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Vermont Pharmaceutical Gift Ban & Disclosure Act Statutory Summary & Analysis

I. An Act Relating to the Marketing of Prescribed Products: Current Status

On June 8, 2009, Governor Jim Douglas of Vermont signed legislation that expands Vermont's existing pharmaceutical marketing disclosure law. The new law, [Chapter 59 of the Vermont Acts of 2009](#) (the "Act") creates the nation's strictest rules regarding marketing activities by the pharmaceutical and medical device industries. As of July 1, 2009, the Act bans nearly all industry gifts to prescribers (including doctors, nurses, and medical staff), as well as gifts to health plan administrators and health care facilities. The Act also strengthens the existing manufacturer expenditure disclosure requirement, and removes certain legal protections pertaining to the disclosure of trade secrets.

The Act received broad bipartisan support, passing unanimously in the Senate and 137-4 in the House. Because the Act substantially expands existing Vermont law regulating pharmaceutical and medical device marketing, its requirements and potential impact are of significant importance to anyone involved in the biotechnology, health care, and drug and device sectors.

II. Background and Overview

Since 2002, Vermont law has regulated pharmaceutical marketing activities by requiring pharmaceutical manufacturers to disclose the value, nature and purpose of certain marketing-related expenses of \$25 or more in value. The prior law also provided an exception to the disclosure requirement for manufacturer trade secrets. The Act has four key elements:

- **Extends** the reach of the law to biological product and medical device manufacturers.
- **Bans** most gifts from manufacturers of prescription drugs, biologics and medical devices to doctors, nurses and health care facilities. The ban also extends to food and free meals.
- **Strengthens** Vermont's existing disclosure law by requiring all manufacturers of prescribed products to report annually all allowable expenditures, including expenditures relating to clinical trials. Transactions that are exempt from disclosure include royalties and licensing, samples of prescription drugs, and rebates and discounts; disclosure is delayed for two years for payments relating to clinical trials.
- **Eliminates** the provision in the prior law that protected trade secrets from disclosure.

III. Summary of Chapter 59 of the Vermont Acts of 2009 (Senate Bill 48)

Section 1 – Definition of “Health Care Professional”

- Defines “health care professional” as a “person, partnership or corporation, other than a facility or institution, licensed or certified or authorized by law to provide professional health care service in this state to an individual during that individual’s medical care, treatment or confinement.”

Section 2 – Legislative Findings

- That Vermonters “spent an estimated \$572 million on prescription and over-the-counter drugs and nondurable medical supplies” in 2007, and that the state of Vermont has a “substantial interest in cost containment and protection of public health.”
- That a 2009 report from the Institute of Medicine found that “acceptance of meals and gifts... are common between physicians and pharmaceutical, medical device and biotechnology companies,” and that these relationships may influence physicians’ prescribing behavior.
- That a 2009 report from the Vermont Attorney General found that, in FY 2008, “pharmaceutical manufacturers reported spending \$2,935,248 in Vermont on fees, travel and other direct payments to Vermont physicians, hospitals and universities...”
- That “there is little or no difference in the marketing of biological products and prescription drugs,” making it “logical and necessary to include biological products to the same extent as prescription drugs...”
- That the Act is “necessary to increase transparency for consumers by requiring disclosure of allowable expenditures and gifts to health care providers and facilities providing health care.”

Section 3a – Additional Definitions

- **Allowable expenditures:** Defines all permissible payments, including:
 - Payments to the sponsor of an educational or medical conference if 1) the payment is not made directly to the health care provider, 2) the funding is used for bona fide educational purposes, and 3) the program content is objective and free from industry control;

- Honoraria and expense reimbursements for health care professionals serving as faculty at educational, medical, or policy-making conferences (with some restrictions);
- For a bona fide clinical trial, gross compensation for the Vermont location(s) involved in the trial, and direct salary support and expenses paid on behalf of investigators to review clinical trials;
- For a research project that “constitutes a systematic investigation” and is used to develop knowledge of “significant value” to the health care community, gross compensation, direct salary support, and expenses;
- Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented discovery; and
- Other “reasonable fees, payments, subsidies or other economic benefits provided by a manufacturer at fair market value.”

- **Bona fide clinical trial:** An FDA-reviewed clinical trial that can be “considered of interest” to health professionals in the field.
- **Clinical trial:** Any study assessing the safety or efficacy of prescribed products, or assessing the relative safety or efficacy of prescribed products in comparison with others.
- **Gift:** Anything of value provided for free, or any payment, food, entertainment, travel, subscription, advance, service or anything else of value provided to a health care provider unless it is an “allowable expenditure,” or unless the health care provider reimburses the payor at fair market value.
- **Health care professional:** A person authorized to prescribe or to recommend prescribed products, and who is either licensed or “lawfully providing health care” in Vermont; a partnership made up of these persons; or an officer or employee of such person.
- **Health care provider:** A health care professional, a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescribed products in Vermont.
- **Manufacturer:** A “pharmaceutical, biological product, or medical device manufacturer or any other person who is engaged in the production, preparation, propagation,

compounding, processing, packaging, repackaging, distributing, or labeling of prescribed products.” The term does not include a wholesale distributor of biological products or a pharmacist.

- **Marketing:** Includes promotion, detailing, or any activity intended to influence sales or market share.
- **Pharmaceutical manufacturer:** Any entity “engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs.”
- **Prescribed product:** Any drug or device in § 201 of the FDC Act (21 U.S.C. § 321) or a biological product as defined in § 351 of the PHS Act (42 U.S.C. § 262).
- **Significant educational, scientific, or policy-making conference or seminar:** Any seminars or events that are accredited by the Accreditation Council for Continuing Medical Education or a comparable organization, offer CME credit, and have multiple presenters on scientific research.

Section 3b – Prohibition, Exclusions and Penalties

- Prohibits any manufacturer of a prescribed product or any wholesale distributor of medical devices to offer or give any gift to a health care provider.
- Excludes from the definition of “gift” the following:
 - Product samples for free distribution;
 - Short-term (90-day) loans of medical devices for evaluation purposes;
 - “Reasonable quantities” of medical device demonstration or evaluation units provided to a health care provider for purposes of assessing appropriate use;
 - Provision or distribution of peer-reviewed materials that serve a “genuine educational function;”
 - Scholarship support for medical students and residents attending scientific conferences;

- Rebates and discounts provided in the normal course of business; and
- FDA-approved labels for prescribed products.

- Authorizes the Attorney General to seek injunctive relief and civil fines of \$10,000 per violation.

Section 4 – Disclosure of Allowable Expenditures and Gifts by Manufacturers of Prescribed Products; Penalties

- Mandates that annually by October 1, manufacturers of prescribed products shall report to the Attorney General for the fiscal year ending the previous June 30 the value, nature, purpose and recipient information of any allowable expenditure or gift permitted under the Act.
 - **Excludes** from disclosure rebates and discounts for prescribed products provided in the normal course of business, royalties and licensing fees, and samples of prescription drugs provided to health care professionals for free distribution.
 - **Delays** disclosure of clinical trials payments for the first two calendar years after such payments are made.
- Requires manufacturers to report annually the name of the expenditure recipient, the recipient’s address and institutional affiliation, prescribed products being marketed, if any, and the recipient’s state board number.
- Allows the Office of Vermont Health Access to examine disclosed data and determine whether and to what extent prescribing patterns by health care providers of products reimbursed by Medicaid, VHAP, Dr. Dynasaur, VermontRX and VPharm may reflect manufacturer influence.
- Requires manufacturers to report annually on July 1 the name and address of the individual who is responsible for the manufacturer’s compliance with the Act, and to pay an annual filing fee of \$500.
- Authorizes the Attorney General to bring actions for injunctive relief, costs, and attorney’s fees, and to impose a fine of not more than \$10,000 per each violation of the Act’s disclosure requirements.

Section 5 – Elimination of Trade Secrets Exemption

- Eliminates statutory trade secret protections for competitively-sensitive information that manufacturers may be obligated to disclose under the Act.

Section 5a – Study of Disclosure of Drug Samples

- Directs the Attorney General to study whether the Act should be further amended to require the disclosure of free drug and device samples.

Section 6 – Additional Definitions

- Defines the terms “average wholesale price,” “pharmaceutical manufacturing company,” and “pharmaceutical marketer,” in relation to the existing statutory provision requiring pharmaceutical marketers to disclose average wholesale prices to authorized providers.

Section 7 – Therapeutic Equivalent Drug Work Group

- Creates a “work group” tasked with increasing the usage of generic drugs.
- Instructs the work group to generate by January 15, 2010, both draft legislation for codifying a generic substitution process, and a sample list of therapeutically equivalent generic drugs that pharmacists would be authorized to substitute for brand drugs.

Sections 8 & 9 – Technical Amendments:
Establishment of a Work Group to Examine Health Care Costs in Corrections / State Membership in National Legislative Association on Prescription Drug Prices.

Section 10 – Appropriation

- Authorizes \$40,000 in FY 2010 to the Attorney General to collect and analyze information collected pursuant to the Act.

Section 11 – Effective Date

- Provides that the Act will take effect on July 1, 2009.
- Clarifies that **pharmaceutical** manufacturers' disclosure obligations for the July 1, 2008 to June 30, 2009 period are covered by the **prior** law. Those disclosures must be filed by November 1, 2009.
- Clarifies that the first disclosure period for **biological product** and **medical device** manufacturers — who were not covered by the prior law — is January 1, 2010 through June 30, 2010. Those disclosures must be filed by October 1, 2010.

IV. Next Steps

The Vermont Attorney General will promulgate rules pertaining to these new statutory provisions. During this process, input from those with an interest in the Vermont biotechnology, health care, and drug and device sectors will be of significant importance. Additionally, manufacturers who provide payments or items of value to health care professionals in Vermont will need to understand, and ensure compliance with, changes to the current Vermont disclosure database.

Foley Hoag has extensive experience advising companies who wish to comment on these types of regulations, as well as assisting companies in meeting their statutory and regulatory obligations as part of a comprehensive compliance program. If you would like to speak further with one of our attorneys regarding these processes, please contact [Colin Zick](#), [Pat Cerundolo](#), [Tad Heuer](#), or any member of Foley Hoag's [Life Sciences](#) and [Government Strategies](#) groups.

