BNA, INC.

PHARMACEUTICAL LAW & INDUSTRY

BNA Employee-Owned Since 1947

REPORT

Pharmaceutical Manufacturing Federal and State Gift and Lobbying Restrictions: Confluence of Laws and Conflict of Standards

BY DAVID E. FRULLA AND JULIE R. VASADY-KOVACS

This article involves ''lobbying,'' with particularly critical information for those involved in pharmaceutical, medical device, or biologics sales to public hospitals, prisons, health service agencies, or other governmental service providers. A medical manufacturing company can face lobbying registration and disclosure rules in a variety of contexts: traditional legislative lobbying; advocacy at the agency level, perhaps to include a drug on a state's Medicaid formulary; or even potentially in the context of making sales to state, city, and county government entities. This latter category of lobbying can come as a surprise to sales representatives who would not ordinarily think of calling themselves ''lobbyists.'' These laws differ between jurisdictions, and can even impose conflicting requirements *within* a single jurisdiction.

Furthermore, lobbying limits and disclosure rules appear here to stay. The U.S. Court of Appeals for the District of Columbia Circuit recently issued its decision in *National Ass'n of Manufacturers v. Taylor*, No. 08-5085 (D.C. Cir., Sept. 9, 2009) (*NAM*), upholding new federal lobbying disclosure provisions, passed in the wake of the Jack Abramoff scandal. *NAM* involved a challenge to provisions of the Honest Leadership and Open Government Act of 2007 requiring formal and informal trade and other associations to disclose the identities of active participants funding their lobbying activities. NAM argued, among other things, that disclosure could chill First Amendment-protected activity. While the opinion was 45 pages long, the D.C. Circuit panel had little difficulty with NAM's arguments, concluding:

> More than fifty years ago, the Supreme Court held that public disclosure of ''who is being hired, who is putting up the money, and how much'' they are spending to influence legislation is a ''vital national interest.''. . . Because nothing has transpired in the last half century to suggest that the national interest in public disclosure of lobbying information is any less vital than it was when the Supreme Court first considered the issue, we reject that challenge.

Slip op. at 2 (citations omitted).

States, and even many larger counties and cities, have their own lobbying disclosure regimes. Each jurisdiction's laws differ. Each jurisdiction defines which ''contacts'' with government officials and employees can amount to lobbying, and how much lobbying ''activity'' must occur before an entity is required to register and report as a lobbyist. ''Lobbying,'' moreover, is not generally defined simply as plying the halls of a state capitol or City Hall. Rather, a range of contacts with departments and agencies, and often these involving government contracting related advocacy, can fall within the definition of lobbying activity. There is no reason to believe *NAM's* rationale would not apply to these laws, if challenged.

Even a wider range of jurisdictions limit, if not prohibit, gifts by private entities to governmental officials and personnel. Such gift limits often are stricter for lobbyists or government contractors. At the federal level, for instance, the act that *NAM* upheld (in other part),

David E. Frulla is a partner in the Washington office of Kelley Drye & Warren LLP. Julie R. Vasady-Kovacs is a consulting counsel in the firm's New York office. Their practices focus on campaign finance and political law, government relations, and public policy.

 ISSN 1542-9547

prohibits gifts to federal legislative branch officials and staff by federally registered lobbyists and entities employing or retaining these lobbyists (subject to a range of exceptions).

Unfortunately, the complexity does not stop there for medical sales teams interacting with government officials and employees. Certain states, most prominently Massachusetts (7 PLIR 648, 6/5/09) and Vermont (7 PLIR 688, 6/12/09), have enacted strict limits and disclosure requirements governing the provision of gifts by drug, device, and biologics makers to medical professionals who can prescribe or recommend the purchase of prescription products. These laws took effect on July 1. Notably, the medical industry-specific gift and disclosure laws apply *in addition to* the lobbying registration and reporting laws in connection with industry participants' interactions with doctors and other medical professionals who are government officials and employees covered by state, county or city lobbying and gift laws.

Medical sales teams also must be aware that the medical industry gift and disclosure rules are not consistent with general state ethics rules. For instance, in Massachusetts, according to the new rules governing pharmaceutical and medical device manufacturers, meals provided to a medical practitioner during an informational presentation by a pharmaceutical or medical device marketing agent, in a hospital or health care provider's office, are permissible as long as the meal is not directly provided to a single provider. Pharmaceutical and medical device manufacturing companies must disclose any economic benefit of at least $50 provided to a covered recipient in connection with the companies' sales and marketing activities. In contrast, the revised Massachusetts gift law, applicable to all government officials and employees, which also is effective as of July 1, makes providing a gift of substantial value (approximately $50) in order to attempt to influence a public official a crime, punishable by a fine of up to $50,000 and/or five years in prison.

Notably, then, in Massachusetts, the medical disclosure law can require disclosure of a gift to a government doctor that would be permissible under the medical gift rules but could subject the giver to a fine and even potential imprisonment under the Commonwealth's ethics laws. Could disclosure of a benefit provided to a Massachusetts public health facility or the person running it, although permissible under the Massachusetts pharmaceutical and medical device rules, potentially result in an investigation and criminal prosecution of the company or the agent who provided the benefit? This would seem to be an extreme and unlikely result but nevertheless a legal possibility.

More likely, however, is that depending on how much time the agent for the medical manufacturing company spends preparing materials and communicating with a Massachusetts state employee or official (25 hours or more in a six-month period), the agent and the company could be required to register and report as a lobbyist under Massachusetts law. So, in addition to providing full disclosure and paying the required registration fees once a year under the Massachusetts pharmaceutical and medical device gift ban and disclosure law, the agent and the company would be required to register as lobbyists and file regular lobbying registration reports twice a year.

In addition to the added and perhaps duplicative information required in the lobbying reports, a blanket restriction prohibits a lobbyist from providing gifts or meals of *any* value to a Massachusetts state employee, in contrast to the $50 limit that applies to the citizenry as a whole. The penalty for violating the Massachusetts lobbying law is a maximum $10,000 fine and five years in prison. Thus, a pharmaceutical or medical manufacturing company selling products to the Commonwealth of Massachusetts also must be mindful of the more restrictive components of the Massachusetts lobbying law in order to protect the company and its sales agents from criminal prosecution.

While the conflicts are less pronounced in Vermont (because the respective medical and general state ethics laws gift limits are essentially uniformly prohibitory), complicated and inconsistent disclosure regimes remain. It would, moreover, require an entirely separate article of equivalent length to describe the details and nuances of Vermont's medical gift and disclosure laws, as construed by the Vermont attorney general's office.

Other jurisdictions which currently require some disclosure of certain payments to doctors or medical manufacturers include Minnesota, California, Maine, West Virginia, and Washington, D.C. Minnesota also requires disclosure of certain government related sales activities as so-called ''procurement lobbying.'' Further, in 2009 at least six states had related medical industry-specific bills or proposals under review, including Colorado, Illinois, Iowa, Minnesota, New York, and Texas, of which Illinois, New York, and Texas also have procurement lobbying laws.

Finally, a company looking for an intelligible federal standard will find no relief. In 2009, Sens. Chuck Grassley (R-Iowa), Herb Kohl (D-Wis.) and Amy Klobuchar (D-Minn.) introduced The Physician Payment Sunshine Act, S. 301 (7 PLIR 127, 1/30/09). That Act, as proposed, does not impose gift limits, and instead only requires disclosure of all payments and provides a list of exceptions to the requirement to disclose any payment over $100. As introduced in the 2009-2010 session of Congress, however, such a federal disclosure requirement would not preempt, but would allow, a stricter state level disclosure standard. Moreover, the federal law would set no uniform standards on gifts to medical professionals and others in the health care industry.

Pharmaceutical and health care manufacturers are well advised to devise a strategy to address governmental sales and advocacy requirements and work to influence what the resulting laws will look like in the future. In addition to a compliance program, a comprehensive understanding of existing state gift and lobbying laws may support how uniform regulation would be highly preferable over these widely varied gifts and political ethics laws. The combined patchwork of overlapping and contradicting regimes not only creates confusion and unnecessary expense (which gets passed to the consumer), but inhibits companies' abilities to expand their markets and develop new products.

  PLIR ISSN 1542-9547