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Vermont Modifies Manufacturer Gift Ban and Reporting Law, Effective July 1, 2011

On May 26, 2011, Vermont Governor Peter Shumlin signed into law Senate Bill 104 ("S.104"), significantly modifying Vermont law banning the provision by manufacturers of gifts to health care providers and requiring disclosure of certain allowable expenditures and gifts to health care providers (18 V.S.A. § 4631a and 18 V.S.A. § 4632). S.104 follows amendments made to the Vermont gift ban and disclosure law enacted just last year. We include below a summary of the modifications pursuant to S.104. Except as otherwise noted, the changes are effective July 1, 2011.

The changes under S.104 will impact pharmaceutical, device, and biological manufacturers, all of which are covered under the Vermont law, to the extent they make expenditures subject to the gift ban or disclosure law. Among other things, these amendments change the reporting period for disclosures of allowable expenditures and permitted gifts. They also—with limited exception—prohibit payments by a manufacturer to a health care provider relating to that provider's participation in "marketing research and surveys," with the precise scope of this prohibition still uncertain. Notwithstanding these and the other changes discussed below, many of the gift ban and disclosure provisions remain unchanged. Nonetheless, the amendments pursuant to S.104 will require consideration by manufacturers and possible system updates and modifications to monitor, track, and report expenditures to Vermont health care providers. In addition, relevant policies, procedures, and training materials may need to be revised.

On June 16, 2011, the Vermont Office of the Attorney General is holding a conference call to discuss the recently-released Draft Consolidated Guide for 2011, available at *http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php*. To the extent this conference call provides helpful insight regarding the below modifications, or Vermont requirements in general, we will provide such additional information regarding the evolving Vermont requirements.

Changes to the Vermont Gift Ban, 18 V.S.A. § 4631a

- **Employee Health Care Expenses.** Allowable expenditures now include a manufacturer's payment of reasonable expenses for employee health care services.
- **Green Mountain Care Board.** Gift restrictions and disclosure requirements related to health care providers are extended to apply to members of the Green Mountain Care Board, an oversight body created under Vermont's health care health reform law.
- **Manufacturers.** The term "manufacturer" is revised to exclude manufacturers whose only prescribed products are classified as Class I by the U.S. Food and Drug Administration ("FDA"), are exempt from pre-market notification under Section 510(k) of the federal Food, Drug and Cosmetic Act, and are sold over-the-counter without a prescription.
- **Patient Assistance Programs.** The term "sample" now excludes prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program ("PAP"). In addition, the language of the exception related to PAPs has been revised to apply to prescribed products generally, as opposed to only prescription drugs.[1] As discussed below with respect to disclosure requirements, such products need not be reported.
- **Device Loans.** The exception authorizing short-term medical device loans to permit evaluation by a health care provider or patient has been extended from 90 days to 120 days. In addition, as discussed below, such loans need not be reported in certain circumstances.
- **Research Payments.** A somewhat confusing new provision has been added prohibiting manufacturers from providing any economic benefit to health care providers in connection with the provider's participation in "research." Although the term research is not defined in the

statute, the Vermont Office of Attorney General issued explanatory materials describing this new prohibition as applying to "research, such as market research or surveys, which does not fall within the allowable expenditures for clinical trials and scientific research, §§ 4631a(a)(1)(C) and (D)." The statutory cross-reference appears to be incorrect,[2] notwithstanding the explanation of the Office of the Attorney General. We are seeking clarification on this issue.

Changes to the Vermont Disclosure Requirements, 18 V.S.A. § 4632

- **Annual Reports.** Manufacturer's annual reports are now due on or before April 1 of each year, instead of by October 1. The report will now be for the preceding calendar year, as opposed to the previous fiscal year ending June 30. There is a transition six-month reporting period for July 1, 2011 through December 31, 2011. Hence, the report due April 1, 2012 will report expenditures made during the last half of 2011 (July 1, 2011 through December 31, 2011). Beginning in April 2013, all disclosures must be made on or before April 1 for the previous calendar year. In addition, annual reports identifying the name and address of the individual responsible for the manufacturer's compliance with the Vermont requirements are now due on January 1, as opposed to July 1. The Attorney General's annual report on disclosures to the general assembly and the governor will now be made on or before October 1, as opposed to April 1.
- **Reporting Fees.** The modifications establish the following schedule of reporting fees for manufacturers filing annual disclosures of expenditures: (1) $500 on July 1, 2011 for fiscal year ending June 30, 2011; (2) $250 for the sixth-month period from July 1, 2011 through December 31, 2011; (3) $500 beginning January 1, 2013 and annually thereafter.
- **Rebates and Discounts.** The provision requiring reporting of "rebates and discounts for prescribed products" has been revised to make clear that the report relates to rebates and discounts provided to health care providers.
- **Clinical Trial Reporting Delay.** The delay for reporting payments for clinical trials is extended from two calendar years to four calendar years after the payment is made. Accordingly, payments for clinical trials must be disclosed after the earlier of the date of approval or clearance of the prescribed product by the FDA for the use for which the clinical trial is conducted, or four calendar years after the date the payment was made.
- **Device Loans.** Short-term medical device loans are now excluded from the reporting requirements, provided the loan results in the purchase, lease, or other comparable arrangement of the medical device after issuance of a certificate of need.
- **Patient Assistance Programs.** Prescribed products distributed for free or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded PAP are now excluded from the reporting requirements at 18 V.S.A. § 4632.
- **Reporting Free Nonprescription Products.** If manufacturers are reporting other allowable expenditures or permitted gifts, they must now also report annually on or before April 1, information related to over-the-counter drugs, nonprescription medical devices, and items of nonprescription durable medical equipment provided to health care providers for free distribution to patients. The public reporting of this information must not include information allowing individual recipient identification or connection of the recipient with the monetary value of the samples provided. This new requirement is effective January 1, 2012.
- **Reportable Information.** With respect to institutions, foundations, and organizations, reportable information now includes federal tax identification numbers or identification numbers assigned by the Attorney General.
- **Electronic Prior Authorization.** A new section has been added related to electronic prior authorization, effective as of passage of S.104. Specifically, the commissioner of Vermont health access and the Vermont information technology leaders, in collaboration with interested parties, must evaluate the use of electronic means for requesting and granting prior authorization for prescription drugs, report such findings no later than January 15, 2012, and make recommendations for processes to develop standards for electronic prior authorizations.
- **Specialty Tier Drugs.** The Vermont law has been modified to provide that prior to July 1, 2012, no health insurer or pharmacy benefit manager may utilize a cost-sharing structure for prescription drugs that imposes on a consumer for any drug a cost-sharing requirement greater than that which applies for nonpreferred brand-name drugs. Similarly, the commissioner of banking, insurance, securities, and health care administration shall not approve any form of a health insurance policy prior to July 1, 2012 that imposes on a consumer for any prescription drug a cost-sharing requirement greater than that which applies for a nonpreferred brand-name

drug. This new provision took effect upon passage of S.104 and applies to all forms that have previously been approved by the department of banking, insurance, securities, and health care administration, or that may in the future be approved by the department.

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[1] Under the previous language, "free prescription drugs" through a "prescription drug manufacturer's" PAP were not subject to the gift ban. As modified, the gift ban now does not apply to "prescribed products" (defined as a drug, device, compound of the same, or biological product) distributed free or at a discount pursuant to a "manufacturer-sponsored or manufacturer-funded" PAP.

[2] Notwithstanding this Attorney General's guidance, the text of the new provision as enacted, excepts from the research prohibition not to the above identified allowable expenditures (§§ 4631a(a)(1)(C) and (D)), but instead §§ 4631a(a)(1)(B) and (C), which relate to allowable expenditures for honoraria and 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, and allowable expenditures for bona fide clinical trials.

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