



Sales Rep Nightmares: Emerging Issues in Marketing Compliance

by John Patrick Oroho, Christine N. Bradshaw, and Christopher R. Corallo

Over the past several years, prescription drug companies have been required to report to various state agencies the promotional expenses incurred in their interactions with healthcare practitioners (HCPs). Medical device companies are increasingly subject to these state disclosure laws as well. Currently, the federal government is also considering legislation that would require both pharmaceutical and medical device manufacturers to disclose “the value, nature and purpose” of promotional expenditures directed toward HCPs.

Many state-regulated interactions with HCPs involve sales representatives, detailers or other company representatives operating in the field and engaged in promotional activities. The regulatory environment for promotional interactions has become quite volatile and states, as well as individual

institutions, are calling for more transparency and accountability. Given pending federal legislation and recent changes to the Pharmaceutical Research and Manufacturers of America’s (PhRMA’s) *Code on Interactions with Healthcare Professionals* and the Advanced Medical Technology Association’s (AdvaMed’s) *Code of Ethics on Interactions with Health Care Professionals*, sales representative training on and awareness of these issues are critical to a company’s efforts to ensure compliance with marketing-related laws and guidelines.

This article focuses on three types of restrictions that go beyond state marketing disclosures: medical school and institutional restrictions on the interactions between sales representatives and HCPs; state or institutional classification of sales representatives as lobbyists under the state or local



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government's lobbying laws; and the sales representative licensure law recently enacted in the District of Columbia, which requires that company representatives become licensed before interacting with HCPs.

Medical Schools and Institutions

Site Access

Many medical institutions, including medical schools and university hospitals, require sales representatives or vendors to register with the institution, make an appointment with specific HCPs, obtain identification badges upon arrival at the facility, and agree to comply with institution policies and procedures prior to gaining access to grounds and staff. A sales representative's access also may be limited to only non-patient areas, unless the institution determines that the sales representative should provide in-service training on devices or other equipment.

Some institutions impose additional procedural requirements. For example, the University of Michigan Health System requires registrants to sign a statement certifying that he or she has received, reviewed and agrees to comply with all policies and guidelines provided by the institution. New Jersey's Hunterdon Healthcare System requires vendors to disclose any conflicts of interest. Other medical institutions, such as the Duke University Health System, require registrants to sign a confidentiality agreement as part of their registration process.

Additionally, many medical institutions require payment of registration fees by either each registering representative or the vendor itself. The University of Illinois Medical Center at Chicago requires registering representatives to pay a \$250 fee

annually. The Hunterdon Healthcare System requires both representatives and the company to register with the institution, and the company/vendor must pay a fee ranging from \$25 to \$250, depending on the extent of the vendor's business relationship with Hunterdon.

Meals & Gifts

Institutions around the country are adopting policies regarding a company representative's ability to provide meals or gifts to HCPs, medical staff, students and other personnel that, in some cases, are more restrictive than state law and industry guidances. As such, it is necessary for companies to take notice of a particular medical institution's definition of the term "gift." Most institutions' policies identify a range of items that may fall under the definition of an unacceptable gift, including all or some of the following: food, pens, pads, mugs, textbooks, office supplies, cash, entertainment, payment for travel, and time and participation associated with continuing medical education events.

In many instances, the definition of "gift" is quite broad. For example, Mount Sinai Medical Center prohibits vendors from giving gifts of *any* value and specifically lists the following as included in this prohibition: cash, any product or service, discounts on products or services, prizes, gift certificates, tickets, loans, meals, transportation, hotel accommodations, use of a company's vehicles or vacation facilities, any securities or participation in stock offerings, *de minimis* gifts and group gifts (such as flower arrangements or chocolates intended to be shared by members of a staff). Some policies allow gifts, but include specific dollar value limitations. The University of Texas Southwestern Medical Center, for example, prohibits "gifts

of significant value (more than \$50/year)" and includes meals, services and entertainment in the definition of "gift."

Generally, medical institution gift policies are being proposed and adopted with language that expressly prohibits gifts of any kind from industry. A sales representative who fails to comply with an institution's vendor relations policy may be suspended or banned from accessing the institution, which may be only one medical facility, or could encompass many facilities.¹

Some institutions' policies go so far as to permanently ban a sales representative *and* his or her company from access to the facility for non-compliance with its rules and regulations governing gifts. Many policies have a tiered system of penalties for non-compliance. For example, the University of Missouri imposes a sanction on the first offense, issues a six-month suspension from its facilities on the second offense and issues a permanent ban after a third offense.

Lobbyist Registration & Disclosure

Individual Institutions

Beyond limiting physical access to their facilities, some medical schools and institutions may require sales or vendor representatives to register and comply with state or local government lobbyist registration requirements. In Florida's Miami-Dade County, the Jackson Health System (JHS) has a policy that requires, among other things, that:

all Vendor Representatives, prior to engaging in any conversation or communication, verbal or written, with a County/JHS Employee or JHS Medical Staff Member for the

purpose of selling, marketing or influencing a decision to purchase any product or service that shall require the expenditure of County/ JHS funds, must first become “registered” with the County as a “lobbyist.”²

In December 2006, the Miami-Dade County Commission on Ethics and Public Trust issued an advisory opinion that concluded that “seeking to influence the action, recommendation or decision of County personnel” triggers the lobbyist registration requirement because University of Miami physicians “are functioning as County personnel when they make decisions regarding particular products and services for use in Jackson facilities.”³

Thus, not only do sales representatives need to register as lobbyists when interacting with HCPs at JHS facilities, they also will be considered lobbyists and must register with Miami-Dade County whenever they interact with any HCP who works with JHS, even if only on a part-time or temporary basis.

State Lobbying Laws

Most states have lobbying laws that regulate interactions between government employees and industry representatives. “Government employees” is often a broadly defined term, and may include public servants, public officials, committee members or other members of administrative bodies. While sales representatives’ actions generally fall outside the scope of most states’ lobbyist laws, at least one state has made clear that its law applies to sales representatives’ interactions with certain HCPs.

In Louisiana, lobbying of executive branch employees occurs when

industry seeks to influence “any act by an executive branch agency or official to effectuate the public powers, functions and duties of an executive branch official or an executive branch agency, including but not limited to any act in the nature of policymaking, rulemaking, adjudication, licensing, regulation or enforcement.”⁴ In January 2006, the Louisiana Board of Ethics was presented with the following issue:

[Do the] educational and detailing practices of pharmaceutical and biotechnology employees directed toward physicians and other healthcare professionals practicing or affiliated with public hospitals, which are conducted for the purposes of educating practitioners about available pharmaceutical products and the risks and benefits associated with drugs to better enable practitioners to make appropriate patient treatment choices, fall within the definition of “lobbying” under the Executive Branch Lobbying Act.⁵

The Board of Ethics concluded, based on its review of Louisiana law, that the detailing practices of pharmaceutical representatives directed toward HCPs at public hospitals would constitute lobbying.⁶

Shortly thereafter, the legislature enacted Senate Bill 320, amending the definition of “executive branch action” to exclude general detailing sessions with HCPs from the purview of “lobbying.” This policy change specifically addressed the issue involving industry detailing activities and interactions with executive branch officials. Under the terms of Senate Bill 320, however, any action taken by a member of the Louisiana Medicaid Pharmaceutical and Therapeutics

Committee (P&T Committee) constitutes “executive branch action” and therefore “any pharmaceutical representative who interacts with a member of the [P&T] Committee *for the purpose of* inclusion of any product on the pharmacopoeia or formulary” must register as a lobbyist and disclose expenditures related to those interactions.⁷

The Louisiana P&T Committee currently consists of 19 members.⁸ If a sales representative interacts with any one of those members for the purpose of discussing the inclusion of his or her company’s products on the state pharmacopoeia or formulary, he or she must register as a lobbyist in Louisiana and file monthly expenditure reports with the Board of Ethics.

On March 30, 2008, the Louisiana legislature enacted Act 9, which added a section to Louisiana’s Code of Governmental Ethics concerning limitations on food, drink and refreshment for public servants.⁹ In July 2008, the Louisiana Board of Ethics was presented with the following question:

[May] physicians who are employees of State Hospitals ... accept lunches and dinners from representatives of pharmaceutical companies and other health-related sources?

The Board of Ethics explained that while public servants are prohibited from receiving any “thing of economic value” from a sales representative, the Code of Governmental Ethics creates an exception for food or drink consumed while the personal guest of the giver.¹⁰ The Board explained that “if a public servant has lunch or dinner with, and in the personal presence of, a pharmaceutical representative,” the Code of Governmental Ethics would not be violated.¹¹ The Board

concluded by noting that the Code of Governmental Ethics specifically restricts “prohibited sources,” including sales representatives, from *purchasing* more than \$50 of food for a public servant, per event.¹²

Sales representatives must be cognizant of their interactions and meal expenditures in Louisiana to ensure that they conform to state law, lobbyist restrictions and regulations. Pharmaceutical companies must train their representatives on the laws applicable to them, and ensure that these representatives are sensitive to the distinctions between HCPs falling within the purview of either the lobbyist law or the Code of Governmental Ethics and most other HCPs in Louisiana who are outside the scope of these laws.

Pharmaceutical Detailer Licensure

Pharmaceutical companies, contract sales organizations and related entities have their own standards and requirements that dictate the qualification requirements a person must satisfy to effectively perform promotional activities on its behalf. The District of Columbia has now entered into the arena of establishing qualifications for sales representatives by passing first-of-its-kind legislation in February 2008.

Under the District of Columbia law, pharmaceutical sales representatives who are hired to sell, market or promote their company’s product to a HCP in the District must be licensed as a “pharmaceutical detailer.”¹³ In June 2008, the District of Columbia’s Department of Health approved regulations that require pharmaceutical detailers to be licensed beginning April 1, 2009.¹⁴

Most states have lobbying laws that regulate interactions between government employees and industry representatives.

Amended regulations were adopted and finalized in April 2009. The revised regulations clarify that the “practice of pharmaceutical detailing” means representing a pharmaceutical manufacturer or labeler and communicating, in person, with a licensed HCP or his or her employee or representative in D.C. in a non-conference setting for the purpose of selling, marketing or promoting a prescription or OTC drug for use in humans, or providing information to sell, market or promote the drug.¹⁵

Sales representatives who seek to detail in the District must complete a New License Application, which requires representatives to provide, among other things:

- Proof of graduation from an institution of higher learning (note that this education requirement may be waived if the sales representative can show proof of full-time employment as a pharmaceutical detailer for a 12-month period);
- Social Security Number;
- Passport photo;
- Drivers License;
- Notarized “Affidavit to Abide by Code of Ethics”; and
- License fee of \$175.

Once the sales representative is licensed, he or she must complete at least 15 hours of continuing education credits approved by the

Board of Pharmacy over the two-year licensure term.¹⁶

The District of Columbia Code of Ethics specifies prohibited interactions, including but not limited to:

- Deceptive or misleading marketing;
- Using a misleading title or designation;
- Attending patient examinations without written patient consent;
- Willfully harassing or intimidating HCPs;
- Making sales calls to a HCP who has requested to no longer receive such calls; and
- Offering a gift or remuneration of any kind to a member of a medication advisory committee.¹⁷

In addition, the Code of Ethics affirmatively requires the detailer to:

- Provide information to HCPs that is accurate and fairly balanced in compliance with FDA policies and practices for providing information to HCPs; and
- Comply with the standards established by the PhRMA Code.¹⁸

There are many components to the detailer law that were created to monitor the activity of detailers. One noteworthy element is the Board of Pharmacy’s authority “to collect information from licensed pharmaceutical detailers relating to their communications with

licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.”¹⁹ Consequently, sales representatives must maintain detailed records of communications and documentation referenced or discussed during the promotional meeting between the pharmaceutical detailer and the HCP.²⁰ This information must be easily accessible, as the representative has only 10 days to forward this information to the Board of Pharmacy once the request is made.²¹ The detailer or his or her company must store these records for at least five years from the date of the communication or contact.²²

One of the most noteworthy additions of the recently amended regulations is that a sales representative may engage in limited detailing

activities while his or her application is being reviewed, provided that the representative’s supervisor is licensed.²³ Under this provision, a representative who has filed his or her application for licensure and has received a “supervised practice” letter from the Board of Pharmacy may engage in the “supervised practice” of detailing for up to 60 days while his or her application is pending.²⁴

In order for pharmaceutical companies to comply with the District of Columbia’s licensure law, it will be imperative for companies to train their representatives who detail in the District on the registration process and ongoing compliance requirements, particularly those involving the compilation of sales call records and documentation. Companies will need to ensure, either through an

internal records system or by sales representative certification, that all detailers in the District comply with the continuing education requirements mandated by the law and relevant regulations.

Conclusion

Effective lines of communication are critical in today’s compliance landscape. Sales Operations and Compliance departments must work together to assess existing and emergent limitations on sales representative site access, gift and meal restrictions, lobbyist registration and reporting requirements, and detailer licensure obligations. In addition, compliance professionals must ensure that their sales personnel understand the true importance of recording and reporting promotional

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expenses. The move by the federal government to adopt disclosure legislation may further complicate internal business decisions regarding expense capture, unless a unified industry approach is adopted. In the interim, annual process and data audits, employee training, timely revisions to policies and procedures, and effective state law monitoring systems are key to maintaining successful sales force compliance strategies. ▲

1 For example, the Jackson Health System in Florida includes the Holtz Children's Hospital, Jackson Mental Health Hospital Center, Jackson Memorial Rehabilitation Center, Ryder Trauma Center, Jackson North Medical Center, Jackson South Community Hospital and all in-patient buildings that are part of Jackson Memorial Hospital.
 2 JHS, Vendor Representative Guidelines (Aug. 22, 2007), available at http://www.jhsmiami.org/workfiles/VendorAccessPolicy_%208.22.07.pdf (last visited Jan. 21, 2009).
 3 Miami-Dade County Commission on Ethics & Public Trust, Advisory Opinion RQ0 06-63 (Dec. 27, 2006).
 4 LA. REV. STAT. ANN. § 49:72(2)(a) (2009).

5 Louisiana Board of Ethics, Advisory Opinion No. 2005-560 (Jan. 17, 2006).
 6 *Id.*
 7 LA. REV. STAT. ANN. § 49:72(2)(b) (emphasis added).
 8 The current list of members can be found at http://www.legis.state.la.us/boards/board_members.asp?board=672 (last visited Jan. 20, 2009).
 9 LA. REV. STAT. ANN. § 42:1115.1.
 10 Louisiana Board of Ethics, Advisory Opinion No. 2008-606 (July 2, 2008); LA. REV. STAT. ANN. § 42:1102(22)(a).
 11 Louisiana Board of Ethics, Advisory Opinion No. 2008-606 (July 2, 2008).
 12 *Id.*; LA. REV. STAT. ANN. § 42:1115.1.
 13 DC CODE § 3-1207.41 et seq. (2009).
 14 DC MUN. REGS. tit. 17, § 8300 et seq. (2009).
 15 *Id.* § 8300.5.
 16 *Id.* § 8306.
 17 *Id.* § 8305.
 18 *Id.*
 19 *Id.* § 8309.1.
 20 *Id.* § 8309.6.
 21 *Id.* § 8309.2.
 22 *Id.* § 8309.4.
 23 *Id.* § 8311.
 24 *Id.*

Jeff Berman has joined the Washington, DC office of the law firm Bryan Cave LLP, in its Public Policy & Governmental Affairs group. Prior to joining Bryan Cave, Berman served as the national delegate director for the Obama presidential campaign. He devised the strategy to focus on the caucus states and every proportional and unpledged delegate allocation to build and preserve the campaign's narrow lead through the primaries and caucuses. Berman supervised compliance with all state laws and petition requirements and tracked all delegates to the Democratic National Convention. At the National Convention, he oversaw the development of the 2008 Democratic Party platform, the creation of a new DNC commission to revise national Democratic Party rules and the resolution of all credentials controversies, including those involving the Florida and Michigan primaries. Berman also negotiated the National Convention nominating procedures to guarantee a unified convention vote for Obama.

Elisabethann Wright has advanced to partnership at Hogan & Hartson LLP, in the

firms' Brussels office. She works in the food, drug, medical device and agriculture sectors.

Michael H. Hinckle rejoins the firm of K&L Gates LLP as a partner in its Research Triangle Park office, in the firm's food and drug practice. Before his return to K&L Gates, Hinckle worked at Synthon Pharmaceuticals, Inc., where he served as Vice President and General Counsel since 2003.

Nanette Mantell has become Managing Partner of Reed Smith LLP's Princeton office, effective immediately. In addition, she recently assumed the position of Vice Chair of the firm's Life Sciences Health Industry Group (LSHI).

Bruce D. Armon, a Partner in Saul Ewing LLP's Business Department and former Chair of its Life Sciences Practice Group, has been appointed Managing Partner of the firm's Philadelphia office. In this capacity, he will oversee more than 100 attorneys who represent local and national clients in corporate, environmental, estates and trusts, healthcare, insurance, litigation and real estate matters. He also serves as the firm's Hiring Partner.