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Life Sciences Health Industry Alert

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Update on Medical Device Manufacturer Marketing Activities: State and Federal Restrictions and Reporting Requirements

As most medical device manufacturers are aware, states are increasingly imposing marketing restrictions on device manufacturers through laws that previously focused more specifically on pharmaceutical manufacturers. These laws affect compliance activities and relationships with providers, and create new reporting obligations. The impact is significant in that these state laws directly influence how companies conduct business and interact with customers, but implementation is complicated by the variations that exist between states.

Some of these state laws are not entirely new. For example, Massachusetts and Vermont have had such laws in place since 2008 and 2009, respectively, and many companies by now have experience with reporting payments to health care professionals, as both Massachusetts and Vermont reports were due in 2010. Nonetheless, additional states have recently adopted marketing laws, and those states that have had laws in place for several years continue to revise the requirements by amendment or publication of additional guidance.

Most significantly, under the federal Patient Protection and Affordable Care Act ("ACA"), beginning March 31, 2013, and annually thereafter, device manufacturers must report payments to physicians and teaching hospitals during the preceding calendar year. This means manufacturers must be prepared to track payments in a comprehensive manner as of January 1, 2012. The Centers for Medicare & Medicaid Services ("CMS") is now in the early stages of developing specific provisions to implement the new ACA provisions, with publication of proposed regulations to occur not later than October 1, 2011. As we report below, CMS recently held a conference call to receive preliminary input from interested parties.

This *Client Alert* provides a brief overview of the existing state marketing laws that apply to device manufacturers, including recent changes to those laws, as well as federal reporting requirements under the ACA. Although the laws discussed may apply broadly to other entities, we refer below specifically to medical device manufacturers. For ease of reference, we include at the end of this *Client Alert* a chart outlining the applicable legal requirements.

California

Effective since July 2005, California's Compliance Program Law requires that "pharmaceutical manufacturers" (defined broadly to include entities that produce devices) develop a comprehensive compliance program ("CCP") and establish a specific maximum annual dollar limit on gifts, promotional materials, or items or activities that the manufacturer may give or otherwise provide to an individual medical or health care professional.

The annual dollar limit need not include:

- Product samples intended for free distribution to patients
- Financial support for continuing medical education ("CME") forums
- Financial support for health educational scholarships
- Fair market value ("FMV") payments made for legitimate professional services provided by a health care professional, including consulting

A manufacturer must also annually declare, in writing, that it is in compliance with its CCP and California law, and make available on its website its CCP and annual declaration of compliance. In addition, a manufacturer must provide a toll-free number for the public to request a copy of the CCP and declaration.

Colorado

Recently enacted Colorado laws also address marketing by medical device manufacturers, but do not appear to require specific action by manufacturers. Under a newly enacted Colorado law, beginning September 30, 2013 and by June 30 of each calendar year thereafter, Colorado's Department of Regulatory Agencies ("DORA") will post on its website copies of the disclosure reports medical device manufacturers are required to submit to the United States Department of Health & Human Services pursuant to section 6002 of the ACA, more fully discussed below.

Less directly, Colorado law also impacts medical device manufacturer relationships with health care providers through its "Michael Skolnik Medical Transparency Act of 2010." Under the Act, any physician applying for a new license or to renew, reinstate, or reactivate a license, and on or after July 1, 2011, additional applicants, including dentists, physician assistances, nurses, and physical therapists, must report specific information to the state, including information pertaining to any health care-related employment or independent contractor contracts with an annual aggregate value that exceeds $5,000. Such information will be available to the public in a searchable format on a website.

Connecticut

Connecticut Senate Bill 428 was enacted June 8, 2010, and required medical device manufacturers to adopt and implement, by January 1, 2011, a code that is consistent with, and minimally contains all of the requirements of, the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

In addition, manufacturers must adopt a CCP that comports with the guidelines provided in the "Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the United States Department of Health & Human Services Office of Inspector General.

The Connecticut Commissioner of Consumer Protection may impose civil penalties of up to $5,000 for violation of the above requirements, or a failure to conduct training or regular audits for compliance with the code.

Massachusetts

Massachusetts was the first state expressly to require financial disclosure from medical device manufacturers. We previously addressed the proposed Massachusetts restrictions and reporting requirements in our *Client Alert*, "Massachusetts Releases Proposed Restrictions on Drug and Device Marketing Activities, Annual Financial Disclosure Requirement," available at http://www.reedsmith.com/publications/search_publications.cfm?widCall1=customWidgets.content_view_1&cit_id=22666. The Massachusetts requirements are among the most restrictive and, in terms of tracking, pose some of the most significant tracking challenges.

The Massachusetts Marketing Code of Conduct Law ("MMCCL") was signed into law in 2008 and includes a variety of requirements related to the relationship between medical device manufacturers and Massachusetts-licensed health care practitioners.

First, the MMCCL requires that a medical device manufacturer adopt a marketing a code of conduct and adopt and submit to the state a description of its training program related to such code of conduct. A manufacturer must also certify to the Department of Public Health that, to the best of its knowledge, it is in compliance with the MMCCL and has conducted an annual audit to monitor such compliance. Further, a manufacturer must adopt and submit policies and procedures for investigating, taking corrective action, and reporting non-compliance with Massachusetts requirements.

Second, the MMCCL limits the provision of meals by medical device manufacturers to health care practitioners. Under the MMCCL, medical device manufacturers may only provide or pay for meals for health care practitioners if the following requirements are met:

- The meal is modest and occasional in nature
- The meal is not part of an entertainment or recreational event
- The meal is offered with an informational presentation or with an agent of the medical device manufacturer present
- The meal is offered, consumed, or provided inside the health care practitioner's office or a hospital setting (including a restaurant located in a hospital)
- The meal is not provided to a health care practitioner's spouse or other guest

Third, the MMCCL addresses CME, third-party scientific or educational conferences, and professional meetings. Under Massachusetts law, a manufacturer may provide reasonable, FMV compensation or reimbursement to health care practitioners serving as speakers or providing actual and substantive services for a CME event, third-party scientific or educational conference, or professional meeting. A manufacturer may also provide sponsorship or payment for any portion of such an event, where the payment is made directly to the conference or meeting organizers. In the case of CME funding, a manufacturer may not provide any advice or guidance to the CME provider regarding the content or faculty of a particular CME program. Further, a manufacturer must separate its CMS grant-making functions from its sales and marketing departments.

The MMCCL prohibits the following with respect to CME, third-party scientific or educational conferences, and professional meetings:

- Providing financial support for travel, lodging, or other personal expenses for non-faculty health care practitioners attending an event, either directly to the individuals or indirectly to the event's sponsor
- Compensating health care practitioners for time spent participating in an event
- Paying for meals directly to health care practitioners at an event, although a sponsor may, at its own discretion, apply financial support for manufacturers to pay for meals for all participants
- Sponsoring or paying for CME that does not meet the Accreditation Counsel for Continuing Medical Education ("ACCME") or equivalent standards, or that provides payment directly to health care practitioners

Fourth, with respect to consulting services, Massachusetts law authorizes reasonable compensation for the bona fide services of health care practitioners, as well as reimbursement for reasonable out-of-pocket costs incurred as a result of the performance of such services, as long as the compensation and reimbursement are paid pursuant to a written agreement.

Fifth, in Massachusetts, medical device manufacturers may pay or reimburse for reasonable expenses related to technical training of health care practitioners on the use of a medical device, provided the amounts or categories of reasonable expenses to be paid (e.g., travel and lodging) are described in a written agreement.

Finally, the MMCCL specifically permits the following:

- Distribution or receipt of peer-reviewed academic, scientific, or clinical information
- Advertising in peer-reviewed academic, scientific, or clinical journals
- Reasonable quantities of demonstration and evaluation units
- Price concessions in the normal course of business (e.g., rebates or discounts)
- Reimbursement information regarding products (e.g., coding and billing information)
- Certain charitable donations

In addition to the MMCCL requirements, Massachusetts requires that companies track and file annual reports on all fees, payments, subsidies, items of value or any other economic benefits valued at $50 or more provided to any Massachusetts covered recipient in the previous calendar year. A Massachusetts covered recipient is a person authorized to prescribe, dispense, or purchase a company's product in Massachusetts, including a hospital, nursing home, pharmacist, health benefit plan administrator or Massachusetts-licensed health care practitioner. The following items or payments are *not* subject to the tracking and disclosure requirement:

- Payments associated with clinical trials and genuine research
- Demonstration and evaluation units
- In-kind items used for charity care
- Confidential price concessions (e.g., rebates and discounts)

The Massachusetts Office of Health and Human Services ("EOHHS") is required to make all disclosed data publically available and easily searchable on its website. In November 2010, the EOHHS published for the first time data required to be reported under Massachusetts law. The release included information related to 2009 industry payments from pharmaceutical and medical device manufacturers for the six-month period July 1, 2009 through December 31, 2009. The data is available in a searchable database, as well as by prepared reports related to, for example, Top 20 Manufacturers and Top 50 Physicians.

Violations of the MMCCL or the disclosure requirements are punishable by a fine of no more than $5,000 for each transaction, occurrence, or event.

Nevada

Nevada law includes certain requirements related to medical device manufacturers, but does not require disclosure of gifts to health care providers; nor does Nevada law expressly ban gifts to health care providers or impose limits on gift amounts.

Effective October 2007, Nevada law requires medical device manufacturers to:

- Adopt a written marketing code of conduct
- Provide training programs for sales and marketing staff on the marketing code
- Conduct annual audits to monitor compliance with the marketing code
- Adopt policies and procedures for investigating noncompliance (including effective reporting mechanisms), taking corrective action, and reporting noncompliance to authorities, as appropriate

Medical device manufacturers must also submit annually to the Nevada Board of Pharmacy, certain information, including a copy of the marketing code of conduct, a description of the training program and investigation policies, and compliance officer information. Additionally, a manufacturer must certify that it has conducted an annual audit and is in compliance with its marketing code of conduct.

Vermont

Vermont's provisions also pose significant tracking challenges for manufacturers. With certain exceptions, Vermont law bans the provision by medical device manufacturers of gifts to health care providers, including health care professionals who regularly practice in Vermont, hospitals, nursing homes, pharmacists, health benefit plan administrators, and any other person authorized to dispense or purchase for distribution prescribed products in Vermont. In addition to the gift ban, Vermont law requires manufacturers to register and report the provision of allowable expenditures and gifts to health care providers.

Under Vermont law, "gifts" are defined as 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 the health care provider provides reimbursement for the item at FMV, or the expenditure is explicitly considered an allowable expenditure under the law.

Allowable expenditures include the following:

- Payments to sponsors of educational conferences
- Honoraria and expenses of health care professionals serving as faculty at an educational conference
- Payments related to clinical trials and research projects
- Payments related to technical training on medical devices
- Royalties and licensing fees
- Interview expenses related to an employment opportunity
- Other reasonable fees, payments, or other economic benefits provided at FMV

In addition to the above allowable expenditures, the following are excluded from the gift ban and are therefore permissible under Vermont law:

- Coffee or other snacks or refreshments at a booth at a conference or seminar
- Reasonable quantities of a nonprescription medical device provided to a health care provider for free distribution to patients
- Short-term (90-day) medical device loans and demonstration/evaluation units
- Peer-reviewed articles and other educational items
- Scholarships for medical students, residents, and fellows
- Rebates and discounts
- FDA labels for prescribed products

- Free products provided to free clinics
- Grants for fellowship salary support

In addition to the above gift restrictions, medical device manufacturers must annually report to the attorney general the value, nature, purpose, and recipient of any allowable expenditures or gift provided to a health care provider, academic institution, nonprofit hospital foundation, and professional, educational, or patient organization representing or serving health care providers or consumers located in or providing services in Vermont. The following need not be reported to the attorney general: royalties/licensing fees, rebates and discounts, certain clinical trials, interview expenses, and coffee and snacks at conference booths. The attorney general must make the reported information publically available and searchable through a website.

For violation of either Vermont's gift ban or disclosure law, the attorney general may bring an action for injunctive relief, costs and attorney's fees, and may impose on a manufacturer that violates the law a civil penalty of up to $10,000 per violation. Each unlawful gift or failure to disclose constitutes a separate violation.

Federal Law

By virtue of the ACA, signed into law March 23, 2010, federal law now joins Massachusetts and Vermont in requiring medical device manufacturers to report certain payments and transfers of value. Section 6002 of the ACA requires annual reporting by manufacturers of payments and other transfers of value furnished to covered recipients. Importantly, under the federal law, covered recipients are limited to physicians and teaching hospitals. The first report is due March 31, 2013, tracking payments made as of January 1, 2012, and the information disclosed will be available to the public on-line.

Under the federal law, anything of value provided to a covered recipient must be reported, unless an exclusion applies. The following are not "payments or other transfers of value" under the ACA and will not need to be reported:

- Payments of less than $10, unless the annual aggregate amount is greater than $100
- Educational materials
- Short-term medical device loans
- Warranty items or services
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in his or her professional capacity
- Discounts and rebates
- In-kind items used for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- Payments for the provision of health care to employees under a self-insurance plan;
- A transfer of anything of value to a covered recipient for non-medical professional services
- Compensation paid to employed covered recipients

The reports required by the ACA must include information regarding the covered recipient; the amount of the payment and dates on which it was provided; a description of the form of the payment (e.g., cash or a cash equivalent, in-kind items or services, stock); a description of the nature of the payment (e.g., consulting fees, gift, food, charitable contribution, grant); and the name of the device, if the payment or other transfer of value is related to marketing, education, or research specific to a covered device.

Any manufacturer that fails to submit the required information in a timely manner will be subject to a civil money penalty ("CMP") of between $1,000 and $10,000 for each payment or other transfer of value not reported, but not to exceed a total of $150,000. Manufacturers that knowingly fail to submit the required reports and information are subject to CMPs between $10,000 and $100,000 for each payment or other transfer of value not reported, but not to exceed a total of $1 million.

Effective January 1, 2012, the federal law preempts any state laws that require manufacturers to disclose or report the same type of information required by ACA. Significantly, however, the federal law does **not** preempt any state law that requires the disclosure of information not covered by ACA or information expressly excluded from disclosure by ACA, including:

- Reportable exclusions greater than $10 in value (or with an annual aggregate greater than $100)
- Payments by entities or persons other than manufacturers
- Payments to entities other than physicians and teaching hospitals
- Payments required to be reported to federal, state, and local agencies for public health surveillance purposes

Accordingly, notwithstanding the ACA, the highly detailed and burdensome Massachusetts and Vermont reporting requirements will still apply. Under both of these laws, the covered recipients for purposes of reporting are defined more broadly than the federal definition of "physicians and teaching hospitals." In other words, manufacturers will have to continue to maintain multiple tracking systems.

As noted, the Secretary of the U.S. Department of Health & Human Services is required to establish, not later than October 1, 2011, procedures related to the submission and public availability of required information. CMS is in the process of preparing regulations related to section 6002, but has not yet released specific guidance regarding the new reporting requirement.

On March 24, 2011, CMS held a telephone conference related to the transparency reports and reporting of physician ownership and investment interests under section 6002. According to CMS, the purpose of the call was to solicit input on certain defined topics, including forms and nature of payment, accessibility and usability of the reported data, and mechanisms for reporting data. CMS noted at the outset of the call that it was participating in a "listening only" role, and therefore, it refused to answer any questions or provide specific guidance. CMS did note that it is working to publish a proposed rule "later this year."

During the call, several commenters noted the importance of clear regulatory guidance and specific definitions. Not surprisingly, commenters also indicated that they were opposed to any efforts by CMS to require manufacturers to report additional forms or natures of payment or transfers of value, or additional categories of reportable information, beyond those already included within section 6002. According to the commenters, the information required by section 6002 will already result in the submission of huge quantities of data. Multiple commenters also emphasized the importance of establishing a process that avoids duplication of payment reporting. Finally, a common theme during the call was the idea that the public release of the reported information should be accompanied by an easily understandable explanation of the information and the relationships that are being reported. Commenters requested that industry have a role in developing any such explanation.

Conclusion

The following chart summarizes the information provided above related to current state and federal laws impacting medical device manufacturers. We continue to monitor pending state and federal legislation on this topic.

As this discussion illustrates, while the various state and federal laws related to medical device manufacturer marketing activities share some similar traits, such as compliance program or reporting requirements, significant variations exist between the different states and the new federal reporting obligations under the ACA. These include, fundamentally, the types of gifts that are prohibited and the specific expenditures that must be reported. Given these variations, and considering the potentially steep penalties that apply in the event of noncompliance, medical device manufacturers must familiarize themselves with the requirements of each applicable state law and section 6002 of the ACA, and stay alert for federal implementation developments. Manufacturers that may have cobbled together tracking systems should take the time to consider more fully how they will track and report payments to health care providers and other entities, as required by these new and divergent requirements.

Please advise if we can provide assistance with these evolving reporting obligations. In the meantime, we will continue to monitor developments.

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Compliance Program Requirements	HCP/HCO Spending Restrictions / Limits	Payment Reporting Obligations	On-line Payment Posting	Citation
CALIFORNIA				
Adopt a comprehensive compliance program ("CCP").	Establish specific annual dollar limits on gifts, promotional materials, or items or activities provided to health care providers.	N/A	N/A	Cal. Health and Safety Code §§ 119400 - 119402
COLORADO				
N/A	N/A	Physicians and other providers (but not manufacturers) must report health care-related contractual relationships, including with medical device manufacturers, valued at more than $5,000 annually.	DORA will post disclosure reports required pursuant to ACA. Information provided by physicians and other providers regarding contractual relationships will also be posted.	Col. Rev. Stat. § 24-34-110 and § 24-34-111
CONNECTICUT				
Adopt and implement a code consistent with the AdvaMed Code, and a CCP that comports with the OIG guidance.	N/A	N/A	N/A	Public Act No. 10-117 (Senate Bill 428)
MASSACHUSETTS				
Adopt a marketing code of conduct, training program, policies and procedures for investigating and responding to non-compliance, and annual auditing function.	Ensure HCP meals, training and consulting services, and CME and related third-party scientific and educational program sponsorship meet specific requirements.	Track and report annually all fees, payments, subsidies, items of value or any other economic benefits valued at $50 or more provided to a covered recipient.	EOHHS will post all disclosed data on its website.	M.G.L. c. 111N and 105 CMR 970.000
NEVADA				
Adopt a marketing code of conduct, training program, internal investigation policies and procedures, and annual compliance audit function. Submit related information to the Board of Pharmacy annually.	N/A	N/A	N/A	Nev. Rev. Stat. § 639.570
VERMONT				
N/A	Provide to health care providers only allowable expenditures and those items excluded from the Vermont gift ban.	Report annually allowable expenditures and gifts to health care providers, academic institutions, nonprofit hospital foundations, and professional, educational, or patient organizations.	Attorney general will make reported information publically available and searchable on-line.	Vt. Stat. Ann. Tit. 18, Ch. 91, §§ 4631a, 4632
ACA				
N/A	N/A	Report annually payments and other transfers of value furnished to physicians and teaching hospitals (first report due 3/31/13).	Disclosed information will be available to the public on-line.	Pub. L. No. 111-148 (to be codified in various sections of 42 U.S.C.)

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