

# S Q U A R <sup>2</sup> E D

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## Compliance Quick Reference

### THE VERMONT GIFT BAN AND DISCLOSURE LAW

FOR

### PRESCRIPTION DRUGS, BIOLOGICAL PRODUCTS AND MEDICAL DEVICES

*Includes information from 11/15/09 Guide to Vermont's Prescribed Products Law for  
FY10 Disclosures*

*and*

*"Answers to Questions from Manufacturers of Prescribed Products" dated 1/8/10*

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ATTACHMENT: Act 59: Vermont Pharmaceutical Marketing Disclosure Law

## About this Compliance Quick Reference

This R-Squared Compliance Quick Reference (the “Quick Reference”) is intended to be just that—an easy-to-read-and-navigate guide to the new requirements. The Quick Reference covers most, but not all, of the new Vermont law, so careful review of the statutory provisions is necessary. We will post updates to this Quick Reference and other information, compliance tools and articles about state and federal disclosure/aggregate spend requirements on the R-Squared website ([www.r2ss.com](http://www.r2ss.com)).

This version contains updates to the R-Squared Compliance Quick Reference dated 12/7/09.<sup>1</sup> These updates include, among other items, new guidance from the Vermont Office of the Attorney General (“Vermont AG” or “AG’s Office”) per the Vermont AG’s latest Vermont Guide updates (dated 11/5/09) and *Answers to Questions from Manufacturers of Prescribed Products* (“Answers to Questions”) document (dated 1/8/10).

In addition, this updated version includes unpublished guidance from Wendy Morgan, Assistant Attorney General for the Vermont Office of the Attorney General, stemming from her appearance at ExL Pharma’s Tracking and Reporting Aggregate Spend Conference on January 12, 2009, in Washington, DC.

Specifically, the Vermont AG addressed:

- Reporting of free samples of medical devices and combination medical devices and prescription drugs
- Clarifying the meaning of “regularly practice”
- Limitations on meals (and other gifts) to office staff
- Food provided in conjunction with market surveys
- Allocating group spend
- Revising the current reporting time periods
- Revisiting the requirement for a written agreement to be formed for training on a medical device
- Likelihood of continued enforcement with the enactment of a federal Sunshine law

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<sup>1</sup> Register to receive a free copy of the R-Squared Compliance Quick Reference for Vermont (1/19/10) or download the Update (1/19/10) at <http://www.r2ss.com/Pages/VermontRegistration.aspx>.

## Introduction

Not to be “outshined” by its neighbor, Massachusetts, which recently promulgated its Marketing Code of Conduct Regulations (click [here](#)<sup>2</sup> for information on those requirements), the State of Vermont enacted a strict gift ban and expanded reporting requirements for marketing expenditures, which became effective on **July 1, 2009**. These new requirements govern manufacturers of prescription drugs, medical devices, and biologics.

The law prohibits gifts, including meals, under most circumstances and expands its existing pharmaceutical marketing disclosure laws to include medical device and biologics manufacturers (and wholesale distributors of medical devices), making it the second state requiring so-called “aggregate spend” disclosure for device manufactures.

To assist the industry with compliance, the Office of the Attorney General of Vermont (“Vermont AG” or “AG’s Office”) hosted a series of teleconferences and has published a *Guide to Vermont’s Marketing Disclosure Law for Prescribed Products for FY10 Disclosures* (the “Vermont Guide”).<sup>3</sup> The latest version of the Guide is dated November 5, 2009. The Vermont legislature afforded the industry approximately one month to come into compliance. Also working under these tight time frames, the AG’s Office (Wendy Morgan and Jay Bailey) have been incredibly accommodating, informative, forthcoming, and helpful. They should be commended for their efforts.

Like the new Massachusetts requirements, these new laws will require meaningful effort to implement *smartly* across an organization. Numerous other states have proposed similar aggregate spend disclosure requirements, and the U.S. Congress has recently proposed several versions of the federal *Physician Payments Sunshine Act*. Widespread tracking of payments and expenses likely will be the reality within one year.

Armed with this knowledge, many life sciences manufacturers, including several of R-Squared’s customers, are seizing the *opportunities* that are embedded within this compliance hairball, including, but not limited to: complete spend management visibility and control; improved data quality, access, and analytic capabilities; marketing program evaluation and prioritization, and enhanced compliance program effectiveness. These organizations are viewing aggregate spend through both *business improvement* and *compliance* lenses.

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<sup>2</sup> If you are viewing a hardcopy version of this Quick Reference, then you can access the page at the following URL: [http://www.r2ss.com/Pages/IntroductionToTheCode\(MA\).aspx](http://www.r2ss.com/Pages/IntroductionToTheCode(MA).aspx)

<sup>3</sup> Click [here](#) to view the Vermont AG’s disclosure information website.

If the company is subject to aggregate spend laws, it will need to make a substantial investment in time and effort to build the infrastructure for compliance anyway, so a smart approach is determining how best to make compliance work *for* your organization.

## When does the law take effect?

The statute was enacted on June 8, 2009, and became effective on **July 1, 2009**. On this date, the gift ban took effect.

Pharmaceutical manufacturers must disclose their marketing expenditures (through June 30, 2009) by November 1, 2009, under the existing law. In subsequent years, however, the deadline for the disclosure of marketing expenditures for pharmaceutical, medical device and biological manufacturing companies will be October 1.

Significantly, manufacturers of medical device and biological products (as well as wholesale distributors of medical devices) must have started tracking certain payments and expenditures on **January 1, 2010**.

## What are some significant changes from the existing Pharmaceutical Marketing Disclosure Law?

The most significant change from the previous Vermont disclosure law is that, in addition to pharmaceutical manufacturing companies, the new law now applies to medical device and biological manufacturers as well as wholesale device distributors.

Moreover, the law now includes a gift ban in addition to the existing disclosure requirements.

The third notable change from the existing disclosure law is the broader list of recipients for which gifts are banned and expenditures are reported. The original law covered marketing costs provided directly or indirectly to any individual or entity in Vermont authorized to prescribe, dispense, or purchase prescription drugs in the state. The new law, however, includes the following recipients:

- any individual or entity authorized to dispense or purchase for distribution prescribed products in Vermont;
- any person who is authorized to prescribe or to recommend prescribed products and who either is licensed by this state to provide or is otherwise lawfully providing health care;

- certain persons affiliated with a health care professional (e.g., officer, employee, agent or contractor); or
- an academic institution or a professional, educational, or patient organization representing or serving health care providers or consumers.

Fourth, the new law removes the “trade secret” exemption which had allowed companies to keep specific expenses private (i.e., the expense would be reported to the state but not available to the public).

A fifth distinction of note is that Vermont eliminated the \$25.00 reporting threshold. Now, any covered expense must be reported (although there is an alternative aggregate disclosure option for items below \$25). According to the Vermont AG, manufacturers will even be required to report the provision of brochures, patient booklets, labels, and label inserts.

## What manufacturers are affected?

Companies covered by the law (i.e., “Covered Companies”) include manufacturers of “prescribed products” (i.e., manufacturers of pharmaceuticals, biological products, and medical devices, or any other person or company engaged in the production, preparation, propagation, compounding, processing, packaging, repackaging, distributing, or labeling of prescribed products for humans). Covered Companies must comply with the gift ban and must report expenditures to the Vermont Attorney General.

Whether a manufacturer is affected by the law turns on whether the product the company manufactures is for humans and falls within 21 U.S.C. § 321 (also referred to as “section 201 of the federal Food, Drug and Cosmetic Act”). For example, in its “Answers to Questions” guidance, the Vermont AG was asked if a company manufactures only components of a prescribed product which it then sells to a pharmaceutical manufacturer for use in a prescribed product is subject to the Act. The Vermont AG responded “If the products do not fall within 21 U.S.C. § 321, they are not subject to the statute.” Presumably, this means that if the component does not fall within § 321, then the manufacturer is not covered by the law. The Vermont AG’s use of the term “products,” however, can be interpreted as vague. What if the component doesn’t fall with § 321, but the prescribed product it is a component for does fall within § 321. Moreover, do both “products” (i.e., both the component and the main product) need to fall outside of § 321?

In addition, According to the Vermont AG, with regards **only to pharmaceutical** products, the law applies only to pharmaceutical manufacturers which are licensed by the Vermont Board of Pharmacy. This is similar to the Minnesota law, in which companies not licensed as a

“manufacturer” in Minnesota do not need to follow the Minnesota gift ban and disclosure requirements.

## What about manufacturers of non-prescribed products?

Originally, Vermont Office of the Attorney General stated that, “[a]lthough the federal statutory sections [21 U.S.C. § 321] cover products that are not prescribed, the Vermont law applies only to prescribed products.” This guidance seemed to suggest that manufacturers of products that are available without a prescription were not subject to these requirements.

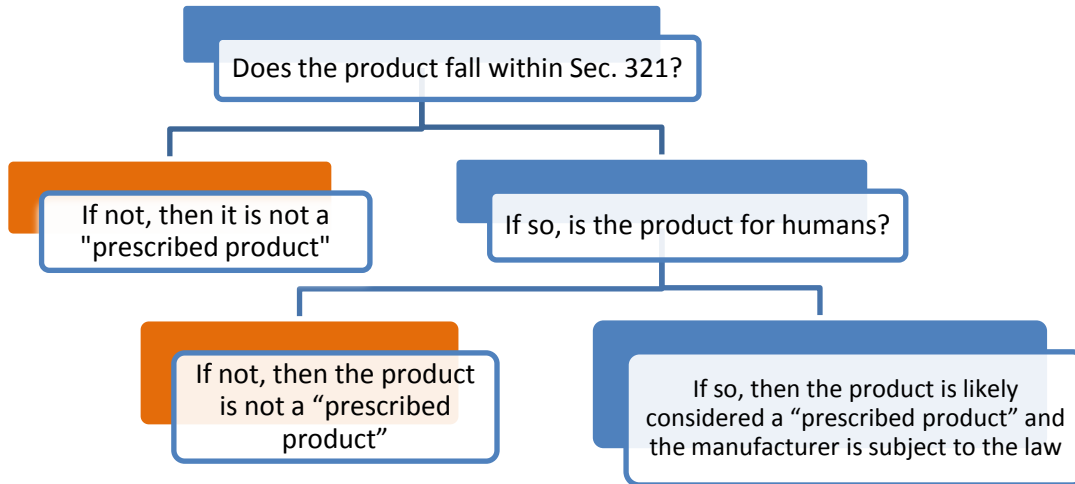
The AG’s Office has since clarified this interpretation. In its guide, the AG stated, “[a]lthough the federal statutory sections cover pharmaceutical products that are not prescribed and drugs and devices for animals, the **Vermont law applies to prescription drugs, biological products, and medical devices for humans**. A company that manufactures *only* products that do not fit within the definition above does not need to report” (bold emphasis added).

Moreover, the Vermont AG clarified in its “Answers to Questions” document that products such as medical equipment – the use of which does not require a prescription – is covered by the law (as long as the product is for humans and falls within § 321). The manufacturer of a diagnostic testing machine in which the patient's physician writes a prescription for the test itself is also subject to the law.

The Vermont AG has also clarified that "implants" (such as a rod or plate used to repair a hip fracture) fall within the definition of a "device" under § 321, and are therefore covered by the law. In addition, a nebulizer used to administer a drug is a prescription device that is covered by the law if the nebulizer falls within 21 U.S.C. § 321.

The AG also provided the following examples of “prescribed products” which are covered by the law: medical oxygen, medical food products, and a CT scanner. However, products that fall within § 321 but are not for humans (e.g., veterinary products) are not subject to these requirements.

In short, a simple way to determine whether a company manufactures a product which is subject to the law is to conduct the following two-pronged analysis:



One last important note is that, according to the Vermont AG, if a company manufactures both “covered products” (i.e., “prescribed products”) and “non-covered products” (i.e., products that do not fall within § 321 or are not for humans), allowable expenditures must be reported (and the gift ban followed) even if the expenses only relate to non-covered products.

## Are distributors covered by the law?

According to the Vermont AG, wholesale distributors of prescription drugs and biological products are not “manufacturers” under the law and, therefore, are not required to follow the gift ban or annual disclosure requirements. However, Covered Companies include wholesale distributors of medical devices. Covered Companies are expressly subject to the gift ban. Moreover, the Vermont AG has stated in its guidance that annual disclosure requirements also apply to wholesale device distributors.

## What does the law require?

The law requires manufacturers and wholesale device distributors to:

- annually complete and submit the Compliance Officer Form (electronically) for the individual responsible for the company’s compliance with the new law. An electronic version of the Compliance Officer Form can be accessed [here](#)<sup>4</sup>.
  - Pharmaceutical manufacturers must complete and submit the Compliance Officer Form by July 1, 2009, which includes the name and address of the individual responsible for the company’s compliance with the new law.
  - Although manufacturers of biological products and medical devices and wholesale device distributors are not required to complete this form until July 1,

<sup>4</sup> If you are viewing a hardcopy version of this Quick Reference, then you can access the form at the following URL: [http://www.atg.state.vt.us/upload/1245082590\\_Compliance\\_Officer\\_Form.pdf](http://www.atg.state.vt.us/upload/1245082590_Compliance_Officer_Form.pdf)

2010, they are encouraged to complete it by July 1, 2009, so that the Vermont AG can distribute compliance guidance and other information.

- pay an annual registration fee of \$500;
  - pharmaceutical manufacturers with expenditures above \$0 for the previous fiscal year must send a \$500 registration fee by July 1, 2009, as required under the original Vermont law.
  - Manufacturers of biological products and medical devices and wholesale device distributors with expenditures to report do not have to file this annual fee until July 1, 2010, and annually thereafter.
- obey the “gift ban”; and
- track and disclose annually to the state any fees, payments and other expenditures provided to HCPs and other enumerated recipients;
  - Pharmaceutical companies must disclose their marketing expenditures (through June 30, 2009) by November 1, 2009, under the original law.
  - In 2010 and subsequent years, however, the deadline for the disclosure of marketing expenditures for all manufacturers and wholesale device distributors will be October 1.

## What is the Gift Ban?

Quite simply, the law prohibits manufacturers of prescribed products and wholesale distributors of medical devices from offering or giving any gift to a health care provider. The Vermont prohibitions are broader than those set forth in the PhRMA and AdvaMed Codes.

There are exceptions to this gift ban and they take 2 forms: (i) “allowable expenditures,” which fall outside the definition of a gift; and (ii) expenditures that fall outside the scope of the gift ban (“not banned”).

The Vermont AG has provided the following as examples of gifts which are **banned** under the law:

- monetary donations from a manufacturer of prescribed products to a doctor or clinic;
- charitable donations to a hospital;
- fellowship for a residency program even if the company does not select the recipient;
- lunch provided in a doctor’s office at which information on a drug is discussed, unless the office reimburses the pharmaceutical representative for the lunch;
- coffee and donuts for the non-prescribing staff in a physician’s office;

- dinner provided anywhere, including outside of Vermont, to a physician who regularly practices in Vermont; and
- providing transportation for a Vermont physician to an event, even if the event takes place outside of Vermont, unless the physician reimburses the reasonable expenses of the trip.

## What is a health care provider?

Health care providers are the individuals and entities that can no longer be offered or provided “gifts” by manufacturers. The term “health care provider” includes:

- a health care professional
- residents and fellows
- hospitals
- nursing homes
- pharmacists
- health benefit plan administrators
- any other person authorized to dispense or purchase for distribution prescribed products in Vermont

Consumers are not considered health care providers.

## Who is a health care professional?

A “health care professional” (included in the definition of health care provider) means a person who is authorized:

- to prescribe<sup>5</sup> or recommend prescribed products; and
- is either:
  - licensed by this state to provide health care; or
  - lawfully providing health care in this state.

In addition, a health care professional includes a partnership or corporation made up of the persons described in the bullet points above.

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<sup>5</sup> According to the Vermont AG, all licensed Physician Assistants, including the credentials “PA” and “PA-C” (certified Physician Assistant), are licensed to prescribe.

Furthermore, the definition of health care professional includes the following affiliated individuals: an officer, employee, agent,<sup>6</sup> or contractor of a person described in the bullet points above 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. However, a person is not considered to be a health care professional if the person is employed solely by a manufacturer.

The statute and regulation do not address if an employee of a covered company is the spouse, significant other, or friend of a healthcare professional. Nonetheless, the Vermont AG has offered guidance about this circumstance and wrote in its “Answers to Questions” document that if a meal or gift is in any way business related, the employee must follow the requirements of the statute. If it is not business related then the law does not apply; it is not the intention of the Vermont AG to restrict personal gift giving.

The inclusion of individuals who can “recommend” prescribed products, however, will present interesting compliance challenges and differing interpretations. In its guidance, the Vermont AG stated that it considers counselors, such as licensed clinical social workers or licensed psychologists, to be in a position to recommend prescribed products and would be covered. Similarly, AG guidance has also suggested that nurses are considered health care professionals (thus, speaker and “other reasonable fee” requirements must be applied to nurses as well). Presumably, all licensed caregivers (even those without prescriptive authority) are in a position to recommend a course of care. Indeed, the array of individuals who can *recommend* prescribed products could be dizzying and companies likely will need to draw reasonable parameters, based on principled criteria and its own “gift” recipients, to determine the scope of the ban and the individuals for whom it will track and report expenses. It should be noted, however, that non-prescribing staff in a physician’s office are included in the definition of health care professional, but non-prescribing staff of a hospital or nursing home are not currently included in the definition unless the staff works for, or at the direction of, a prescriber.”

From a data capture standpoint, and particularly for those organizations attacking these requirements from both a business improvement/analytics *and* compliance perspective (e.g., organizations seeking to obtain an accurate picture of all corporate spend, perform analyses, prioritize spending, etc.), we recommend capturing what we refer to as the “super set” — capture all of the data, and report only that which is required.

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<sup>6</sup> The AG clarified the term “agent” by determining in its “Answers to Questions” document that a dietician who works with a physician and consults with patients in a clinical setting is considered an “agent” of the health care professional.

## What is a Gift?

A “gift” is:

- 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, unless it is an “allowable expenditure” or the health care provider reimburses the cost at fair market value.

Thus, the provision to Vermont health care providers (including health care providers who regularly practice in Vermont) of anything of value, including meals, for free is prohibited.

According to the Vermont Guide, two **examples** of banned gifts are “monetary donations from a manufacturer of prescribed products to a doctor or clinic” and “lunch provided in a doctor’s office at which information on a drug is discussed, unless the office reimburses the pharmaceutical representative for the lunch.”

It would seem that this latter statement disregards certain of the allowable expenditures (e.g., the allowable expenditure for fair market value exchanges), which arguably permits meals in a doctor’s office in certain circumstances. For example, what if the lunch is provided in the office of a doctor with which the company maintains a consulting relationship and the physician is rendering services throughout the lunch? Arguably, such a meal would be permissible as a fair market value exchange, which is an “allowable expenditure.”

Indeed, in its “Answers to Questions” document, the Vermont AG concluded that market research, whether or not blind, paid at fair market value is an allowable expenditure under the provision for “other reasonable fees at fair market value,” although such payments must be reported. The Vermont AG has also stated that food provided in conjunction with market research “would not be allowed unless the health care providers reimbursed the manufacturer for the food,” but the Vermont AG did not address if the meal was part of the fair market value compensation.

## What are “allowable expenditures”?

“Allowable expenditures” are payments made to (or expenses incurred on behalf of) Vermont health care providers that are not considered gifts for purposes of the gift ban (i.e., a “non-gift”). A payment or expense must meet specific criteria in order to be considered an allowable expenditure. Although these are not considered gifts, manufacturers (and device distributors)

are nevertheless required to track and report such payments and expenditures (except for royalties and licensing fees) on an annual basis.

There are the following seven categories of allowable expenditures:

- **Third Party Conference Sponsorship.** Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:
  - the payment is not made directly to a health care provider;
  - funding is used solely for bona fide educational purposes; and
  - all program content is objective, free from industry control, and does not promote specific products.

*Example of allowed expenditure:* Monies given to an academic institution for a conference meeting the above criteria must be reported and may be used by the academic institution for any expenses of the educational program, including meals.

*Example of prohibited expenditure:* Support provided to a hospital for a manufacturer-run conference.

- **Speaker Fees.** 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, provided:
  - there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and
  - the content of the presentation, including slides and written materials, is determined by the health care professional.
- **Clinical Trial Fees.** For a bona fide clinical trial:
  - gross compensation for the Vermont location or locations involved;
  - direct salary support per principal investigator and other health care professionals per year; and
  - expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.
- **Research Fees.** For a research project that 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:

- gross compensation;
  - direct salary support per health care professional; and
  - expenses paid on behalf of each health care professional.
- **Technical Training Related Expenses.** Payment or reimbursement for the reasonable expenses, including food, travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer. These expenditures are allowable whether or not CME credits are available for the training. Costs of setting up and providing training on a medical device where the prescribers are not paid by the manufacturer for their time or expenses in taking the training need not be reported.
    - *Examples:* The cost of a cadaver used in the training need not be reported. The cost of a hotel room for an individual health care professional does need to be reported.

Expenditures on employees of hospitals, nursing homes and pharmacists, if such employees are not prescribers, e.g. an X-ray technician or an LPN, are allowable and need not be reported at this time.

- **Royalties and licensing fees.** 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. The payment of royalties and licensing fees does not need to be disclosed.
- **Fair Market Value Exchange.** Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.
  - *Examples include:*
    - Expenses for advisory meetings or product development meetings, even those including food, as long as the payment for the work is at fair market value.
    - Payment to a physician to present information to other physicians, even without CME accreditation; no food may be provided if the presentation takes place in Vermont or is to prescribers who regularly practice in Vermont.
    - A “clinical trial” which is not FDA-approved is an allowable expense if it meets the requirements of a “research project,” or may be an allowable expense if it is a payment for fair market value.

Being that the law prohibits all gifts—a term that is broadly defined—the scope and meaning of allowable expenditures and not-banned activities set the parameters for permissible payments to and on behalf of health care providers. Perhaps of the greatest significance is the last category of allowable expenditures for Fair Market Value Exchanges.

The plain language of this provision states that any payments provided at fair market value are allowable expenditures. Presumably meals and other expenses/payments when set forth in an agreement as part of the fair market value compensation would be permitted.

However, the second example (“Payment to a physician to present information to other physicians, even without CME accreditation; no food may be provided if the presentation takes place in Vermont or is to prescribers who regularly practice in Vermont”) would be an obvious example if not for the qualification “no food may be provided” which adds confusion. If the food is part of the fair market value calculation, it would seem to satisfy the requirements.

In its “Answers to Questions” document, the Vermont AG concluded that market research paid at fair market value is an allowable expenditure under the provision for “other reasonable fees at fair market value.” Such payments, however, must be reported. Presumably, using this logic a payment for market research and similar activities could be paid with food if the food is part of the fair market value calculation. It should be noted that the Vermont AG has stated in its “Answers to Questions” document that food provided in conjunction with a survey “would not be allowed unless the health care providers reimbursed the manufacturer for the food,” but the Vermont AG did not address if the meal was part of the fair market value compensation.

Another curious aspect of this guidance is that a literal reading of this provision (“no food may be provided if the presentation takes place in Vermont ....”) could yield the determination that a meal cannot be provided to a VT-licensed health care professional (who does not regularly practice in Vermont) *if the presentation takes place in Vermont*. This likely is semantic and not intentional, as it would be a new concept—i.e., event location—which is not supported by the language of the statute. Future clarification of this guidance would be helpful.

## What are “Not-Banned” Expenditures?

As noted above, there are two types of exceptions to the Vermont gift ban: (i) allowable expenditures (discussed above); and (ii) unaffected or “not banned” expenditures, which are the following expenditures that fall outside the scope of the gift ban.

- **Product Samples.** Free samples of a prescribed product provided to a health care provider for free distribution to patients. This includes the labels and package inserts approved by the federal Food and Drug Administration for the samples and free samples

provided to a Vermont prescriber for humanitarian needs to be distributed outside the United States.

- **Loaner Units.** 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. These devices will be returned to the device manufacturer.
  - *Examples include:* a medical imaging instrument loaned for evaluation purposes, such as an X-ray; the loan of an ultrasound machine to an office to replace a broken machine until the office receives a replacement.
- **Demonstration/Evaluation Units.** 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 determine whether and when to use or recommend the product in the future. Unlike Loaner Units, these devices are single-use or provided for patient education purposes.
  - *Example of a demonstration unit:* a model of a prosthetic device to be used in a knee replacement for the purpose of illustrating information to the patient.
  - *Example of an Evaluation Unit:* single-use instruments that will not be returned to the device manufacturer, such as disposable devices for endometrial ablation or urodynamic testing.
- **Educational Items.** 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.
  - *Examples include:* Brochures for patients, including ones that display a corporate logo; medical books or product information for physicians; models of human anatomy; and other visual aids to be used with patients.
- **Financial Support for Trainees.** 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.** Rebates and discounts for prescribed products provided in the normal course of business.

- **Product Labels.** Labels approved by the federal Food and Drug Administration for prescribed products.
- **Gifts to academic institutions and professional, educational, or patient organizations** representing or serving health care providers or consumers are not banned, but must be reported.

### **Is the University of Vermont considered an “academic institution” or “health care provider”?**

The Vermont AG has stated in its Guide that the University of Vermont (which includes a College of Medicine) is an academic institution. Therefore, gifts may be provided to the University, but they must be reported.

### **Is the donation to an academic institution for a CME program banned?**

The Vermont Guide lists several “not-banned” expenditures, including gifts to academic institutions and professional, educational, or patient organizations representing or serving health care providers or consumers.

In its guide, the Vermont AG clarified that the donation to an academic institution for a CME program is not banned, but must be reported.

### **Can a payment be made to a hospital that is sponsoring an educational conference?**

Conference sponsorship is not banned as long as (1) the event is a significant educational, medical, scientific, or policy-making conference or seminar, (2) the payment is not made directly to a health care provider, (3) the funding is used solely for bona fide educational purposes, and (4) all program content is objective, free from industry control, and does not promote specific products.

Originally, during a conference call, the question was posed whether a payment to the hospital sponsoring an educational conference is banned under the law. The Vermont representative gave a strict interpretation of the statute and stated that because the payment is made directly to a health care provider (i.e., the hospital), the payment is banned.

The Vermont AG's Office has since clarified this interpretation and concluded in its "Answers to Questions" document that a payment to the hospital for staff time is an allowable expenditure (which must be reported) if the total is reasonable and each component is at fair market value. Payment to the hospital for food, however, is banned (unless the hospital or recipient pays fair market value for the food). It should also be noted that the Vermont AG considers the University of Vermont (which includes a College of Medicine) an academic institution. Therefore, gifts may be provided to the University, but they must be reported.

The law also exempts from the gift ban scholarships 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 as long as the recipient of the scholarship or other support is selected by the association. The Vermont representative stated that an association likely includes a hospital. Therefore, it begs the question whether a scholarship can be provided to a hospital in order to support its students, residents or fellows to participate in a conference sponsored by the hospital itself.

### **May a health care provider act as the repository for money paid by a Covered Company to help pay expenses of a conference?**

According to the AG's Office, to not run afoul of the Vermont law, the donation should not run through a health care provider; instead, it should run through an academic institution or through a professional, educational, or patient organization representing or servicing health care providers or consumers. The payment to these entities must be reported.

### **Can a Covered Company sponsor a fellowship for a residency program?**

According to the Vermont Guide, a manufacturer/wholesale device distributor may not sponsor a fellowship for a residency program because the sponsorship is considered a banned gift. In fact, the sponsorship is banned even if the company does not select the recipient of the fellowship.

As industry support of fellowship programs is longstanding, commonplace, and is expressly permitted under the AdvaMed Code (and not prohibited under the PhRMA Code), this prohibition promises to be quite disruptive—both to the manufacturers and the programs that have grown accustomed to this financial support.

Although this type of fellowship is explicitly banned, the following is allowed and must be reported: "Scholarships 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 as long as the recipient of the scholarship or other support is selected by the association.”

### **May a Covered Company pay health care providers to provide feedback through market research surveys?**

In its “Answers to Questions” document, the Vermont AG concluded that market research paid at fair market value is an allowable expenditure under the provision for “other reasonable fees at fair market value.” Such payments, however, must be reported. Moreover, the Vermont AG expressly stated that this type of payment is allowed whether or not the survey is blind.

If a covered company hires an independent third party vendor to conduct blind market research studies at various conferences, and the vendor provides payment to participants, the payments made by the vendor (and the payments to the vendor) do not have to be reported if the physician does not learn which company is paying for the survey.

The Vermont AG was asked whether food may be provided in conjunction with the survey. In its “Answers to Questions” document, the Vermont AG responded that “food would not be allowed unless the health care providers reimbursed the manufacturer for the food.” The Vermont AG did not take into consideration, however, whether food would be allowed if it was part of the fair market value compensation.

### **Does the gift ban apply to VT-licensed physicians who regulatory practice out-of-state?**

In general, the Vermont law bans gifts to Vermont-licensed health care providers. However, the Vermont AG allows gifts to be provided to health care providers with an active Vermont license in certain circumstances if the provider does not regularly practice in Vermont.

Originally, the Vermont AG stated that VT-licensed health care providers who are also licensed in another state (such as New Hampshire) may not receive a gift from manufacturers and distributors covered by the law if the provider’s “primary office” is located in Vermont.

In its guidance, the Vermont AG clarified that the gift may be not provided if the provider “regularly practices” in Vermont. Furthermore, even if the gift is not banned, it must still be reported because the provider is licensed in Vermont.

Therefore, taking a Vermont prescriber who regularly practices in Vermont to dinner in New Hampshire is banned. In contrast, taking a Vermont health care provider who does not regularly practice in Vermont to dinner in New Hampshire is not banned, but must be reported.

One important note about this guidance is that the Vermont AG has not definitively stated what is meant by “regularly practices.” For example, is the gift allowed if the provider practices in another state slightly more than Vermont? It appears that the answer to this question is “no.” In a private conversation with Wendy Morgan, Assistant Attorney General in Vermont, Ms. Morgan told R-Squared that a health care provider “regularly practices” in Vermont even if the provider practices a majority of the time in a state other than Vermont. Ms. Morgan stated that even if the health care provider practices in Vermont once a month, this is still considered to be “regularly practicing” and the gift ban must be followed. Therefore, Covered Companies would be well-advised to interpret the phrase “regularly practices” broadly to include most forms of reoccurring practice in Vermont. In fact, in its “Answers to Questions” document, the Vermont AG has stated that Covered Companies “may assume that any health care provider with an active Vermont license ‘regularly practices’ in Vermont.”

## What is the deal with meals?

The definition of the term “gift” is defined very broadly under the law and expressly includes “food.” Consequently, most meals with VT-licensed health care providers who regularly practice in Vermont are prohibited under this law. Indeed, the Vermont Guide offers the following as an example of a banned gift: “lunch provided in a doctor’s office at which information on a drug is discussed, unless the office reimburses the pharmaceutical representative for the lunch.”

The following is a summary of **food-related examples** discussed during the guidance calls with the Vermont AG as well as in the AG’s “Answers to Questions” document:

Example 1: A company representative provides lunch to a medical office with Vermont-licensed physicians in connection with an educational presentation.

Guidance for Example 1: Although the AG’s Office has stated in its guidance that the company cannot provide free food to a VT-licensed health care provider who regularly practices in Vermont, the company can provide the lunch to the office as long as the cost of the lunch is reimbursed by the office. Similarly, the company can simply bring food to the presentation but the office or individual attendees must purchase (at cost) whatever food is consumed. The same rule applies if it is a promotional or other type of non-educational presentation. Furthermore, the same rule applies if the presentation takes place outside of the office.

Example 2: The company hosts a technical training session and invites Vermont-licensed health care professionals to participate. The company wants to provide food to the participants.

Guidance for Example 2: The law states that a Covered Company may provide “[p]ayment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.” During the conference call, the Vermont representative stated that reasonable expenses can include the provision of a meal.

Example 3: The company wants to provide a tour of its facility, which is outside the state of Vermont, and modest refreshments (soda and cookies) to prospective customers. Would that activity be prohibited by Vermont law?

Guidance for Example 3: The AG’s Office has stated in its guidance that the company cannot provide free food (including modest refreshments) to a health care provider who regularly practices in Vermont. However, the company may provide free meals outside Vermont to a physician who is licensed in Vermont but who does not regularly practice in Vermont, although the company must report such expenditures.

Example 4: The company offers a CME activity to physicians from Vermont and New Hampshire to attend a CME activity in which a physician would speak for one hour on a new drug that the company makes. Can the company provide a modest dinner at a restaurant in order to entice physicians to attend?

Guidance for Example 4: The company cannot provide free food to a health care provider who regularly practices in Vermont. The company may provide free meals outside Vermont to a physician who is licensed in Vermont but who does not regularly practice in Vermont, although the company must report such expenditures. No expenses would have to be reported for physicians who are only licensed in New Hampshire.

Example 5: If a health care provider is participating in a speaker program, would meals be allowed either in the office/hospital setting or in an outside setting? Would meals be permissible for either the speaker or attendees?

Guidance for Example 5: Free meals to prescribers **and their staff** are banned in or outside the **prescriber's office**. Similarly, in its guide the AG states that “coffee and donuts for the non-prescribing staff in a **physician’s office**” (emphasis added) are banned. A speaker may provide

meals, however, as long as the prescriber reimburses the speaker for the fair market value of the meals. The Vermont AG also states in its guidance that “[a]t this time, the gift ban does not extend to staff members of a hospital or nursing home that do not work for, or at the direction of, a prescriber.”

It is important to note that this guidance does not necessarily mean that non-prescribing staff (of a hospital, nursing home or pharmacist) who are “recommenders” of prescribed products may be provided free meals, although it appears that the AG’s Office may be narrowing the scope of “recommenders” to licensed individuals such as licensed clinical social workers or licensed psychologists. Nonetheless, there is a clear distinction involving non-prescribing staff for a physician’s office as opposed to a hospital or nursing home.

If the speaker program meets the requirements of “honoraria and payment of expenses,” then the meal can be provided to the speaker but must be reported. On the other hand, if it does not meet those requirements (e.g., if the speaker will not be speaking at a bona fide significant educational conference), such as at a speaker training program, then the expense is allowed only if it is at fair market value and must be reported.

Example 6: The company wants to provide meals to health care professionals serving on the company’s advisory board.

Guidance for Example 6: In an effort to clarify the fair market value provision of allowable expenditures, the Attorney General’s Office has stated that as long as the meal (or other transfers of value) is provided to the health care professionals at fair market value, then they are allowed.

It is important to note, however, that if meals (or other generally prohibited transfers of value) are provided in a technical training session or to a speaker, the Attorney General’s Office has stated that certain elements must be described in a written agreement. In addition, meals generally cannot be provided to attendees at a conference.

## **Can a charitable contribution be made to a hospital?**

No. Under the law’s gift ban, a charitable contribution made to any health care provider (including a hospital) is prohibited. Similarly, grants provided to free clinics are also banned under the law.

## **Can a donation be made to the foundation of a hospital or academic institution?**

In its “Answers to Questions” document, the Vermont AG has determined that a donation to a foundation of a hospital is a gift and is banned. However, if the institution is an academic institution, the gift is not banned but must be reported.

This guidance may be subject to challenge, however, in instances where the hospital foundations are 1) completely separate from the hospital itself (e.g., separately incorporated) and 2) not “healthcare providers” under the Vermont law – which would likely include many, if not most, hospital foundations. Therefore, it remains to be seen whether this Vermont AG guidance is a supportable interpretation.

## **Can a company’s charitable foundation provide donations to health care providers?**

If a covered company established and endowed a charitable foundation that provides a variety of charitable donations to bona fide U.S. charities, the charitable foundation may provide donations to health care providers if the foundation is a separate legal entity and has a separate board of directors.

## **Can medical textbooks be provided to health care providers?**

Yes. The gift ban does not apply to 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. On a teleconference call and in the Vermont Guide, the Vermont AG explicitly stated that this exception to the gift ban includes medical textbooks, anatomical models, brochures, and posters.

## **Is the replacement of a damaged device for free of charge allowed?**

During the call, a question was posed whether a Covered Company can repair a damaged device for a health care provider free of charge. According to the Attorney General’s Office, if the purchase was made pursuant to a written agreement which included the repair of the device free of charge, then the service is allowed. While not specifically asked, it appears that the response hinged on the existence of a contractual obligation to provide the replacement

unit. In the absence of such an affirmative obligation, such a replacement arguably is prohibited.

## **Can a Covered Company support a benefit golf tournament by providing the golf balls?**

According to the Vermont AG in its “Answers to Questions” document, if the sponsor of an event meets the definition of a health care provider, then a manufacturer may not provide free golf balls because that would be considered a gift. If the sponsor is an academic institution or a professional, educational, or patient organization representing or serving health care providers or consumers, the gift is allowed and must be reported. If the sponsor is neither of the above, the gift is allowed and need not be reported.

The AG’s guidance to this question, however, does not address whether any golfers at the event are VT-licensed health care providers who regularly practice in Vermont. A narrow interpretation of the law would conclude that the covered manufacturer would be banned from providing golf balls to such health care professionals because the balls would be a gift. In the alternative, the manufacturer might be allowed to provide the sponsor with a donation, and the sponsor (without any influence from the manufacturer) could choose to use the donation for free golf balls. Does the analysis change if the balls contain a symbol or product name associated with the manufacturer? Arguably, the conclusion may not change because, by analogy, independent sponsors are allowed to create signs that a particular manufacturer sponsored a lunch as long as the manufacturer did not request that the donation be used toward a lunch.

## **Can meals be provided to the staff of health care providers?**

In short, there are limited circumstances in which meals can be provided to the staff of health care providers. It should be noted, however, that in the Vermont statute, the ban on gifts (which includes meals) applies to any “health care provider,” which includes health care professionals.

The Vermont AG appears to make a distinction between staff in a physician’s office as opposed to the staff of a hospital or nursing home. In its “Answers to Questions” document, the Vermont AG has stated generally that manufacturers of prescribed products are prohibited from giving meals to health care professionals, including employees of prescribers who, in the course of their employment, do work related to or supportive of the provision of health care.

Similarly, the AG states that “Free meals to prescribers and their staff are banned in or outside the **prescriber’s office**” (emphasis added). In addition, in its guide the AG states that “coffee and donuts for the non-prescribing staff in a **physician’s office**” (emphasis added) are banned. A speaker may provide meals, however, as long as the prescriber reimburses the speaker for the fair market value of the meals.

Conversely, the Vermont AG clarified in its “Answers to Questions” document that “[a]t this time, the gift ban does not extend to staff members of a hospital or nursing home that do not work for, or at the direction of, a prescriber.” The Vermont AG has removed previous guidance allowing meals provided to pharmacy staff, but this should not necessarily be interpreted to indicate that such meals would be prohibited.

In determining whether a meal is banned, it should be noted that anyone who fits under broad definition of “health care professional” would likely be included as a prohibited gift recipient. The definition of health care professional includes certain officers, employees, agents, or contractors of individual health care professionals, whereas the definition of health care provider does not include such language other than the extent it applies to health care professionals.

It should also be noted that the above guidance does not necessarily mean that non-prescribing staff of a hospital, nursing home or pharmacist who are “recommenders” of prescribed products may be provided free meals, although it appears that the AG’s Office may be narrowing the scope of “recommenders” to licensed individuals such as licensed clinical social workers or licensed psychologists.

## **Does a written agreement need to be formed for training on a device?**

Under the Vermont statute, Covered Companies are allowed to provide for the payment and reimbursement of expenses (including travel and lodging) to “health care professionals” in order to train the professionals on the use of a medical device **as long as** such expenses and the amounts or categories of reasonable expenses to be paid are described in a **written agreement** between the “health care provider” and the Covered Company. The issue many device companies have raised is that, in order to be considered an “allowable expenditure,” this provision appears to require that a written agreement be established for both trainers **and trainees** who are licensed physicians in Vermont.

The Vermont AG, and specifically Wendy Morgan, are sensitive to the need to train physicians on the safe and appropriate use of medical devices and have been helpful in attempting to amend these requirements. Such a change, however, would require legislative action. To that

end, Ms. Morgan has afforded R-Squared the opportunity to submit comments and propose a viable solution to this requirement which would be amenable to the medical device industry. Stay tuned for future updates.

## What are the disclosure/reporting (“Aggregate Spend”) requirements?

Annually on or before October 1 of each year, every manufacturer of prescribed products must disclose to the Vermont AG for the fiscal year ending the previous June 30<sup>th</sup> the value, nature, and purpose, and recipient information of an allowable expenditure or not-banned item provided to a(n):

- health care provider;
- academic institution; or
- professional, educational, or patient organization representing or serving health care providers or consumers.

However, the following expenditures do not have to be reported:

- royalties and licensing fees;
- rebates and discounts for prescribed products provided in the normal course of business; or
- free samples of prescription drugs (both chemical compounds and biologics) provided to a health care professional for free distribution to patients need not be reported, but free samples of medical devices and combination medical devices and prescription drugs must be reported.

In addition, payments for clinical trials do not always have to be reported in the same year they are made, but they do have to be reported under the delayed reporting requirements set forth in the law. See below (“Must payments for clinical trials be reported?”) for more details.

## What information must be reported?

Disclosure shall be made electronically on a form and in a manner prescribed by Vermont AG. At a minimum, the law requires manufacturers to disclose to the state on an annual basis the following information relating to reportable expenditures:

- **Value/amount of expenditure** (fair market value of the benefit, rounded to the nearest dollar);

- **Nature** – Identify the nature of the economic benefit given (e.g., cash/check, educational materials (such as books, journals, or brochures), donated demonstration or evaluation units of medical devices, loan of medical devices, free samples of medical devices or combination medical devices and prescription drugs, other, or an out-of-state gift or allowable expense to a Vermont-licensed prescriber). *Do not use “other” unless the expenditure does not fit into one of the supplied categories;*
  - An “out-of-state gift or allowable expenditure” can be used only if you verify that the recipient does not regularly practice in Vermont and you report the value, nature (e.g. food, travel, lodging), and purpose of the expenditure. If the recipient does regularly practice in Vermont, any gift is banned and any other expenditure must fall within the definitions of allowable expenditures.
- **Purpose** – Identify the primary purpose of the expenditure (e.g., conference sponsorship; speaker honoraria or expenses for serving on seminar faculty; seminar scholarship for unidentified medical students; technical training on a medical device; bona fide clinical trial; research project; gift to academic institution or to a professional, educational, or patient organization representing or servicing health care providers or consumers; other marketing; or other). Do not use “other” for “other marketing” unless the expenditure does not fit into one of the supplied categories.
  - Expenses for clinical trials need not be reported until the earlier of the fiscal year in which the Food and Drug Administration has approved or cleared the prescribed product or the second fiscal year after the payment was made.
  - Note: You must notify the Vermont Attorney General of any clinical trial for which disclosure of an expenditure is delayed. Use the form provided for this purpose on the Attorney General’s website.
- **Recipient information**, including address, state board number and institutional affiliation (e.g. doctors; other prescribers; health benefit plan administrators; hospitals or clinics; nursing homes; pharmacists; any other health care provider; academic institutions; and a professional, educational, or patient organization representing or serving health care providers or consumers);
  - Manufacturers must include the Vermont license number of the prescriber or pharmacist. All license numbers are in the form of three digits, dash, seven digits (i.e., xxx-xxxxxxx).
  - Use a license number of “000-0000000” for any recipient who is not a prescriber or pharmacist (i.e., hospitals; nursing homes; health benefit plan administrators; others authorized to dispense or purchase prescribed products for distribution; academic institutions; and professional, educational, and patient organizations representing or serving health care providers or consumers). In its “Answers to Questions” document, the Vermont AG stated that Covered Companies

will be asked to verify that an individual with a license number of 000-0000000 is a health benefit plan administrator or a person authorized (but not licensed) to dispense or purchase prescribed products.

- **Name(s) of the product(s)**, if a prescribed product(s) is being marketed,

These requirements are similar, but distinct, to other state laws and the impending federal *Physician Payments Sunshine Act* provisions. Because of the wide range of reportable expenditures and the sheer amount of information that manufactures must collect, track, sort and report under this and other laws, all but the smallest companies will need a solution to manage compliance. Indeed, based on our experience, maintaining a current and accurate vendor/third party master for use with internal systems is a significant challenge by itself (i.e., to ensure that the Dr. John Smith in one program is the same Dr. John Smith referenced in another software program).

Before making any decisions as to the best approach and strategy, we recommend that you demonstrate our SpendTracker® software. [SpendTracker®](#) is the only fully configurable end-to-end solution for aggregate spend that allows the linking of all upstream and downstream compliance together with spend pre-approval capabilities. [SpendTracker®](#) includes an up-to-date third-party master that includes all health care professionals and other health care providers in Vermont. In fact, our master list includes all of the requisite information above and more.

## **How is the value of brochures, labels, and other non-sale items valued and reported?**

Manufacturers and wholesale device distributors can either report the fair market value of the item, rounded to the nearest dollar, or elect to make “Alternative Aggregate Disclosures.” Specifically, the Vermont Guide states:

For gifts that are not banned but are of a fair market value below \$25, such as a small number of educational brochures provided to a prescriber, the manufacturer may elect to report the expenditures for all Vermont prescribers or institutions in the aggregate. For items that are not customarily sold (such as educational brochures for patient use), the value is the manufacturer’s cost of production. For items that are produced for national use, the value is the portion of the manufacturer’s cost attributable to Vermont.

## What is the dollar threshold which triggers reporting?

There is no dollar threshold. Although the existing Pharmaceutical Marketing Disclosure Law did not require manufacturers to report expenditures which were less than \$25.00, this new law requires manufacturers to report any amount above \$0, no matter how small. This is a significant departure from most state disclosure laws, but the House draft of the Federal Sunshine bill is not much different. In fact, at least one version requires disclosures of all spend above \$5.

As discussed above, for gifts that are not banned but are of a fair market value below \$25, such as a small number of educational brochures provided to a prescriber, the manufacturer may elect to report the expenditures for all Vermont prescribers or institutions in the aggregate.

## What are the deadlines for disclosure?

According to the Vermont Guide:

No later than July 1, 2010, each manufacturer of prescribed products must disclose to the Vermont Office of the Attorney General the name and address of the person responsible for the company’s compliance with the law. The Attorney General refers to that person as the “compliance officer.”

All manufacturers of prescribed products are encouraged to file the Compliance Officer Form as soon as possible so that we can readily contact you about how to comply with Vermont law.

For the October 1, 2010, report due under the new law, pharmaceutical manufacturers must disclose marketing expenditures from the 12-month period of July 1, 2009, – June 30, 2010, whereas biologic and medical device manufacturers (and device distributors) must disclose marketing expenditures from the 6-month period of January 1, 2010, – June 30, 2010.

In subsequent years, however, the disclosure schedule for all manufacturers (and device distributors) is as follows:

Report Due	Covering activities that take place during the following time period
October 1, 2011	July 1, 2010, to June 30, 2011
October 1, 2012	July 1, 2011, to June 30, 2012

It appears, however, that these timeframes may change in the near future. During Wendy Morgan's appearance at ExL Pharma's Tracking and Reporting Aggregate Spend Conference on January 12, 2009, Ms. Morgan inquired whether the audience (which consisted primarily of compliance officials in the pharmaceutical, biologic, and medical device industry) would prefer the reporting requirements to be based on the fiscal year (as currently set forth) or the calendar year. The audience responded with a resounding preference for calendar year terms. Therefore, we expect the Vermont AG to issue new guidance in connection with this change.

### **Are there fees associated with annual reports? What if there is nothing to report?**

Any company with expenditures to report in FY10 must also pay a \$500 registration fee by July 1, 2010.

Manufacturers of prescribed products with no expenditures to report who file the Compliance Officer Form need not file a fee and need not take further action prior to the October 1 deadline.

### **What if the company does not know if it will have expenditures to report?**

According to the Vermont Guide, "[s]ometimes a company will not know by July 1 whether it has been marketing to a Vermont prescriber because the prescriber holds dual licenses in Vermont and another state, such as New Hampshire. In this case, the company should file the Compliance Officer Form by July 1 indicating 'no expenditures to report' and, before filing disclosures, file a new Compliance Officer Form and send in the \$500 registration fee. The Vermont AG will use the most recent compliance officer information."

### **How are annual reports filed?**

A company can make disclosures either (1) by entering the data through a form on the Attorney General's website or (2) by downloading an Access-based database from the website, entering the data, and returning the database to the Attorney General's office. Either process will require the new username and password submitted in the Compliance Officer Form.

Data that does not comply with the Vermont AG's guidance will be returned to the Compliance Officer for corrections and resubmission. The Attorney General's Office will make every effort to verify compliance within five working days of receipt of the data.

The October 1, 2010, deadline for all submissions is not meant for any data that is returned to the company for corrections unless it is resubmitted with no errors by October 1.

### **How does a Covered Company make corrections to a submitted report?**

Companies should make every effort to submit correct data. For example, if a company is concerned that it may have the wrong license number for a prescriber, the company should communicate with the prescriber (and not the AG's Office) to get the correct information (i.e., his or her license number or the license number(s) of the appropriate prescriber(s) to whom the expenditure should be associated) before submitting data.

However, if the reporting company finds that it has submitted incorrect data after the data has been submitted to and accepted by the Office of the Attorney General, the responsible company official is instructed by the Vermont AG to send an email identifying both the submitted data and the corrected data to: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us). The Vermont AG will email an acknowledgement of receipt.

### **Must payments for clinical trials be reported?**

Yes, but reporting may be delayed in certain circumstances.

Allowable expenditures for clinical trials are limited to payments for "bona fide clinical trials." A "clinical trial" is 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. A "bona fide clinical trial" includes only an FDA-reviewed clinical trial that constitutes "research" as that term is 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.

The only authorized expenditures for a clinical trial are:

- (1) gross compensation for the Vermont location or locations involved,

(2) direct salary support per principal investigator and other health care professionals per year, and

(3) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

If the clinical trial is funded through a “per enrolled patient fee” that does not itemize component costs, the total of those fees should be reported as gross compensation under (1) above, with no expenditures under (2) above.

Such payments must be disclosed after the **earlier** of:

- the date of the approval or clearance of the prescribed product by the Food and Drug Administration; or
- two calendar years after the date the payment was made.

For a clinical trial for which disclosure is delayed, although the payment may not have to be reported in the same year, the manufacturer must report to the Vermont attorney general the following information:

- the clinical trial;
- the start date; and
- the web link to the clinical trial registration on the national clinical trials registry.

According to the Vermont Guide, beginning October 1, 2010, information regarding all ongoing clinical trials must be reported, providing the minimum information if the trial is less than two calendar years old and the FDA has not approved or cleared the prescribed product, and otherwise providing complete information on the expenditures for the trial since July 1, 2009, for pharmaceutical manufacturers, or since January 1, 2010, for manufacturers of biological products or medical devices. Expenditures made prior to those dates need not be reported.

The Vermont Guide further provides, “[i]f a clinical trial contract entered into before July 1, 2009, contains confidentiality provisions protecting the identity of or amount of any expenditure to a recipient, the names and amounts must be reported but will be kept confidential by the Attorney General’s Office.” Clinical trial agreements entered into on or after July 1, 2009, may not contain confidentiality clauses that would violate Vermont’s disclosure law.

## **Are samples exempt from reporting and the gift ban?**

Under the Vermont law, companies do not have to disclose “samples of a prescription drug provided to a health care professional for free distribution to patients.” The Vermont AG originally appeared to have expanded the scope of this exemption to include samples of all “prescribed products” (i.e., not just prescription drugs). However, the Vermont AG clarified in its guide that although free samples of prescription drugs (both chemical compounds and biologics) need not be reported, free samples of medical devices and combination medical devices and prescription drugs must be reported.

Furthermore, the Vermont AG has stated in its Guide that this exemption also applies to vouchers and discount coupons for samples of prescribed products given to a health care provider.

The Vermont AG has also reiterated that donations of samples of prescribed products are not banned if the samples are for humanitarian needs and to be distributed abroad, and, as described above, it does not appear that such samples of prescription drugs (both chemical compounds and biologics) need to be reported at this time, but free samples of medical devices and combination medical devices and prescription drugs must be reported. It should be mentioned that in the Vermont AG “Answers to Questions” document, previous guidance still appears in which the Vermont AG has stated that the samples do not need to be reported if they are prescription drugs, but do need to be reported if they are medical devices or biologics. Nonetheless, the Vermont AG appears to be aware of this discrepancy and will likely edit this prior guidance to conform to its latest interpretation.

## **Are continuing medical education (CME) grants programs exempt from disclosure?**

No. According to the Vermont AG in its guide, unrestricted grants for CME must be disclosed but disclosure is limited to the value, nature, and purpose of the grant and the name of the grantee; the names of the individual participants in such a program need not be disclosed.

The Vermont AG also adds that the costs of maintaining a table at a conference or seminar, which is outside of Vermont and not limited to Vermont prescribers or institutions, need not be reported. However, if payment for the table would be made to a Vermont health care provider, it is presently banned under the law. If the conference is in Vermont and is organized by an academic institution or a professional, educational, or patient organization, it is permitted if it meets the definition of an “allowable expenditure,” and must be reported. The payment may include fees to have a commercial display at the conference.

The Vermont AG has also determined that a company may sponsor a CME program put on by a non-profit educational organization which has Vermont prescribers on its board of directors if the non-profit is not one of the entities within the definition of “health care provider,” and the sponsorship meets the requirements of an “allowable expenditure.”

One question in the Vermont AG’s “Answers to Questions” document involved payments to a hospital for a CME program in Vermont (such as a visiting professor program at a local hospital) that is part of a larger national program. Payment to the hospital for food is not allowed unless the hospital or recipient pays fair market value for the food. If the payment to the hospital is for staff time, however, the payment is allowed and should be reported if the payment is from a manufacturer of prescribed products because it is “an allowable expenditure if the total is reasonable and each component [is] at fair market value.” Similarly, payment from a covered manufacturer to a speaker or physician faculty member speaking in Vermont may be an allowable expense (and therefore reportable) if the honoraria requirements are met.

In contrast, if a manufacturer of prescribed products donates money to a CME provider which, without any input from the manufacturer, selects a Vermont prescriber to be a presenter, neither the manufacturer nor the CME provider need to report the donation. Any payment by a CME accreditation company which is not a manufacturer of prescribed products does not fall within the statute.

### **Must expenditures that occur outside the State of Vermont be reported?**

According to the Vermont AG, if the recipient has an active license in Vermont, then all expenses associated with that recipient must be reported. Furthermore, if the marketing expense involves a recipient with an active license in Vermont but takes place out-of-state, that expense still must be reported.

In contrast, the Vermont AG stated in its guide that marketing expenditures incurred on behalf of an Ohio physician (or any other out-of-state health care professional) who holds an inactive Vermont license need not be reported.

Remember, however, that the gift ban (which is separate from the reporting requirement) only applies if the recipient has an active license in Vermont **and** regularly practices in Vermont.

## **Does the value have to be reported for the loan of a medical device or sample of a medical device or biologic?**

Loans less than 90 days must be reported. According to the Vermont Guide, the value for providing a loan of a medical device does not have to be reported, “but the fact of the loan must be reported.” The Vermont Representative had explained during a previous conference call that all other required information (nature, purpose, recipient, etc.) must be captured and reported. The value of \$0 should be reported. Loans greater than 90 days are banned.

Similarly, the Vermont AG wrote in its guide that companies should report the value of \$0 for free samples of medical devices and combination medical devices and prescription drugs.

## **How is group spend allocated?**

Assuming the expenses of a training, educational, scientific or similar event attended by a Vermont health care provider (including a Vermont-licensed health care professional who regularly practices in Vermont) is an allowable expenditure and/or not-banned gift, the Covered Company must allocate to the Vermont health care provider a certain percentage of the total value even when the event is attended by others who are not licensed health care providers in Vermont. In order to determine the percentage, the Vermont AG stated in its “Answers to Questions” document that the Covered Company “should divide the total expenditures provided to the attendees of the event by the total number of health care providers, and then allocate the resulting quotient to each Vermont health care provider.”

Although this response is helpful, it only addresses “health care providers and others who are not licensed in Vermont;” that is to say, it does not address whether individuals who attend the event but are not health care providers would be included in the number of total attendees. If non-health care providers are excluded from the calculation, then the value allocated to health care providers would appear greater. Future clarification is needed.

## **How is value allocated when the expenditure is provided to a practice with multiple health care professionals?**

The Vermont Guide states that the value of a permitted gift or allowable expenditure provided to a practice with multiple prescribers must be allocated among the relevant prescribers.

For example, if the gift is a \$160 model of a leg used to explain what occurs when a knee is replaced, and the office has two physicians who might use it and three who would not, the

expense should be divided by two and attributed to the two who would use the model. If the manufacturer does not know how many health care professionals in the office would use the model, the expense should be divided by five and attributed to each health care professional in the practice.

Allocating group spend in accordance with this guidance will prove challenging in several respects. First, to identify the denominator for purposes of allocation, reporting organizations would need information about physician groups/affiliation data, including the breakdown of specialties within the group. At a minimum, it would seem that the total number of physicians within a group practice presumably is required information.

### **Must labels that are provided to health care providers be reported?**

The Vermont Guide provides that, “[f]ree samples of prescription drugs (chemical compounds and biologics) provided to a health care professional for free distribution to patients, and the labels for those samples” do not need to be reported.

It remains unclear whether manufacturers should report labels, package inserts, etc., that are provided to a health care provider not in connection with a sample. It sounds like a strange inquiry, but then again, manufacturers are expected to report the provision of brochures.

### **What are the penalties for failing to comply with the law?**

**Unlawful gifts** – Companies that provide a gift in violation of the gift ban may be fined a civil penalty of up to \$10,000 per violation. Violations can be very costly because the law considers each unlawful gift to be a separate violation.

**Unlawful failure to disclose** – Companies that fail to disclose one of the many types of marketing expenditures covered by the statute may be fined a civil penalty of up to \$10,000 per violation. Similar to the above, each unlawful failure to disclose shall constitute a separate violation.

### **What happens to disclosed information?**

The Vermont AG must file an annual report with the Vermont legislature and the Governor by April 1, 2011. After the report is issued, the Attorney General will make all disclosed data publically available and searchable on an internet website.

## Will the law still be enforced if Sunshine is passed?

At ExL Pharma's Tracking and Reporting Aggregate Spend Conference on January 12, 2009, Wendy Morgan stated that, although it has not formally been discussed, she expects that the Vermont disclosure and gift ban law will continue to be enforced even if a federal version is enacted. Moreover, there has yet to be any federal Sunshine bill which would fully preempt Vermont requirements.

## Are there any other state laws with similar requirements?

Yes, there are several states with laws that contain some, but not all, of the requirements contained in the Vermont law. Certain of these state laws apply only to pharmaceutical manufacturers, but most of the recently proposed laws also govern medical device manufacturers. In addition, we saw a wave of proposed laws which died in 2009. Nonetheless, some proposed laws have not died, and we expect a new wave of laws to be proposed in 2010.

For pharmaceutical companies, in addition to Vermont, the following 5 states and jurisdictions have enacted statutes which require payment/gift disclosure: Maine, Minnesota, Massachusetts (click [here](#) for the Massachusetts R-Squared Compliance Quick Reference Guide), West Virginia, District of Columbia, as well as a number of states and counties with lobbying disclosure laws applicable to healthcare professionals. As of March 16, 2010, the following 10 states have proposed laws or recommended regulations that require pharmaceutical payment/gift disclosure: Alaska, Arizona, Colorado, Connecticut, Hawaii, Illinois, New Jersey, New York and Ohio, as well as a bill modifying the requirements in Minnesota. Four states (California, Nevada, Vermont and Massachusetts) also mandate the adoption of compliance requirements around healthcare professionals.

For medical device companies, Vermont is the second state to require payment/gift disclosure (Massachusetts was the first). Also, as of March 16, 2010, the following 7 states have proposed laws or recommended regulations that require pharmaceutical payment/gift disclosure: Arizona, Colorado, Connecticut, Hawaii, Minnesota, New Jersey and New York. In addition, Nevada and (arguably) California are joined by Massachusetts and Vermont as states which mandate the adoption of compliance requirements around healthcare professionals.

Finally, the proposed federal **Physician Payments Sunshine Act** also would apply to both pharmaceutical and device manufacturers. This law would require broad disclosures of manufacturer payments and expenditures—"aggregate spend"—for all 50 states. Although the federal Sunshine bill will likely include a provision which "preempts" part of the state laws, it

appears that most – if not all – of the state laws will still remain in effect. Therefore, companies will likely have to comply with many different types of requirements.

## Are there solutions out there that minimize the burden of compliance?

Yes. R-Squared's [SpendTracker®](#) was built *expressly* for the data collection work and reporting required by the new Vermont law (as well as other state disclosure laws and the proposed federal *Physician Payments Sunshine Act*).

With this **configurable** solution, you can **integrate** with existing IT systems, streamline and automate the **collection, tracking, sorting, reporting** and **disclosure**, required by all existing state laws – all while generating solid evidence of your compliance at the same time.

[SpendTracker®](#) seamlessly interfaces with existing customer masters and the [IMS HCRS® data set](#), which is arguably the most comprehensive data base of health care professionals and organizations available, allowing for easy retrieval and population of *accurate* and *up-to-date* data. The software works with or as an organization's third party master. It is the most powerful aggregate spend solution on the market today.

**Be up and running in about 60 days.** Since these programs are already alive and working in companies much like yours, there is no need to build systems from scratch. Depending on your situation, you can have a solution in place in as short as 60 days, and the system can be fully **configured** for your operations and business processes. R-Squared and its partners at IMS Health handle all the implementation for you.

**Delivers precisely what the laws require.** The outputs and controls required by the Vermont law (and other state laws) are already built into the functionality of [SpendTracker®](#). These were all developed *specifically* around the requirements of transparency and “sunshine” regulations – under the direction of health care lawyers and regulatory compliance experts.

**Compare, Compare, Compare!** After year-long RFP processes involving outside consultants and technical/functional score sheets, and virtually all of the competition, the R-Squared/IMS Health team were recently awarded two significant aggregate spend solution engagements. In both cases, SpendTracker was determined to be “technologically superior” and “greater value” than the competition. Request a demonstration today.

## About R-Squared

R-Squared is a developer of “Evidence-Based Compliance” solutions for the health care and life sciences industries, including: [SpendTracker®](#), an end-to-end, fully configurable solution that captures, sorts, tracks, analyzes and reports on all spend data to both facilitate state reporting requirements and provide fully mineable data for improved business performance and analytics. Through patent-pending extensions to Microsoft SharePoint, our affordable solutions integrate seamlessly with existing accounting and expense software and also enhance significantly the power, functionality and value of your other SharePoint deployments; [Arrangements Keeper®](#), a complete contract management and compliance solution that manages needs assessments, contract performance and payment, complete with built-in compliance rules for fair market value and strong internal controls to evidence compliance with the FCPA (Foreign Corrupt Practices Act) and federal Anti-kickback statute; [Grants Keeper<sup>SM</sup>](#), a customized solution that automates your grant submission and approval processes, which increases the effectiveness of your grant program while saving your company time and money. This solution offers full end-to-end grant processing and management through a secure website portal; and [CIMS<sup>SM</sup>](#), a fully-integrated, state-of-the-art conflicts and disclosure management system that facilitates the electronic dissemination, completion, management and storage of tailored Conflict of Interest/Financial Disclosure Statements. Designed to evidence and facilitate 21 CFR Part 54 and other compliance measures, authorized users may check completion status, sort and report on the Statements by clinical study, physician, product, noted conflicts/relationships, and other data points. Disclosed conflicts and/or financial relationships can be flagged and automatically routed for review and follow up. All Statements are stored centrally for easy search and retrieval. Visit us at [www.r2ss.com](http://www.r2ss.com).

## About the Authors

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impact pharmaceutical and medical device compliance programs. Marc writes and presents on topics related to aggregate spend, and engages in frequent communication with state representatives responsible for the aggregate spend requirements. In addition, Marc is a published author who has received numerous awards for his writings on the health care industry.

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# ATTACHMENT

**Act 59: VERMONT PHARMACEUTICAL MARKETING DISCLOSURE LAW**

**No. 59. An act relating to the marketing of prescribed products.**

(S.48)

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 4631(b) is amended to read:

(b) As used in this section:

\* \* \*

(3) "Health care professional" shall have the same meaning as health care provider in section 9402 of this title.

\* \* \*

Sec. 2. LEGISLATIVE FINDINGS; INTENT

(a) The general assembly finds that the legislative findings in Sec. 1 of No. 80 of the Acts of 2007 provide a sound basis for instituting a ban of certain gifts to prescribers and disclosure of marketing activities as provided for in this act. Findings (1) through (8), (13), (15), (17), (19), and (21) shall be incorporated into this act by reference.

(b) The general assembly also finds:

(1) In 2007, Vermonters spent an estimated \$572 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2002, spending was about \$377 million. Between 2002 and 2007, the average annual increase in spending was 8.7 percent, which is slightly higher than the average increase in overall health care spending during this same period.

(2) According to the U.S. District Court for the District of Vermont in IMS v. Sorrell, Docket No. 1:07-CV-188 (Apr. 23, 2009), the state of Vermont has a substantial interest in cost containment and the protection of public health.

(3) The court in IMS v. Sorrell found that research shows that doctors are influenced by the marketing efforts of pharmaceutical companies, and that doctors who attend talks sponsored by a pharmaceutical company often prescribe that company's drug more than a competitor's drugs.

(4) The court in IMS v. Sorrell also found that drug detailing encourages doctors to prescribe newer, more expensive, and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines.

(5) According to a 2009 report from the Institute of Medicine of the National Academies, acceptance of meals and gifts and other relationships are common between physicians and pharmaceutical, medical device, and biotechnology companies. The report found that these relationships may influence physicians to prescribe a company's medicines even when evidence indicates another drug would be more beneficial to the patient.

(6) According to the April 2009 Report of Vermont Attorney General William H. Sorrell, in fiscal year 2008, pharmaceutical manufacturers reported spending \$2,935,248.00 in Vermont on fees, travel expenses, and other direct payments to Vermont physicians, hospitals, universities, and others for the purpose of marketing their products. Of Vermont's 4,573 licensed health care

professionals, 2,280 were recipients. Of the above amount, approximately \$2.1 million in payments went to physicians. The top 100 individual recipients received nearly \$1,770,000.00 in fiscal year 2008.

(7) Of the disclosures reported by pharmaceutical manufacturers, only 17 percent were available to the public due to the current trade secret exemption in state law.

(8) According to the attorney general, expenditures on food totaled \$861,911.70, or 29.36 percent of all marketing expenditures. Of the 1,132 recipients of food in fiscal year 2008, 20.36 percent had \$500.00 or more expended on them, including 11.31 percent who had \$1,000.00 or more expended on them. 41.1 percent of the 1,132 recipients of food received food valued at \$100.00 or less. The individual recipient with the greatest reported food expenditure received \$15,793.78 in food for him- or herself and any colleagues who may not prescribe.

(9) The federal Office of Inspector General (OIG) has taken enforcement action against several medical device manufacturers in recent years for violations of fraud and abuse laws. Through its investigations, the OIG found medical device manufacturers providing kickbacks to physicians in the form of all-expense-paid trips, false consulting arrangements, meals, and other gifts. The OIG recommends subjecting the financial relationships between medical device manufacturers and physicians to reporting requirements and greater transparency.

(10) There is little or no difference in the marketing of biological products and prescription drugs. It is logical and necessary to include biological products to the same extent as prescription drugs to ensure appropriate and consistent transparency and reduce real or perceived conflicts of interest.

(11) This 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. This act is also necessary to reduce real or perceived conflicts of interest which undermine patient confidence in health care providers and increase health care costs by influencing prescribing patterns. Limitations on gifts and increased transparency are expected to save money for consumers, businesses, and the state by reducing the promotion of expensive prescription drugs, biological products, and medical devices, and to protect public health by reducing sales-oriented information to prescribers.

Sec. 3. 18 V.S.A. § 4631a is added to read:

§ 4631a. GIFTS BY MANUFACTURERS OF PRESCRIBED PRODUCTS

(a) As used in this section:

(1) “Allowable expenditures” means:

(A) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:

(i) the payment is not made directly to a health care provider;

(ii) funding is used solely for bona fide educational purposes; and

(iii) all program content is objective, free from industry control, and does not promote specific products.

(B) 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, provided:

(i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and

(ii) the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) For a bona fide clinical trial:

(i) gross compensation for the Vermont location or locations involved;

(ii) direct salary support per principal investigator and other health care professionals per year; and

(iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

(D) For a research project that 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:

(i) gross compensation;

(ii) direct salary support per health care professional; and

(iii) expenses paid on behalf of each health care professional.

(E) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.

(F) 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.

(G) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

(2) “Bona fide clinical trial” means an FDA-reviewed clinical trial that constitutes “research” as that term is 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.

(3) “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.

(4) “Gift” means:

(A) Anything of value provided to a health care provider for free; or

(B) Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless:

(i) it is an allowable expenditure as defined in subdivision (a)(1) of this section; or

(ii) the health care provider reimburses the cost at fair market value.

(5)(A) “Health care professional” means:

(i) a person who is authorized to prescribe or to recommend prescribed products and who either is licensed by this state to provide or is otherwise lawfully providing health care in this state; or

(ii) a partnership or corporation made up of the persons described in subdivision (i) of this subdivision (5)(A); or

(iii) an officer, employee, agent, or contractor of a person described in subdivision (i) of this subdivision (5)(A) 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.

(B) The term shall not include a person described in subdivision (A) of this subdivision (5) who is employed solely by a manufacturer.

(6) “Health care provider” means 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 this state.

(7) “Manufacturer” means 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 licensed under chapter 36 of Title 26.

(8) “Marketing” shall include promotion, detailing, or any activity that is intended to be used or is used to influence sales or market share or to evaluate the effectiveness of a professional sales force.

(9) “Pharmaceutical manufacturer” means any entity which is 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. The term does not include a wholesale distributor of prescription drugs or a pharmacist licensed under chapter 36 of Title 26.

(10) “Prescribed product” means a drug or device as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262.

(11) “Significant educational, scientific, or policy-making conference or seminar” means an educational, scientific, or policy-making conference or seminar that:

(A) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization; and

(B) offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

(b)(1) It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a health care provider.



(2) The prohibition set forth in subdivision (1) of this subsection shall not apply to any of the following:

(A) Samples of a prescribed product provided to a health care provider for free distribution to patients.

(B) 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.

(C) 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 determine whether and when to use or recommend the product in the future.

(D) 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.

(E) 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.

(F) Rebates and discounts for prescribed products provided in the normal course of business.

(G) Labels approved by the federal Food and Drug Administration for prescribed products.

(c) The 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 this section a civil penalty of no more than \$10,000.00 per violation. Each unlawful gift shall constitute a separate violation.

Sec. 4. 18 V.S.A. § 4632 is amended to read:

§ 4632. ~~PHARMACEUTICAL MARKETERS~~ DISCLOSURE OF  
ALLOWABLE EXPENDITURES AND GIFTS BY  
MANUFACTURERS OF PRESCRIBED PRODUCTS

(a)(1) Annually on or before ~~December~~ October 1 of each year, every ~~pharmaceutical manufacturing company~~ manufacturer of prescribed products shall disclose to the office of the attorney general for the fiscal year ending the previous June 30th the value, nature, ~~and~~ purpose, and recipient information 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 this state. Disclosure shall include the name of the recipient. Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require pharmaceutical manufacturing companies to report the value, nature, and purpose of all gift expenditures according to specific categories. The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before April 1.~~

(A) any allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title to any health care provider, except:

(i) royalties and licensing fees as described in subdivision 4631a(a)(1)(F) of this title;

(ii) rebates and discounts for prescribed products provided in the normal course of business as described in subdivision 4631a(b)(2)(F) of this title;

(iii) payments for clinical trials as described in subdivision 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subdivision (iii), the manufacturer shall identify to the attorney general the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry; and

(iv) samples of a prescription drug provided to a health care professional for free distribution to patients.

(B) any allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title to an academic institution or to a professional, educational, or patient organization representing or serving health care providers or consumers, except:

(i) royalties and licensing fees as described in subdivision 4631a(a)(1)(F) of this title;

(ii) rebates and discounts for prescribed products provided in the normal course of business as described in subdivision 4631a(b)(2)(F) of this title;

(iii) payments for clinical trials as described in subdivision 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subdivision (iii), the manufacturer shall identify to the attorney general the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry; and

(iv) samples of a prescription drug provided to a health care professional for free distribution to patients.

~~(2) Annually on October July 1, each company subject to the provisions of this section~~ manufacturer of prescribed products also shall disclose to the office of the attorney general; the name and address of the individual responsible for the ~~company's~~ manufacturer's compliance with the provisions of this section, ~~or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's~~ compliance with the provisions of this section.

~~(3) The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1, except that~~

~~the office may disclose the information to the department of health and the office of Vermont health access for the purpose of informing and prioritizing the activities of the evidence based education program in subchapter 2 of chapter 91 of Title 18. The department of health and the office of Vermont health access shall keep the information confidential. The disclosure form shall permit the company to identify any information that it claims is a trade secret as defined in subdivision 317(c)(9) of Title 1. In the event that the attorney general receives a request for any information designated as a trade secret, the attorney general shall promptly notify the company of such request. Within 30 days after such notification, the company shall respond to the requester and the attorney general by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret. Any requester aggrieved by the company's response may apply to the superior court of Washington County for a declaration that the company's claim of trade secret is invalid. The attorney general shall not be made a party to the superior court proceeding. Prior to and during the pendency of the superior court proceeding, the attorney general shall keep confidential the information that has been claimed as trade secret information, except that the attorney general may provide the requested information to the court under seal.~~

~~(4) The following shall be exempt from disclosure:~~

~~(A) free samples of prescription drugs intended to be distributed to patients;~~

~~(B) the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;~~

~~(C) any gift, fee, payment, subsidy or other economic benefit the value of which is less than \$25.00;~~

~~(D) 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; and~~

~~(E) prescription drug rebates and discounts.~~

(3) Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require manufacturers of prescribed products to report each allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title including:

(A) except as otherwise provided in subdivision (a)(2) of this section, the value, nature, and purpose of each allowable expenditure, and gift permitted under subdivision 4631a(b)(2) of this title according to specific categories identified by the office of the attorney general;

(B) the name of the recipient;

(C) the recipient's address;

(D) the recipient's institutional affiliation;

(E) prescribed product or products being marketed, if any; and

(F) the recipient's state board number.

(4) The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before April 1. The report shall include:

(A) Information on allowable expenditures and gifts required to be disclosed under this section, which shall be presented in both aggregate form and by selected types of health care providers or individual health care providers, as prioritized each year by the office.

(B) Information on violations and enforcement actions brought pursuant to this section and section 4631a of this title.

(5) After issuance of the report required by subdivision (a)(5) of this section, the office of the attorney general shall make all disclosed data used for the report publicly available and searchable through an Internet website.

(6) The office of Vermont health access shall examine the data available from the office of the attorney general for relevant expenditures and determine whether and to what extent prescribing patterns by health care providers of prescribed products reimbursed by Medicaid, VHAP, Dr. Dynasaur, VermontRx, and VPharm may reflect manufacturer influence. The office may

select the data most relevant to its analysis. The office shall report its analysis annually to the general assembly and the governor on or before October 1.

(b)(1) Annually on July 1, the office of the attorney general shall collect a \$500.00 fee from each manufacturer of prescribed products filing annual disclosures of expenditures greater than zero described in subsection (a) of this section.

(2) Fees collected under this section shall fund collection and analysis of information on activities related to the marketing of prescribed products under sections 4631a and 4632 of Title 18. The fees shall be collected in a special fund assigned to the office.

(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and ~~attorneys~~ attorney's fees, and to impose on a pharmaceutical manufacturing company manufacturer of prescribed products that fails to disclose as required by subsection (a) of this section a civil penalty of no more than \$10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation.

~~(e) As used in this section:~~

~~(1) "Approved clinical trial" means a clinical trial that has been approved by the U.S. Food and Drug Administration (FDA) or has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection~~

~~standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.~~

~~(2) “Bona fide clinical trial” means an approved clinical trial that constitutes “research” as that term is defined in 45 C.F.R. § 46.102 when the results of the research can be published freely by the investigator and reasonably can be considered to be of interest to scientists or medical practitioners working in the particular field of inquiry.~~

~~(3) “Clinical trial” means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies, or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.~~

~~(4) “Pharmaceutical marketer” means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor’s representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.~~

~~(5) “Pharmaceutical manufacturing company” means any entity which is engaged in the production, preparation, propagation, compounding,~~

~~conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or 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. The term does not include a wholesale drug distributor or pharmacist licensed under chapter 36 of Title 26.~~

~~(6) “Unrestricted grant” means any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity.~~

~~(d) Disclosures of unrestricted grants for continuing medical education programs shall be limited to the value, nature, and purpose of the grant and the name of the grantee. It shall not include disclosure of the individual participants in such a program~~ The terms used in this section shall have the same meanings as they do in section 4631a of this title.

Sec. 5. 1 V.S.A. § 317(c) is amended to read:

(c) The following public records are exempt from public inspection and copying:

\* \* \*

(9) trade secrets, including, ~~but not limited to,~~ any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it, except that the disclosures required by section 4632 of Title 18 shall not be included in this subdivision;

Sec. 5a. STUDY OF DISCLOSURE OF DRUG SAMPLES

(a) The attorney general's office shall conduct a review, in consultation with the commission on health care reform, of the advisability of modifying section 4632 of Title 18 to require the disclosure of information about the provision of samples to health care providers by manufacturers of prescribed products.

(b) The attorney general's office shall provide a report of its findings to the house committee on health care and the senate committees on finance and on health and welfare no later than December 15, 2009.

Sec. 6. 18 V.S.A. § 4633(d) is amended to read:

(d) As used in this section:

(1) "Average wholesale price" or "AWP" means the wholesale price charged on a specific commodity that is assigned by the ~~drug manufacturer~~ pharmaceutical manufacturing company and listed in a nationally recognized drug pricing file.

(2) “Pharmaceutical manufacturing company” ~~is defined by subdivision 4632(e)(5) of this title~~ shall have the same meaning as “pharmaceutical manufacturer” in section 4631a of this title.

(3) “Pharmaceutical marketer” ~~is defined by subdivision 4632(e)(4) of this title~~ means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in marketing, as that term is defined in section 4631a of this title.

\* \* \* Therapeutic Substitution of Prescription Drugs \* \* \*

#### Sec. 7. THERAPEUTIC EQUIVALENT DRUG WORK GROUP

(a) It is the intent of the general assembly to explore increasing the usage of generic drugs by allowing pharmacists to substitute a therapeutically equivalent generic drug from a specified list when a physician prescribes a more expensive brand-name drug in the same class. This section creates a work group to recommend a sample list and a process for substitution for consideration by the general assembly. A “therapeutically equivalent generic drug” means a generic drug which is in the same class as a brand-name drug but is not necessarily chemically equivalent.

(b) A work group is created to generate a proposed list by class of drugs to describe which generic drug or drugs could be substituted when a physician prescribes a more expensive brand name drug in the same class, with equivalent dosages for the substitution.

(c)(1) The work group shall consist of two physicians appointed by the Vermont Medical Society, two pharmacists appointed by the Vermont pharmacy association, and three representatives of the drug utilization review board.

(2) A representative of the drug utilization review board shall convene the first meeting of the work group. The work group shall organize itself with a chair or cochairs for the purposes of scheduling and conducting meetings.

(3) The work group shall consult with medical specialists and organizations representing patients when necessary to determine whether a substitution is advisable and safe for a particular condition or when the work group deems it necessary to have additional information of a specialized nature.

(d) The proposed list shall not include drugs used to treat severe and persistent mental illness.

(e) The work group shall transmit the list of therapeutically equivalent generic drugs to the board of medical practice established under chapter 23 of Title 26 and the board of pharmacy established under subchapter 2 of chapter 36 of Title 26 for review and comment. The board of medical practice and the board of pharmacy shall review the list of therapeutically equivalent generic drugs jointly to determine whether the list appropriately provides for substitutions. The boards shall provide comments to the work group no later than 60 days after receiving the list.

(f) No later than January 15, 2010, the work group shall provide a report to the house committees on health care and on human services and the senate committees on finance and on health and welfare on the list generated, the comments provided by the boards of medical practice and of pharmacy, patient advocacy organizations, and any other information the work group deems relevant to the consideration of draft legislation.

Sec. 8. 2 V.S.A. chapter 26 is amended to read:

CHAPTER 26. ~~NORTHEAST NATIONAL~~ NATIONAL LEGISLATIVE ASSOCIATION  
ON PRESCRIPTION ~~DRUGS PRICING~~ DRUG PRICES

§ 951. ~~NORTHEAST NATIONAL~~ NATIONAL LEGISLATIVE ASSOCIATION ON  
PRESCRIPTION ~~DRUGS PRICING~~ DRUG PRICES

(a) The general assembly finds that the ~~Northeast National~~ National Legislative Association on Prescription ~~Drugs Pricing~~ Drug Prices is a nonprofit organization of legislators formed for the purpose of making prescription drugs more affordable and accessible to citizens of the member states. The general assembly further finds that the activities of the Association provide a public benefit to the people of the state of Vermont.

(b) On or before January 15, upon the convening of each biennial session of the general assembly, three directors shall be appointed by the speaker, which may include the speaker, and three directors shall be appointed by the committee on committees, which may include a member of the committee on committees, to serve as the Vermont directors of the ~~Northeast National~~ National

Legislative Association on Prescription ~~Drugs Pricing~~ Drug Prices. Directors so appointed from each body shall not all be from the same party. Directors so appointed shall serve until new members are appointed.

(c) For meetings of the Association, directors who are legislators shall be entitled to per diem compensation and reimbursement of expenses in accordance with section 406 of Title 2. If the lieutenant governor is appointed as a director pursuant to subsection (b) of this section, his or her compensation and expenses shall be paid from the appropriation made to the office of the lieutenant governor.

(d) The Vermont directors of the Association shall report to the general assembly on or before January 1 of each year with a summary of the activities of the Association, and any findings and recommendations for making prescription drugs more affordable and accessible to Vermonters.

#### Sec. 8a. HEALTH CARE COSTS IN CORRECTIONS WORK GROUP

(a) The director of health care reform, in consultation with the commissioner of corrections, shall convene a work group to:

(1) review the recommendations of the Heinz Family Philanthropies report entitled Making Connections: Utilizing the 340B Drug Pricing Program; and

(2) establish a mechanism for providing health services and prescriptions through a network of federally qualified health centers, disproportionate share hospitals, and other covered entities eligible under the

Veterans Health Care Act of 1992, Public Law 102-585, codified at Section 340B of the Public Health Service Act.

(b) The work group shall include representatives from:

- (1) Bi-State Primary Care Association;
- (2) Fletcher Allen Health Care;
- (3) Vermont Association of Hospitals and Health Systems;
- (4) Behavioral Health Network;
- (5) Heinz Family Philanthropies; and
- (6) other interested stakeholders.

(c) No later than July 31, 2009, the work group shall provide a report to the commission on health care reform and the corrections oversight committee.

Sec. 9. 33 V.S.A. § 1998(c)(4)(A) is amended to read:

(4) The actions of the commissioners, the director, and the secretary shall include:

(A) active collaboration with the ~~Northeast~~ National Legislative Association on Prescription Drugs in the Association's efforts to establish a ~~Prescription Drug Fair Price Coalition~~ Drug Prices;

Sec. 10. APPROPRIATION

In fiscal year 2010, the sum of \$40,000.00 is appropriated to the office of the attorney general from a special fund assigned to the office for the purposes of collecting and analyzing information on activities related to the marketing of prescribed products under sections 4631a, 4632, and 4633 of Title 18.

Sec. 11. EFFECTIVE DATE

This act shall take effect July 1, 2009, except:

(1) pharmaceutical manufacturers shall file by November 1, 2009 disclosures based on the law in effect on June 30, 2009 required by subdivision 4632 of Title 18 for the time period July 1, 2008 to June 30, 2009; and

(2) manufacturers of biological products and medical devices shall file by October 1, 2010 disclosures required by subdivisions 4632(a)(1) and (2) of Title 18 for the time period January 1, 2010 to June 30, 2010.

(3) Sec. 8a of this act, establishing a work group to examine health care costs in corrections, shall take effect upon passage.

Approved: June 8, 2009