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New Pharmaceutical Detailing Regulations Raise Compliance Considerations for Manufacturers

In early 2008, the District of Columbia City Council passed the SafeRX Amendment Act (the "Act"), introduced by Council Member David Catania.[1] The Act requires pharmaceutical "detailers," which includes both employees and independent contractors of pharmaceutical manufacturers, to be licensed by the District of Columbia Board of Pharmacy (the "Board") by April 1, 2009. Pursuant to the Act and regulations issued by the Board Aug. 29, 2008,[2] once a pharmaceutical detailer has been licensed by the Board, he or she must, among other things, (1) comply with the PhRMA Code on Interactions with Healthcare Professionals ("the PhRMA Code"), as well as additional requirements; (2) earn continuing education credits; and (3) follow stringent document retention requirements. This *Client Alert* summarizes the Act and the Board's regulations, and includes a list of considerations for manufacturers whose employees and independent contractors must be licensed to work in the District of Columbia.

Parties Subject to the Licensure Requirement

Under the Act, all individuals practicing "pharmaceutical detailing" in the District of Columbia must be licensed by the Board by April 1, 2009. Both the Act and the new regulations define "pharmaceutical detailing" as:

> the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product.[3]

The regulations further specify that a "Pharmaceutical Company" is "any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biologic product, including any person acting as its agent or representative." "Labeler" means "an entity or person that receives pharmaceutical products from a manufacturer or wholesaler and repackages those pharmaceuticals for later retail sale and that has a labeler code from the [FDA]."[4]

According to these definitions, therefore, an individual who meets all three of the following criteria must be licensed:

- Represents (a) a pharmaceutical manufacturer or an entity that produces, prepares, propagates, compounds, converts or processes a drug or biologic, either as an employee or as an independent contractor, or (b) a labeler
- Communicates *in person* with a licensed health professional, or his/her employees or representatives located in the District of Columbia
- Communicates with the intention to sell, provide information about or promote a drug

Importantly, the District of Columbia licensure requirements only apply to pharmaceutical representatives and not medical device representatives.

Licensure and Compliance Requirements

The Act requires individuals who meet the definition of a pharmaceutical detailer to comply with the following:

- ***Application.*** Submit a detailed application to the Board.[5]
- ***Education.*** Meet both pre-application and continuing educational requirements. An applicant must be a graduate of an approved institution of higher education as recognized by the Board. (This requirement can be waived to the extent that the detailer can demonstrate that the individual

has practiced pharmaceutical detailing on a full-time or substantially full-time basis for at least 12 months.) The Board's regulations also require licensed detailers to take at least 15 hours of approved continuing education credits over the course of the two-year term of the license.[6]

- ***Code of Ethics.*** Comply with the PhRMA Code and additional ethical considerations listed in the Board's regulations. Specifically, detailers are prohibited from:
  - Engaging in deceptive or misleading marketing
  - Using a title that would lead a health professional to conclude that the detailer is a licensed health professional (unless the detailer holds an active license to practice)
  - Attending patient examinations without written patient consent
  - Harassing, intimidating or coercing a licensed health professional
  - Making sales calls on a professional who has requested in writing that the detailer stop
  - Offering gifts or remuneration to a member of a medication advisory committee
  - Using inducements or misleading statements to access to a health professional
  - Providing inaccurate or not fairly balanced information, or information otherwise inconsistent with FDA-approved labeling[7]
- ***Document Retention.*** Maintain documentation and information relating to communications with licensed health professionals or their employees or representatives. Such information must be maintained by the detailer for a period of five years from the date of communication with the health professional. In addition, a detailer must notify the Board within 10 days of the end of his or her relationship with a drug company, and provide the Board the contact information of the person within the company who may be contacted for retrieving the detailer's records.[8]
- ***Renewal.*** Renew the detailing license every two years. (A detailer has up to 60 days post-expiration to renew.)[9]
- ***Penalties.*** Individuals who fail to comply with the pharmaceutical detailing licensure requirements are subject to a fine of up to $10,000.[10] Furthermore, failure to provide information and documentation requested by the Board are subject to potential disciplinary action by the Board, which could include imposition of civil fines or revocation of a license.[11]

Compliance Considerations for Manufacturers

While the Act and regulations apply directly to detailers only, manufacturers are indirectly impacted as employers of detailers. In other words, as a practical (and legal) matter, manufacturers could have compliance obligations associated with the Act. The following is a list of some compliance considerations for manufacturers:

- ***Detailers Subject to the Licensure Requirement.*** Manufacturers should consider determining which employees or contractors are practicing pharmaceutical detailing under the Act. While traditional sales representatives are likely covered, it is unclear whether other types of employees and agents would be required to hold a license as well. Neither the Act nor the Board answers the following questions:
  - Are employees/agents who represent manufacturers before managed care companies or other payors "detailers" when they present—i.e., "provide information about"—a drug to a pharmaceutical and therapeutics committee consisting of doctors?
  - Are medical science liaisons detailing when they provide scientific information about a product to a physician?
  - Are executives or non-sales people who discuss a product with a physician or other health care professionals "detailing"?

In determining which employees or independent contractors must seek licensure, manufacturers may want to consider the purpose of the Act. (According to its sponsor, David Catania, the Act was intended to "protect District residents from…harmful prescription drug marketing practices" and to target "*pharmaceutical sales representatives*."[12])

- ***Documentation.*** Manufacturers should consider setting up documentation policies for detailers. While the Act and the Board's regulations are silent as to how a detailer must maintain documentation, manufacturers should consider:
  - Establishing parameters for what types of documentation the detailer should maintain and what qualifies as a "communication" that triggers the five-year documentation period.

- Developing policies and procedures regarding when documentation should be sent to the manufacturer, or regarding how detailers should maintain files.
- Requiring detailers to log the date and time of all communications with health care professionals.
- Engaging personnel at the company who are responsible for contacting District of Columbia detailers to collect copies of all documentation at regular intervals.
- Providing reimbursement for detailers' document retention efforts or requiring detailers to submit documentation immediately to the company upon any communication with a health professional.

- ***Location.*** Manufacturers should consider the locations of their detailers, in particular those Maryland and Virginia detailers who might also work in the District of Columbia. The District of Columbia metropolitan area includes significant portions of Virginia and Maryland and, as such, Maryland and Virginia detailers may focus on a handful of practices that are technically in the District of Columbia.
- ***Application, Renewal, Continuing Education.*** Manufacturers should consider developing policies and procedures to ensure that (a) detailers' licensure applications are filed in a timely manner and contain accurate information, (b) licenses are renewed at appropriate times, and (c) detailers are maintaining their continuing education credits as required by the regulation. These policies and procedures could also designate an employee at the company who reviews and signs off on all District of Columbia license applications.
- ***Privacy.*** Manufacturers should consider taking steps to ensure that personnel responsible for overseeing the District of Columbia licensure process (if any) safeguard the private information found on the District of Columbia application (e.g., responses to questions on criminal history, mental or medical conditions, treatment for substance abuse, etc.). Also, employees and contractors should be assured that any information appearing on the applications will be kept strictly confidential.
- ***Training.*** Manufacturers should consider training detailers on each of the licensure requirements, especially the code of ethics.
- ***Fees, Penalties.*** Manufacturers should consider whether they will pay for employees' or contractors' fees incurred in applying to be licensed, renewing a license, or taking continuing education credits, if necessary. This could involve developing policies and procedures regarding when the detailer or the company should be responsible for any fines or penalties incurred by the detailer.

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1 *See* D.C. CODE § 3-1207.41, *et seq.* (2008).

2 *See* D.C. MUN. REGS. tit. 17, § 8300, *et seq.* (2008).

3 *Id.* § 8399.1.

4 *Id.*

5 *Id.* § 8304.

6 *See id.* § 8306.

7 *See id.* § 8305.

8 *See id.* § 8309.

9 *See id.* § 8306.9.

10 *Id.* § 8300.3.

11 *See id.* § 8309.3; *see also* D.C. CODE § 3-1205.14 (2008).

12 *See http://www.davidcatania.com/content/view/288/75/* (emphasis added).

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