

Porzio Pharmaceutical Alert

Louisiana Weighs in on Drug Samples and Lobbying

*An Overview of Recent Opinions
by Louisiana's Board of Ethics*

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By: John Patrick Oroho, Esq. and Scott S. Liebman, Esq.
Managing Editor: Steven P. Benenson, Esq.*

Introduction

Louisiana's Board of Ethics ("Board") recently issued two important opinions concerning the regulation of pharmaceutical detailing and sampling. The Board provided guidance on whether drug samples constitute "things of value" that can be furnished to practitioners with privileges or on the staff at public hospitals and whether educational and detailing activities qualify as lobbying under Louisiana law. This update offers an overview of these recent developments in Louisiana.

Drug Samples as Things of Value

On February 13, 2006, the Board posted on its website an opinion letter on whether prescription drug samples qualify as "things of economic value," which cannot be distributed to public officials. Under the Code of Governmental Ethics, a public official is any individual, "whether compensated or not, who is an administrative officer or official of a governmental entity who is not filling an elected office." LA. REV. STAT. ANN. § 42:1102(18)(a). The Board previously determined that practitioners at public hospitals are public officials because those hospitals are under the control of the executive branch. As a result, physicians and licensed practitioners with privileges or on staff at public facilities are "public officials" exercising "executive action." As further explained below, the prescribing of medication at a public hospital has been determined to constitute executive action.

*John Patrick Oroho is a principal and Scott S. Liebman is an associate with the law firm of Porzio, Bromberg & Newman, P.C., with offices in Morristown, New Jersey and New York City. They are members of the firm's Pharmaceutical Marketing & Sales Compliance and Litigation Department. Mr. Oroho also serves as the Executive Vice President of Porzio Pharmaceutical Services, LLC. Steven P. Benenson is a principal with the firm and a team leader of the Department.

According to the Code, public officials cannot accept items of economic value, except compensation or benefits from the governmental entity for the performance of duties of their office or position. LA. REV. STAT. ANN. § 42:1111A(1). The Code further forbids the acceptance of gifts or gratuities from any individual with a significant financial interest in the public official's duties. LA. REV. STAT. ANN. § 42:1115(B)(2). This prohibition, however, excludes promotional items with nominal resale value. LA. REV. STAT. ANN. § 42:1102(22)(a).

Samples are defined under the Prescription Drug Marketing Act ("PDMA") as free product intended to promote the sale of a product. 21 C.F.R § 203.3(i). The PDMA further provides that the sale of prescription drug samples is unlawful. The Board nonetheless found that samples have "substantial resale value." The Board opined that because samples have more than nominal resale value, the "promotional item exception does not appear to apply." The Board, however, explained that samples can be "donated" to practitioners at public hospitals or clinics for the treatment of patients at those institutions. Consequently, practitioners at public institutions can accept samples as long as they are used for treating patients in public hospitals or clinics.

Given the narrow question that was posed to the Board, it would now appear that pharmaceutical companies can distribute drug samples to state healthcare professionals so long as those samples are used at the state hospital facility. The opinion does not specifically answer, however, whether practitioners with private practices and state hospital privileges can receive a separate shipment of samples in their private offices. The Board's opinion places the additional burden on pharmaceutical companies of not only validating physicians, but also ascertaining whether they qualify as a public official under Louisiana law.

Educational and Detailing Activities as Lobbying

Last month, the Board determined that lobbying, under the Executive Branch Lobbying Act, applies to educational and detailing practices conducted by pharmaceutical employees, which are aimed at healthcare professionals practicing at or affiliated with state hospitals. According to the Board, activities directed at educating practitioners at state hospitals concerning a drug's risks and rewards constitute "lobbying."

Lobbying, as defined in LA. REV. STAT. ANN. § 49:72(6), is "any direct act or communication with an executive branch official, the purpose of which is to aid in influencing an executive branch action." The Board reasoned that state hospital physicians and licensed practitioners are executive branch officials because they are within the purview of the Department of Health and Hospitals.

Further, the statute defines executive branch action as any "duty of an executive branch official." The Board concluded that prescribing medications is a duty of a physician and

consequently constitutes an executive branch action. Therefore, any conduct intending to influence the prescribing practices of a practitioner at a state hospital is lobbying. Notably, the Board also concluded that placing a drug on a hospital formulary list constitutes “an executive branch action” and taking action to have a drug placed on a formulary constitutes “lobbying.”

As a result, pharmaceutical employees engaged in educational or detailing practices aimed at healthcare professionals practicing or affiliated with public hospitals are subject to Louisiana’s lobbying laws. Pharmaceutical representatives must register with the Board any expenditure exceeding \$500 within 5 days of making the expenditure. Expenditures typically include gifts, payments, or any item of value over \$10. LA. REV. STAT. ANN. § 49:72(5). Generally, during a six-month period, only the total lobbying expenditures for each department and agency are reported, without any specific itemization. If, however, an individual expenditure exceeds \$50, or a single official’s six-month total exceeds \$250, then the lobbyist must itemize and disclose the recipient’s name and the total expenditures for the recipient. LA. REV. STAT. ANN. § 49:76(E). The Board has not specifically answered whether these reporting requirements apply to drug samples.

Conclusion

The Board’s recent opinions set new parameters and now subject certain activities to lobbying regulations. These opinions, however, provide limited answers and pose numerous new questions. For example, if a physician has a private practice and state hospital privileges, may the physician receive samples for his private practice separate and apart from the samples designated for the public hospital? Also, does drug sampling trigger reporting requirements under Louisiana’s lobbying laws?

The deployment of sales representatives differs from company to company. Some have hospital specific representatives, as well as, representatives that call on private practices. Others have representatives that perform both functions. The manner in which companies will confront the issues raised above may differ based on the individual circumstances of that company.