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# Vermont Enacts Revised HCP Disclosure Requirements, Gift Ban

Vermont's governor has signed S. 48, a law that would revise the state's current pharmaceutical marketing disclosure requirements. The new statute expands the application of Vermont's current requirement that pharmaceutical manufacturers annually disclose certain expenditures made in connection to interactions with Vermont health care professionals. Under the revised law, the disclosure requirement now also applies to medical device companies. Further, the revised law adds a ban on certain items and expenditures that was not included in the previous version. Notably, this gift ban may go into effect as early as **July 1, 2009**. The following summarizes the revised Vermont law, including key dates for compliance.

## I. Scope

The revised Vermont law applies to "manufacturers of prescribed products." A "manufacturer" is defined to mean "a pharmaceutical, biological product, or medical device manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, packaging, repacking, distributing, or labeling or prescribed products."[1] Further, a "prescribed product" means a drug or device or biological product.[2] (Notably, the previous version of the Vermont law applied only to "pharmaceutical manufacturing companies" that were engaged in the production of prescription drugs.[3])

Importantly, the revised disclosure requirement does not apply exclusively to items or expenditures made in connection with marketing activities. The original law, in contrast, was limited to items and payments "provided in connection with detailing, promotional, or other marketing activities."[4]

## II. Requirements/Restrictions

Effective **July 1, 2009**, Vermont will impose a ban on providing items and making certain payments to health care providers (the "gift ban"). Specifically, the Vermont law makes it "unlawful for any manufacturer of a prescribed product…to offer or give any gift to a health care provider."[5] This new gift ban, therefore, could significantly impact how drug and device companies interact with "health care providers" in Vermont. Under the law, a "health care provider" is defined as:

- "[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]."[6]

A "health care professional" is defined as:

- A person who is authorized to prescribe or to recommend prescribed products, and who either is licensed by Vermont to provide or is otherwise lawfully providing health care in Vermont; or
- A partnership or corporation made up of these persons; or
- An officer, employee, agent, or contractor of these persons who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals.[7]

Further, a "gift" is defined as:

- Anything of value provided to a health care provider for free; or
- Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider.[8]

A "gift" under the law does not include "allowable expenditures" (defined below), items specifically excluded from the ban, or items that the health care provider pays for "at fair market value."[9]

### *A. Allowable Expenditures in Vermont*

The following chart details those expenditures or payments in Vermont that are allowable under the law. The chart also lists certain rules and parameters around each of these types of payments.

| ALLOWABLE EXPENDITURE | RULES / PARAMETERS |
|---|---|
| Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar[10] | A "significant educational, scientific, or policy-making conference or seminar" is defined as an educational, scientific, or policy-making conference or seminar that: (1) is accredited by ACCME or a comparable organization and (2) offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.[11]<br>Restrictions on payment:<br>• The payment cannot be made directly to a health care provider<br>• Funding must used solely for bona fide educational purposes<br>• All program content must be objective, free from industry control, and cannot promote specific products[12] |
| Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide "significant educational, medical, scientific, or policy-making conference or seminar"[13] | Restrictions:<br>• There must be an explicit contract with specific deliverables that are restricted to medical issues, not marketing activities<br>• The content of the presentation, including slides and written materials, must be determined by the health care professional |
| Payments associated with a "bona fide clinical trial"[14] | A "bona fide clinical trial" means an FDA-reviewed clinical trial that constitutes "research" (as defined in 45 C.F.R. § 46.102) and reasonably can be considered to be of interest to scientists or health care professionals working in the particular field of inquiry.[15]<br>Allowable expenditures include:<br>• Gross compensation for the Vermont location or locations involved<br>• Direct salary support per principal investigator and other health care professionals per year<br>• Expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial[16] |
| Payments for "research projects"[17] | A "research project" constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry.<br>Allowable expenditures include:<br>• Gross compensation<br>• Direct salary support per health care professional<br>• Expenses paid on behalf of each health care professional[18] |
| Payment / reimbursement of expenses associated with medical device training[19] | Allowable expenditures include:<br>• Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for the technical training of individual health care professionals on the use of a medical device.<br>Restrictions on payment:<br>• The commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid must be described in a written agreement between the health care provider and the manufacturer.[20] |
| Royalties and licensing fees[21] | Allowable expenditures include:<br>• Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.[22] |
| Other payments[23] | Allowable expenditures include:<br>• Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.[24]<br>• Note: While this appears to permit payment of compensation for the fair market value of consulting services, this is not explicit in the statute. |

### *B. Gifts that are Prohibited in Vermont*

The following chart details those ***items*** that cannot be provided to a health care provider in Vermont.

| PROHIBITED GIFT | RULES / PARAMETERS |
|---|---|
| "Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider." | This does not include:<br>• "Allowable Expenditures" (listed above)<br>• Items for which the health care provider reimburses the cost at fair market value.[25] |
| "Anything of value provided to a health care provider for free"[26] | This appears to be a broad, catch-all category. |

### *C. Exemptions from the Gift Ban*

Items not subject to the gift ban (and therefore can be provided) are the following:

- Samples of a prescribed product provided to a health care provider for free distribution to patients.
- The loan of a medical device for a short-term trial period, **not to exceed 90 days**, to permit evaluation of a medical device by a health care provider or patient.
- The provision of reasonable quantities of medical device demonstration or evaluation units to a health care provider to assess the appropriate use and function of the product, and to determine whether and when to use or recommend the product in the future.
- The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients.
- Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association, if the recipient of the scholarship or other support is selected by the association.
- Rebates and discounts for prescribed products provided in the normal course of business.
- Labels approved by the FDA.[27]

### *D. Penalties*

The Vermont attorney general may bring an action in Washington Superior Court for injunctive relief, costs, and attorney's fees, and may impose on a manufacturer that violates the ban a civil penalty of no more than $10,000 per violation. Furthermore, each unlawful gift constitutes a separate violation.[28]

## III. Disclosure Requirements

### A. Allowable Expenditures, Gifts

Pursuant to the revised Vermont law, each year by **October 1**, drug and device manufacturers must disclose to the Vermont attorney general (1) any "allowable expenditure" or (2) "gift" (see tables in Section II above) provided to ***any health care provider.***[29]

In addition, each year by **October 1**, drug and device manufacturers must disclose to the Vermont attorney general (1) any "allowable expenditure" or (2) "gift" provided to ***any academic institution or to a professional, educational or patient organization representing or serving health care providers or consumers.***[30]

In both instances, disclosures would apply to the previous July 1-June 30 timeframe.

Manufacturers are not required to disclose the following:

- Royalties and licensing fees
- Rebates and discounts for prescribed products provided in the normal course of business
- Payments for "clinical trials"[31]

In addition, disclosure will be made on a form and in a manner prescribed by the Vermont attorney general and will include:

- The value, nature, and purpose of each allowable expenditure and gift
- The name of the recipient
- The recipient's address
- The recipient's institutional affiliation
- Prescribed product or products being marketing, if any
- The recipient's state board number[32]

Initial disclosures are due:

- **November 1, 2009**, for the time period July 1, 2008 – June 30, 2009 for pharmaceutical manufacturers pursuant to the current requirements. Starting **October 1, 2010**, pharmaceutical manufacturers would be required to disclose under the new requirements for the period July 1, 2009 – June 30, 2010.
- **October 1, 2010**, for the time period January 1, 2010 – June 30, 2010 for medical device and biologics manufacturers.

Importantly, there is no *de minimis* reporting exception or minimal threshold dollar value of items or payments that must be disclosed under the Vermont law. Further, the law does not limit disclosable items or payments only to those expenditures made or items provided in connection with marketing activities.[33]

### B. Other Disclosure Requirements

In addition, annually on ***July 1***, drug and device manufacturers are required to disclose to the Vermont attorney general the name and address of the individual responsible for the manufacturer's compliance with the provisions of the Vermont law.[34]

The Vermont law also requires drug and device manufacturers to disclose information related to product samples. Specifically, the Vermont law requires that annually, on or before **October 1** of each year, manufacturers must disclose to the attorney general, the receiving health care provider's information, and the brand name, generic name, quantity, and dosage of samples, or a prescribed product provided for free distribution to patients.[35]

### C. Other Information

Other details regarding the disclosure requirement include the following:

- All disclosed data will be made publicly available and searchable through an Internet website.[36]
- A filing fee of $500 is due **July 1** of each year.[37]
- Vermont's law does not protect company trade secrets from public disclosure.[38]
- The Vermont attorney general may bring an action in Washington Superior Court for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to disclose a civil penalty of no more than $10,000 per violation. Each unlawful failure to disclose constitutes a separate violation.[39]

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1 18 V.S.A. § 4631a(a)(7) [new].

2 18 V.S.A. § 4631a(a)(9) [new].

3 18 V.S.A. § 4632(c)(5) [current].

4 18 V.S.A. § 4632(a)(1) [current].

5 18 V.S.A. § 4631a(b)(1) [new].

6 18 V.S.A. § 4631a(a)(6) [new].

7 18 V.S.A. § 4631a(a)(5) [new]. Note that persons authorized to prescribe in Vermont include physicians, dentists, naturopathic physicians, nurse practitioners, optometrists, osteopaths, physician's assistants, podiatrists, scientific investigators, and veterinarians.

8 18 V.S.A. § 4631a(a)(4) [new].

9 18 V.S.A. § 4631a(a)(4) [new].

10 18 V.S.A. § 4631a(a)(1)(A) [new].

11 18 V.S.A. § 4631a(a)(11) [new].

12 18 V.S.A. § 4631a(a)(11) [new].

13 18 V.S.A. § 4631a(a)(1)(B) [new].

14 18 V.S.A. § 4631a(a)(1)(C) [new].

15 18 V.S.A. § 4631a(a)(2) [new].

16 "Clinical trial" means any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies. 18 V.S.A. § 4631a(a)(3) [new].

17 18 V.S.A. § 4631a(a)(1)(D) [new].

18 18 V.S.A. § 4631a(a)(1)(D) [new].

19 18 V.S.A. § 4631a(a)(1)(E) [new].

20 18 V.S.A. § 4631a(a)(1)(E) [new].

21 18 V.S.A. § 4631a(a)(1)(F) [new].

22 18 V.S.A. § 4631a(a)(1)(F) [new].

23 18 V.S.A. § 4631a(a)(1)(G) [new].

24 18 V.S.A. § 4631a(a)(1)(G) [new].

25 18 V.S.A. § 4631a(a)(4)(B) [new].

26 18 V.S.A. § 4631a(a)(4)(A) [new].

27 18 4631a(b)(2)(A)-(G) [new].

28 18 V.S.A. § 4631a(c) [new].

29 18 V.S.A. § 4632(a)(1)(A) [new].

30 18 V.S.A. § 4632(a)(1)(B) [new].

31 But, payments for clinical trials must be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the FDA, or two calendar years after the date the payment was made. Such disclosure must also list the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry. 18 V.S.A. §§ 4632(a)(1)(A)(iii), 4632(a)(1)(B)(iii) [new]. "Clinical trial" means any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies. 18 V.S.A. § 4631a(a)(3) [new].

32 18 V.S.A. § 4632(a)(4) [new].

*33* The original Vermont statute required "every pharmaceutical manufacturing company [to] disclose to the [Vermont Attorney General] the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in [Vermont]." The following payments were exempt from disclosure:

- Free samples of prescription drugs intended to be distributed to patients.
- The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials.
- Any gift, fee, payment, subsidy, or other economic benefit, the value of which is less than $25.
- Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association, if the recipient of the scholarship or other support is selected by the association.
- Prescription drug rebates and discounts.

*See* 18 V.S.A. § 4632(a)(1), 4632(a)(4).

34 18 V.S.A. § 4632(a)(3) [new].

35 18 V.S.A. § 4632(a)(2) [new].

36 18 V.S.A. § 4632(a)(6) [new].

37 18 V.S.A. § 4632(b) [new].

38 1 V.S.A. § 317(c)(9) [new].

39 18 V.S.A. § 4632(c) [new].

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