

The Perfect Storm: Weathering the Convergence of Federal, State and Industry Regulations Impacting Pharmaceutical Sales and Marketing Representatives

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The Pharmaceutical Research and Manufacturers of America (PhRMA) Code, Office of the Inspector General (OIG) Guidance and the Prescription Drug Marketing Act,¹ are just some of the federal and industry laws and guidances with which pharmaceutical companies and their representatives must comply in order to market pharmaceutical products in the United States. Once you add to this list the various state laws and medical school interaction policies that regulate interactions between pharmaceutical sales representatives and healthcare professionals (HCPs), marketing and detailing becomes a veritable crucible for the unwary.

The last few years have seen an increase in scrutiny by industry groups, federal regulators and consumer watchdogs on the sale and promotion of

pharmaceutical products. The effects of such scrutiny can be seen in the issuance of revised versions of existing codes of conduct, such as the PhRMA Code, and new laws. Although the pharmaceutical industry has increased its efforts to employ alternatives to the “rep-centric” sales model, representatives remain a centerpiece of pharmaceutical company sales and marketing strategies. As a result, the states have continued to increase their efforts to regulate sales representatives’ interactions with HCPs, creating a perfect storm for pharmaceutical marketing and sales compliance.

Federal and Industry Codes of Conduct

The OIG’s 2003 Compliance Program Guidance for Pharmaceutical Manufacturers² (OIG Guidance) addresses the key elements of an effective compliance

program, including the development of written policies and procedures, effective training programs, and auditing and monitoring procedures.

Although compliance with the OIG Guidance is voluntary, a company’s failure to implement an effective compliance program can result in serious consequences, including federal and state criminal and civil monetary penalties and the imposition of corporate integrity agreements. Accordingly, sales representatives must be trained on the requirements of a company’s compliance program and should also be required to certify compliance with the same.

The industry has also promulgated voluntary codes of conduct to create uniformity and assist industry members in complying with the law. For example, the 2009 PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code),³ with which the member companies of PhRMA have voluntarily undertaken to comply, provides guidelines for sales representative interactions with physicians and other prescribers. This version of the Code, which replaces the 2002 PhRMA Code, differs from its predecessor in a number of key respects.

For example, whereas the old Code permitted sales representatives to offer



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meals to HCPs outside of the office setting, the revised Code limits the provision of meals to in-office and hospital settings. The revised Code also no longer permits the offer of practice-related reminder items such as pens, note pads and mugs.

While the PhRMA Code and OIG Guidance remain voluntary, several states have passed legislation that would make these guidance documents mandatory. Thus, it is no longer the case that companies may choose to comply with a particular guidance. If you do business in California, Nevada, Massachusetts or the District of Columbia—compliance with one or both of these guidances is required as a matter of law.

State Disclosure and Limitation Laws

Currently, California, Maine, West Virginia, Vermont, Minnesota, Massachusetts and the District of Columbia impose some form of disclosure requirement on companies whose sales representatives market pharmaceutical products to HCPs within their borders. Generally, these laws require companies to disclose the value, nature and purpose of gifts, fees, payments and subsidies valued at more than a specified dollar amount.

For example, Minnesota, which enacted the first such law in 1993, requires distributors to annually disclose the nature and value of “all payments, honoraria, reimbursement or other compensation” totaling \$100 or more.⁴ The state also imposes a ban on gifts to HCPs that exceed \$50 per year.⁵

Vermont followed suit nearly a decade later with a law requiring companies to annually disclose “the value, nature and purpose” of gifts, fees and other payments provided directly or indirectly to HCPs.⁶ The prototype established by Ver-

mont was subsequently mirrored in the District of Columbia⁷ and Maine⁸ laws. In addition to incorporating the requirements of the Vermont law, the District of Columbia and Maine laws also require companies to disclose expenses associated with the advertising and direct promotion of drugs through various media.

On June 8, 2009, Vermont amended its law to prohibit companies from offering or giving any gift to a HCP as of July 1, 2009. The gift ban is more restrictive than the PhRMA Code and covers anything of value provided to a HCP for free, including food, entertainment, gifts or payments, unless an item is explicitly allowed or the HCP reimburses the cost at fair market value.

Of the disclosure states, West Virginia’s⁹ law is unique in that it requires pharmaceutical companies to report the total number of prescribers receiving gifts, fees and payments exceeding \$100 or more and the total amount spent on advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups within the state.¹⁰ A listing of individual practitioners is not required in West Virginia.

While a number of these laws, such as the Minnesota and Vermont laws, have been in existence for quite some time, the newcomers to the state disclosure arena are rewriting the rules on gift disclosure. Massachusetts¹¹ has combined all of the most vexing elements of the gift disclosure and code of conduct laws and guidances. Truly unique, the Massachusetts law contains a state gift-reporting component, a requirement to adhere to a code of conduct that is more restrictive than the PhRMA Code, along with new restrictions on the use of prescriber identifiable data, and standards for the funding of continuing medical education events.

In order to effectively comply with laws that either affirmatively ban gifts, such as Minnesota, or which impose gift reporting thresholds, companies must have systems in place to track these expenditures. Sales representatives must be trained to enter these types of expenses in a centralized system that allows the company to audit whether any of these limits have been met. In addition, companies must have procedures in place to ensure that other functions within the company, for example, the grants and advertising groups, understand what types of expenses are reportable and how best to report such data.

State Codes of Conduct

California

California¹² was the first state to introduce a law mandating compliance with “voluntary” codes of conduct. The law, which was passed in 2005, requires companies to adopt a Comprehensive Compliance Program (CCP) that is in accordance with both the OIG Guidance and the most recent version of the PhRMA Code.

As part of its CCP, a company must annually set a spend limit on gifts and meals to California HCPs and publicly post that limit, along with a copy of its CCP and certification of compliance. For sales representatives and sales managers, marketing in California and organizing national programs that may include California HCPs requires being mindful of the spend limit and whether that limit has been exceeded for any individual HCPs. This task is no doubt complicated by the sheer size of the California market and number of HCPs.

Nevada

On June 14, 2007, Nevada’s governor signed a law that imposes disclosure requirements on pharmaceutical and

medical device companies.¹³ The final regulations implementing the law were approved on January 30, 2008.¹⁴

Pursuant to Nevada's law, manufacturers and wholesalers who employ a person to sell or market a drug, medicine, chemical, device or appliance in the state must file annual submissions with the Nevada Board of Pharmacy confirming compliance with the law's training, investigation and auditing requirements.¹⁵ The law requires manufacturers and wholesalers to adopt a Marketing Code of Conduct setting forth the company's "practices and standards that govern the marketing and sale of its products."¹⁶

According to the law, a company may adopt either the PhRMA Code or AdvaMed Code¹⁷ without modification in lieu of creating its own marketing code of conduct.¹⁸ To the extent that a company chooses to create its own marketing code of conduct, it must ensure that it contains all of the elements addressed in the PhRMA Code or AdvaMed Code.¹⁹

Massachusetts

In addition to requiring companies to disclose the value, nature and purpose of gifts provided to HCPs, the Massachusetts law also requires companies to adopt and certify compliance with the Massachusetts Department of Health's Marketing Code of Conduct provisions.²⁰ The Massachusetts Code of Conduct provisions closely track the PhRMA Code and AdvaMed Code, but are more restrictive than either in a number of instances.

For example, the Massachusetts law restricts meals to in-office and in-hospital settings, regardless of who within the pharmaceutical company sales chain is providing the meal. By contrast, the PhRMA Code's restriction on in-office and in-hospital meals applies only to sales representatives and their imme-

diately supervisors. The Massachusetts law would, however, permit meals to be provided pursuant to a consulting agreement so long as the meal represents compensation to the HCP for bona fide services. Additionally, the Massachusetts Code of Conduct requires companies to fund Continuing Medical Education (CME) that is accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an equivalent accrediting body. The PhRMA Code does not appear to limit companies to funding only accredited programs.

In order to effectively comply with the Massachusetts law, companies will need to develop systems not only to maintain detailed and comprehensive accounts of practitioner spend, but also to comply with the restrictive Marketing Code of Conduct. Company training of sales, marketing and administrative personnel responsible for business in Massachusetts will be critical to ensuring compliance with the Massachusetts' unique requirements.

State Detailer Licensing Laws

Perhaps the most unique response to the challenge of regulating pharmaceutical detailing comes from the District of Columbia, which not only requires companies to report gifts, meals, payments and subsidies provided to District HCPs, but, as of April 1, 2009, also requires sales representatives to obtain a license to "practice pharmaceutical detailing" in the District while certifying compliance with a marketing code of ethics.

The process of obtaining a pharmaceutical detailing license can be quite cumbersome, not only for the affected pharmaceutical sales representative, but also for the company, which must create systems to track and monitor its representatives' licenses. In order to obtain an initial license, the sales representative

must take the following steps: 1) submit a certification of graduation from an "institution of higher learning" (defined as a 2- or 4-year college degree); 2) complete the actual application for licensure, which requests both personal and employment information; 3) complete a notarized affidavit certifying compliance with a "code of ethics;" and 4) submit two passport-sized photos.

Further, sales representatives who interact with District of Columbia HCPs must keep detailed records about those interactions. These records include not only the contact information for the HCP or the employee or representative of the HCP, but also details about the types of promotional materials left with the individual and whether any sample products were provided. Significantly, some sales expense systems may not be configured to capture this type of information. Companies may need to create a paper form to capture this information until its internal systems can be updated with new fields.

Pharmaceutical detailing licenses must be renewed every two years. A prerequisite of renewal is proof of having completed at least 15 credit hours of continuing education. To fulfill this requirement, a company may tailor its existing training programs to count towards the 15 credit hours. Alternatively, a company may contract with an outside vendor to create company specific training modules to satisfy the continuing education component. It is clear that the District of Columbia licensure requirements are a continuing obligation that must be worked into a company's overall marketing procedures.

Facility Codes of Conduct

Individual medical schools and teaching institutions have also lent their voices to the chorus of "Pharma Free" protes-

tors by enacting interaction policies and codes of conduct that severely restrict pharmaceutical representative contact with institution HCPs.

The policies and guidelines are quite diverse and impose prohibitions and limitations that directly impact the manner in which pharmaceutical companies and their representatives interact with medical school faculty, staff and students.

Policies generally restrict the following: 1) gift giving to faculty, staff and students; 2) site access to faculty, staff and students; 3) drug sample distribution; 4) continuing medical education programs sponsored by industry; 5) scholarships/grants sponsored by industry; and 6) purchasing and formulary committees staffed by medical school personnel.

With respect to “site access,” these policies often prohibit industry representatives from accessing patients and patient-care areas. Such policies will permit industry representatives to access faculty, staff and students by appointment only. Many of these policies require industry representatives to register or check in before meeting with faculty, staff and students.

For example, the University of North Carolina at Chapel Hill School of Medicine has imposed a policy that requires vendors to have a previously scheduled appointment to visit the school’s facility. The policy prohibits representatives from accessing outpatient clinics, inpatient areas, patient waiting areas, department or division offices or the administrative areas of the Pharmacy and Purchasing Departments. Representatives must additionally check in at the medical school facility and wear identifying badges at all times while in the facility.

By contrast, Florida State University College of Medicine has a policy that prohibits industry representative access

to faculty, students, residents or staff on school property, except for the purpose of discussing or providing an unrestricted educational grant.

The primary obstacle facing companies and their sales representatives with respect to these initiatives is knowing which schools actually have these policies in place before the sales representative visits the location.

Conclusion

To effectively weather the storm of federal, state and industry regulation of HCP interactions, companies must have not only effective policies and procedures in place, but also systems to monitor sales representative compliance with those policies and procedures. In addition, once the company has decided how it will approach compliance with a particular law or code of conduct, it must implement training programs to ensure that its field force understands the company’s expectations regarding compliance.

For example, in the context of the District of Columbia’s licensure law, companies must determine at the outset both how to train sales representatives on the law’s requirements and how to monitor the status of both their licenses and continuing education credits. Whether training for this and other laws is handled directly by marketing or whether the responsibility for training is delegated to the compliance department, there should be collaboration amongst the various departments, including legal, to ensure that the relevant provisions of these laws and guidances are addressed.

Regardless of whether a particular law or guidance imposes direct requirements on pharmaceutical sales representatives, the ultimate responsibility for compliance rests with the pharmaceutical company. Therefore, awareness of both existing laws and pending legislation is

the necessary first step in developing a compliant marketing program. ▲

- 1 21 C.F.R. § 203.30 (2005).
- 2 68 C.F.R. at 23732. Copies of the Guidance can be found on the OIG website at <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.
- 3 The PhRMA Code is found at: <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.
- 4 See Minn. Stat. § 151.47(f) (2008).
- 5 See Minn. Stat. § 461 (2008).
- 6 See Vt. Stat. Ann. tit 18 § 4632 (a)(1) (2008).
- 7 See D.C. Code § 48-833.01-.03 (2008).
- 8 See Me. Rev. Stat. Ann. tit. 22 § 2698-A (2008).
- 9 See W. Va. Code § 5A-3C-13 (2008).
- 10 See W. Va. Code § 206-1 (2008). According to the law, advertising costs may be calculated by dividing the West Virginia population receiving the DTC communication by the population of the nation or region and multiplying the quotient by the total amount the reporting entity spent on advertising in the nation or the named region.
- 11 See Mass. Gen. Laws ch 305, § 111n (2008); 105 Mass. Code Regs. 970.000 (2008).
- 12 See Cal. Health & Safety Code § 119402(a)-(e) (2008).
- 13 See Nev. Rev. Stat. § 639.570 (2008).
- 14 See Nev. Admin. Regs. R122-07 (2008).
- 15 See Nev. Rev. Stat. § 639.570.
- 16 *Id.* at § 639.570(1)(a).
- 17 The Advanced Medical Technology Association Code of Ethics on Interactions with Healthcare Professionals (AdvaMed Code) provides sales and marketing guidance for device companies. The AdvaMed Code is found at: <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.
- 18 *Id.*
- 19 *Id.*
- 20 See 105 Mass. Code Regs. 970.000 (2008).