

Another Brick in the Wall—DC Enacts Law Regulating Pharmaceutical Marketing



By Jeffrey N. Wasserstein and Bryon F. Powell

On 25 April 2008, the *SafeRx Amendment Act* of 2008 went into effect after having narrowly passed the District of Columbia Council (DC Council) earlier this year.¹ The act has the potential to significantly impact how pharmaceuticals are marketed and prescribed in Washington, DC (the District). In part, the act makes DC's 3,000–4,000 pharmaceutical detailers the first in the nation to need a license to market pharmaceuticals to licensed health professionals or their employees.² The act also requires physicians to explain any off-label use of pharmaceuticals to patients and establishes a program to educate the District's prescribers about cheaper prescription options.³

Regulation of Detailers

The act prohibits the unlicensed practice of pharmaceutical detailing, which it defines 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 purposes of selling, providing information about, or in any way promoting a pharmaceutical product.”⁴ Individuals who practice detailing without a license could be fined up to \$10,000.⁵

To become a licensed detailer in the District, an applicant must submit a notarized statement stating that he or she understands and agrees to the District's pharmaceutical detailing requirements.⁶ Only a college graduate can become a detailer; however, the educational requirements can be waived for any applicant who has worked full time as a detailer for at least 12 months.⁷ Licensed detailers will need to fulfill continuing education requirements established by the mayor.⁸

Once licensed, detailers face two primary prohibitions under the act. First, detailers are prohibited from engaging in any deceptive or misleading marketing of a pharmaceutical product.⁹ Second, they are prohibited from using a title or designation that would cause a

licensed health practitioner or the practitioner's employees to think the detailer is a licensed health practitioner—unless, of course, the detailer actually is a licensed health practitioner.¹⁰ This prohibition is redundant of a DC law that already prohibits an individual from falsely using or implying representations that he or she is engaged in any one of a long list of health occupations.¹¹ In addition, detailers may not attend a patient examination unless the patient consents, which is already a requirement under the *Health Insurance Portability and Accountability Act* of 1996 (*HIPAA*).¹² The act also requires detailers to adhere to a code of ethics to be established by the DC Board of Pharmacy.¹³ The board's new authority to collect information from detailers relating to their communications with licensed health professionals and the professionals' employees will help it enforce the code of ethics.¹⁴

Costs and Who Bears Them

The act's sponsor, DC Councilman David Catania, cited pharmaceutical costs as one reason the licensure of detailers is necessary.¹⁵ Although the amount spent on detailing has increased from \$2.5 billion in 1996 to \$4 billion in 2000 (without factoring in the cost of drug samples), it is unclear how this law alleviates cost to patients.¹⁶ Nothing in the act directly limits such spending in the District. Instead, supporters are hoping it will result in a sales shift from brand-name drugs to less-expensive alternatives, usually generic drugs. This hope may be wishful thinking considering nothing currently in the act's detailer-related provisions encourages such a shift.

Two other economic effects are more likely to result from the act. First, detailers or, more probably, the pharmaceutical companies for which they work, will need to pay a licensing fee.¹⁷ Although these fees are likely to be trivial when compared to overall detailing costs, they obviously will not lower the cost of pharmaceuticals. A second, more significant, cost will be borne by the District in establishing

and maintaining the detailing licensure system, developing the detailer code of ethics and enforcing the regulatory system that emerges from the act and code of ethics.

Existing Guidance and Laws

Catania has stated that “[d]etailers have been known to resort to questionable methods, including providing gifts and meals to doctors, in order [to] promote their drugs.”¹⁸ While it “authorizes” the Board of Pharmacy to develop a code of ethics, the act itself does not contain any provisions prohibiting or even limiting gifts a detailer can give to a physician.¹⁹

Pharmaceutical companies marketing in the District are not currently subject to a mandatory marketing code of ethics. However, in 1990 the American Medical Association (AMA) developed a voluntary guide for pharmaceutical companies’ interactions with physicians, which the companies immediately began adopting.²⁰ Any complacency within industry was shattered when, in October 2001, TAP Pharmaceutical Products Inc. agreed to pay a \$875 million settlement in connection with its fraudulent drug pricing and marketing of Lupron.²¹ Less than a year later, industry adopted its own voluntary guidelines on interactions with healthcare professionals.²² Facing the threat of substantial federal penalties, and with several states mandating that pharmaceutical companies develop marketing codes of conduct,²³ companies have typically adopted such codes nationwide and require detailers to undergo training two or more times each year.²⁴

The federal government also plays a role, albeit a limited one, in regulating the activities of detailers. The Food and Drug Administration (FDA) primarily regulates the activities of detailers by placing limitations on when and how they may distribute information regarding uses for their products. With vigorous competition for sales within therapeutic areas, it is common for companies to report detailers from competing companies to FDA for alleged marketing violations. Even with industry self-reporting, the agency has been accused of being lax on marketing enforcement.²⁵ FDA frequently claims it has limited resources to devote to enforcing marketing laws and, therefore, must limit its enforcement actions to the most egregious or widespread violations. In addition, pharmaceutical companies and detailers marketing to the federal government are subject to federal anti-kickback and federal fraud and abuse laws, which respectively bar the giving

of gifts to induce sales and the making of false statements to the federal government.²⁶

Conclusion

The *SafeRx Act* adds to the patchwork of local enforcement of detailing ethics. As explained above, detailers are likely to report their competitors’ violations; therefore, if given sufficient resources, the DC Board may be another watchdog of which to be wary. However, it is yet to be seen whether the District can or will provide sufficient resources to enforce the act.²⁷

Although the impact of this new law is far from certain, it is clear that in the absence of uniform federal regulation, states are likely to continue enacting legislation to regulate pharmaceutical marketing. Each year seems to bring additional requirements to the crazy-quilt system of regulating pharmaceutical marketing across federal and state lines.

REFERENCES

1. *SafeRx Amendment Act* of 2008, D.C. Act 17-0282, 17th Legis. Sess. (D.C. 2008) (as enrolled); 55DC Reg. 4462 (25 April 2008). All citations to D.C. Act 17-0282 will be to the enrolled version of the bill unless otherwise noted.
2. D.C. Act 17-0282 § 101-03; Nikita Stewart, “Catania’s Bill Would Regulate Pharmaceutical Salespeople,” *The Washington Post*, 9 December 2007 at C11. In recent years, bills proposing the licensure of pharmaceutical detailers have been unsuccessfully introduced. *See, e.g.*, West Virginia HB 4062 (2004). However, states have enacted legislation requiring pharmaceutical manufacturers to adopt marketing codes of conduct. *See, e.g.*, Cal. Health & Safety Code § 119402; Nev. Rev. Stat. § 639.570.
3. D.C. Act 17-0282 §§ 201-04, 401-04. These provisions will not be covered by this article.
4. *Id.* § 102(b).
5. *Id.* § 102(g).
6. *Id.*
7. *Id.*
8. *Id.*
9. *Id.* A previous version of the act explicitly deemed off-label information to be deceptive or misleading marketing. *SafeRx Act* of 2007, Bill 17-0364, 17th Legis. Sess. § 101(f) (D.C. 2007) (as engrossed).
10. D.C. Act 17-0282 § 102(g).
11. D.C. Code § 3-1210.03. Another DC statute generally prohibits an individual from representing to the public “by title, description of services, methods, or procedures, or otherwise that the person is authorized to practice the health occupation in the District” unless they are authorized to practice that health occupation. *Id.* § 3-1210.02. The *SafeRx Act’s* penalty for violating its professional misrepresentation provision is a fine of less than \$10,000, which is one of the penalties available under the two pre-existing professional misrepresentation provisions. D.C. Act 17-0282 § 102(g); D.C. Code § 3-1201.07.

12. D.C. Act 17-0282 § 102(g).
13. *Id.* § 102(c), (g).
14. *Id.* § 102(c).
15. Press Release, Office of Councilmember David A. Catania, "D.C. Council Passes Safe Rx Act" (8 January 2008).
16. Steven Findlay, National Institute for Health Care Management, Prescription Drugs and Mass Media Advertising, 2000 5 (2001).
17. D.C. Act 17-0282 § 102(g).
18. Press Release, Office of Councilmember David A. Catania, *supra* note 15.
19. D.C. Act 17-0282 § 102(c). The *AccessRx Act* of 2004, which was co-introduced by Catania, mandated that prescription drug manufacturers and labelers annually report all marketing costs for prescription drugs in the District, including "all expenses associated with food, entertainment, gifts valued at more than \$25, and anything provided to a health care professional for less than market value." *AccessRx Act* of 2004 § 303(a)(2)(B).
20. The AMA adopted the guide in 1990 and repeatedly updated it with the most recent update in 2004. American Medical Association, E-8.061 Gifts to Physicians from Industry. The Pharmaceutical Manufacturer's Association adopted the AMA's guidelines two days after they were issued by the AMA. CALPIRG, "Tis Always the Season for Giving 3 (September 2004).
21. Department of Justice, Press Release, "TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges" (3 October 2001).
22. PhRMA, Code on Interactions with Healthcare Professionals (Rev. 2004) (PhRMA Code).
23. *See, e.g.*, Cal. Health & Safety Code § 119402; Nev. Rev. Stat. § 639.570. Lawmakers in both California and Nevada saw fit to incorporate the PhRMA Code into their respective states' pharmaceutical marketing requirements.
24. "Catania's Bill Would Regulate Pharmaceutical Salespeople," *supra* note 2.
25. Kevin B. O'Reilly, "New Plan Would Require D.C. Drug Detailers to be Licensed," *American Medical News*, Feb. 11, 2008 (quoting Jerome L. Avorn, MD, professor at Harvard Medical School, "[FDA] has not been as aggressive as one would like in containing problematic marketing in the last seven years.>").
26. *See, e.g.*, 42 U.S.C. § 1320a-7B, 7C.
27. Vandana Sinha, "Pharmaceutical Rep Licensing Bill Survives First D.C. Council Vote," *Washington Business Journal*, 11 December 2007 (quoting DC Councilwoman Muriel Bowser, "[The act] promises exactly what the FDA can't accomplish.>").

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