Vermont Bans Free Meals and Gifts; Broadens Disclosure Requirements to Cover Medical Device Companies

Vermont continues to impose significant new restrictions on the marketing and related practices of pharmaceutical companies and has introduced new regulation of medical device companies. Legislation, adopted this month and effective July 1:

- significantly expands the scope of manufacturers who are required to disclose payments to health care providers by including medical device companies and others not covered by current law;
- eliminates the current widely used trade secret exemption from publication of disclosures; and
- imposes a broadly applicable gift ban that will eliminate many common practices, including free meals and charitable donations to health care providers.

The new law incorporates the legislative findings about the cost of prescription drugs that also served as the underpinning for a recent federal district court decision upholding Vermont's rigorous restrictions on the use of prescriber identified data. (See Ropes and Gray's previous Alert on this decision.) Reflecting the same general policy, the new legislation also requires the creation of a "Therapeutic Equivalent Drug Work group" as part of an effort to expand permitted therapeutic substitution. (Full text of the law here.)

Initial guidance from the Vermont Attorney General has already been issued and can be accessed at the Office of the Attorney General website. We advise our clients to check this website periodically for additional guidance and the resolution of issues that the drug and device industries have already raised about implementation of the new law.

Additional Manufacturers and Wholesalers Covered For First Time

In a notable departure from the existing law, the new law governs the manufacturers of pharmaceuticals, medical devices and biological products, referred to as "manufacturers of a prescribed product," and specifically covers wholesale distributors of medical devices. The current disclosure law applies only to manufacturers, packagers, labelers, and distributors of prescription drugs.

Regulation of Conduct through a Gift Ban

The new law bans gifts to health care providers by any manufacturer of a prescribed product.

Health care providers include any health care professional (defined as any Vermont licensed prescriber or a prescriber lawfully providing health care in Vermont), hospital, nursing home, pharmacy, health benefit plan administrator or any person authorized to dispense or purchase for distribution prescribed products in Vermont.

Gifts are anything of value provided to a health care provider for free, or any payment, food, entertainment, travel, subscription, advance, or service provided to a health care provider, unless: 1) the health care provider provides reimbursement for the item at fair market value or 2) the expenditure is explicitly considered an allowable expenditure under the law. The Attorney General's office has confirmed that a charitable donation to a hospital is something of value provided to a health care provider, and therefore prohibited under the new law.

Allowable expenditures include:

- Sponsorship of educational, medical, scientific, or policy-making conferences or seminars, with certain restrictions. Payments cannot be made "directly to a health care provider," so that direct funding of hospital-based medical education programs is no longer permitted in Vermont;
- Honoraria and payment for the expenses of a health care professional who serves on the faculty of a bona fide significant educational, medical, scientific, or policy-making conference or seminar, with certain restrictions;
- Support of bona fide clinical trials;
- Certain other research that involves a "systematic investigation" and can be considered to be of significant scientific interest or value;
- Reasonable expenses associated with training of health care professionals on the use of medical devices, provided that the terms of payment are in writing;
- Certain royalties and licensing fees paid to health care providers; and
- Reasonable payments provided by a manufacturer at fair market value.

In addition to the enumerated allowable expenditures, specifically exempted from the gift ban are:

- Prescription drug samples provided for free distribution to patients;
- Short-term (less then 90-day) trial loans of medical devices;
- A reasonable amount of medical device demonstration or evaluation units to permit assessment of the product;
- Peer-reviewed academic, scientific, or clinical articles or journals or other educational items provided to health care professionals for the benefit of patients;
- Scholarships or other support for medical students, residents, and fellows to attend conferences hosted by professional associations, provided that the recipient is selected by the association and not by the manufacturer or distributor;
- Rebates and discounts for prescribed products provided in the normal course of business;
- Labels approved by the FDA for prescribed products; and
- Payment, food, entertainment, travel, subscriptions, advances, services, or anything else of value that the health care provider reimburses at fair market value.

Disclosure Requirements

The new law, like the current law, requires annual disclosure of certain expenditures to the Vermont Office of the Attorney General. Manufacturers of a prescribed product must generally disclose allowable expenditures and non-prohibited gifts provided to Vermont health care providers and to academic institutions or a professional, educational, or patient organization representing or serving health care providers or consumers. Disclosure exemptions exist for:

- Certain royalties and licensing fees;
- The provision of prescription drug samples;
- Rebates and discounts provided in the normal course of business; and
- Payments for certain clinical trials until 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 (but disclosure of the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry is required).

Disclosures must include the following information:

- The value, nature, and purpose of each benefit according to specific categories identified by the Vermont Office of the Attorney General;
- The name, address, state board number and institutional affiliation of the recipient; and
- The prescribed product or products being marketed.

Significantly, the new law eliminates the current law's trade secret protection for disclosures. This change was made in response to a finding that only 17 percent of the disclosures made in 2008 were available to the public due to trade secret protection in the current law.

Timeline

Conduct requirements take effect July 1, 2009. Pharmaceutical manufacturers are directed to follow the current Vermont law for disclosure reports filed November 1, 2009 (covering July 1, 2008 to June 30, 2009). Pharmaceutical manufacturers must track allowable expenditures and gifts under the new Vermont law beginning July 1, 2009. Medical device and biological product manufacturers must track allowable expenditures and gifts under the new law beginning January 1, 2010. All manufacturers must report under the new law starting with reports filed October 1, 2010.

Enforcement

As with Vermont's current pharmaceutical marketing law, the Attorney General is authorized to bring enforcement actions against violators, including civil penalties of up to $10,000 per violation.

Conclusions and Recommendations

While compliance with the rigorous requirements of the current Vermont reporting law has been a challenge for the pharmaceutical industry, the new law presents additional hurdles for currently reporting companies and for the new entities now covered by the expanded statute.

The most immediate impact of the new conduct requirements may be the end of the free meal traditionally provided by manufacturers to facilitate detailing, information exchange or promotional speaker programs. Going forward, we expect to be involved in sorting out questions left open by the statute's definition of allowable expenditures. For example, although support for independent medical education and scholarships is specifically permitted, other types of grants are not enumerated as allowable expenditures. Because of ambiguities in the new statute, the Vermont Attorney General's Office has been asked to consider specific issues, such as the applicability of the conduct and reporting requirements to interactions and activities outside Vermont, and whether the allowable exception for fair market value payments is intended to permit the wide range of consultant arrangements permitted by the PhRMA and AdvaMed Codes.

If you have specific questions regarding the new statute or the evolving guidance, please contact your regular Ropes & Gray contact.

Finally, we will continue to track Vermont's efforts to require therapeutic substitution and share those developments with you.