 1, 2011.

2011 Guide and Conference Call: We hope to have a draft 2011 Guide incorporating the 2011 Samples Guide distributed by early June, and to hold a conference call on June 16 at 1pm EST. If possible, please send your questions in advance to prescribedproducts@atg.state.vt.us. We plan to issue the final 2011 Guide by July 1, 2011.

FY2011 Compliance Officer Form and \$500 fee: Companies which will have expenditures to report for FY2011 (July 1, 2010, through June 30, 2011), must file a new Compliance Officer Form and pay the \$500 annual reporting fee by July 1, 2011.