



## Client Alert

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### **New Vermont Law Modifies Gift Reporting Requirements for Drug and Medical Device Manufacturers**

Vermont passed a new law on May 6, 2011, entitled "An Act Relating to Modifications to the Ban on Gifts by Manufacturers of Prescribed Products" (Act No. 51), which clarifies and modifies the gift ban and reporting requirements for most drug and medical device manufacturers in the state.<sup>1</sup> Since 2009, the state has banned most industry gifts to healthcare providers and also required manufacturers of pharmaceuticals, medical devices and biological products to file an annual report that provides information on the company's marketing expenditures and identifies a compliance officer.

The new law went into effect May 26, 2011, except as indicated below. Specifically, the new law:

- excludes from the scope of the gift ban and disclosure law manufacturers whose only prescribed products are over-the-counter drugs sold without a prescription and Class I devices that are exempt from the Food and Drug Administration's pre-market notification requirements;
- prohibits manufacturers from paying healthcare providers to participate in most research activities, except for clinical trials and significant research projects;
- exempts the following activities from the gift ban: 1) short-term loans of medical devices for 120 days or less, where the loan results in the issuance of a certificate of need and a sale or lease; and 2) prescribed products (i.e., drug or device) provided for free or at discounted prices through a manufacturer's patient assistance program;
- prohibits, until July 1, 2012, health insurers and pharmacy benefit managers from imposing an insurance policy that requires consumers to pay a greater co-payment for prescription drug products than the co-payment required for a non-preferred brand name product;<sup>2</sup>
- extends the prohibition on receiving gifts from manufacturers to include members of the Green Mountain Care Board, which oversees

<sup>1</sup> A copy of the new law is available at <http://www.leg.state.vt.us/docs/2012/Acts/ACT051.pdf>.

<sup>2</sup> Similarly, the Commissioner of Banking, Insurance, Securities, and Health Care Administration is prohibited from approving such an insurance policy until July 1, 2012.

the first single payer health plan for the state and expands the reporting requirement to include any amounts expended on the Green Mountain Care Board;<sup>3</sup>

- requires the Office of the Attorney General to obtain information regarding the distribution of non-prescription drug samples and devices;
- modifies the annual reporting period for required disclosures (of permitted gifts and allowable expenses) from the state fiscal year to a calendar year and changes the reporting deadline from October 1 to April 1 of each year (although the new law will not change the report due October 1, 2011);
- changes the annual disclosure deadline for a manufacturer's compliance officer from July 1 to January 1 of each year;
- imposes a fee schedule for each manufacturer of a prescribed product (i.e., drug or device) that files an annual disclosure with expenditures greater than \$0 in a reporting period;<sup>4</sup> and
- requires the Commissioner of Vermont Health Access and state technology leaders to evaluate and report their findings on the use of electronic means to request and grant prior authorization for prescription drugs by January 15, 2012.

<sup>3</sup> Under a single payer health plan, all medical care would be funded from a single insurance pool, typically run, in part or in whole, by the state.

<sup>4</sup> For the fiscal year ending June 30, 2011, manufacturers with expenditures of greater than \$0 must pay a \$500 fee by July 1, 2011. In January 2012, a \$250 fee is due from such manufacturers for the reporting period from July 1, 2011, through December 31, 2011. Starting January 1, 2013, the \$500 fee is due from each manufacturer of a prescribed product that files an annual disclosure with expenditures greater than zero for the 2012 calendar year.

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