

Authors

Linda Pissott Reig, Esq.
Principal – PORZIO,
BROMBERG & NEWMAN, P.C.
lpreig@pbnlaw.com

Christopher R. Corallo
Senior Regulatory
Analyst – PORZIO
PHARMACEUTICAL
SERVICES, LLC
corallo@porziopharma.com

John Patrick Oroho, Esq.
Principal – PORZIO,
BROMBERG & NEWMAN, P.C.
jporoho@pbnlaw.com

Managing Editor

Steven P. Benenson, Esq.
Principal – PORZIO,
BROMBERG & NEWMAN, P.C.
spbenenson@pbnlaw.com

About Porzio

Porzio, Bromberg & Newman P.C. provides a broad array of litigation, corporate, transactional and counseling services to clients and has offices in Morristown and Brick, New Jersey, and New York City. For over 30 years, we have represented pharmaceutical and medical device manufacturers in complex litigations and counseled them on regulatory issues and risk management strategies. Our

Newly Enacted Nevada Statute Requires Adoption of a "Marketing Code of Conduct."

On June 13, 2007, Nevada enacted a law to require companies that employ "a person to sell or market a drug, medicine, chemical, device or appliance" to adopt a marketing code of conduct that incorporates the principles of the Code on Interactions with Healthcare Professionals of the Pharmaceutical Research and Manufacturers of America ("PhRMA Code").

In addition, Nevada's new law requires manufacturers and wholesalers to (1) adopt a training program to provide regular training, (2) conduct annual audits, (3) adopt policies and procedures to investigate instances of noncompliance, and (4) identify a compliance officer to develop, operate and monitor the marketing code of conduct. In annual reports to Nevada, each company must submit a copy of its marketing code, a description of its training program, a description of its investigation policies and the name, title, and address of its compliance officer, as well as certify that an annual audit was conducted and the company is "in compliance" with its marketing code of conduct.

The law's effective date is October 1, 2007, and requires the Nevada Board of Pharmacy to adopt regulations "providing for the time of submission and the form of the information required" as well as to define "compliance" for purposes of the annual certification. The Board of Pharmacy will submit biennial reports to the Governor and Legislature summarizing the information submitted. In addition, a website will be maintained "concerning the compliance of all wholesalers and manufacturers."

Pharmaceutical Sales & Marketing Compliance Department counsels clients on PDMA compliance, state sample distribution laws, state marketing disclosure and marketing prohibition laws, federal laws governing promotional materials and product labeling, federal and state anti-kickback laws, and risk management issues. To learn more about the capabilities of our Pharmaceutical Sales & Marketing Compliance Department, [click here](#).

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Porzio Pharmaceutical Services, LLC, (PPS), a wholly owned subsidiary of Porzio, Bromberg & Newman P.C., is dedicated to helping pharmaceutical and medical device manufacturers, wholesale distributors, labelers, and sales and sales support companies master the continually changing regulatory environment that impacts their business. PPS provides the pharmaceutical industry with informational resources, enabling companies to stay compliant with the growing body of federal and state regulations governing pharmaceutical marketing and sales. For more information on PPS, [click here](#).

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Nevada Statute's Legislative History

The initial version of the Nevada bill (AB 128) proposed that wholesalers and manufacturers would report "the value, nature, and purpose" of any gifts and other economic benefits provided to health care professionals in excess of \$100 to the Office of the Attorney General. The original proposal would have provided the following exemptions: (1) free product samples; (2) reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial or study; (3) any scholarship or educational support; or (4) honoraria or reimbursement for expenses in connection with educational or scientific conferences.

On May 21, 2007, however, the Nevada Assembly passed an amended version of the bill that excluded the "gift" disclosure requirements and focused on requiring companies to adopt marketing codes of conduct, conduct employee training, and certify compliance with industry standards for pharmaceutical marketing.

Comparison with California Law

Aspects of Nevada's newly enacted law are comparable to California law. Under the California Health & Safety Code (§ 119402), each company is required to annually declare in writing that they are in compliance with the law's requirements and the company's Comprehensive Compliance Program ("CCP"). In addition, both the marketing code required in Nevada and the CCP required in California must incorporate the guidelines in the PhRMA Code.

Unlike the Nevada law, however, California law also mandates that drug companies follow the April 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers" from the Health and Human Services Office of Inspector General ("OIG Guidance").

In addition, under the California statute, each company must establish a specific annual dollar limit on gifts, promotional materials, or items or activities that the company can provide an individual healthcare professional. Each company must make its CCP and written compliance declaration available on its website as well as through a toll-free telephone number.

Unlike Nevada's law, however, California's statute does not explicitly require companies to describe their training program and investigation policies, as well as certify that an annual audit was conducted in connection with the company's annual report of compliance.

Conclusion

Nevada now joins the ranks of several other states – including California, Maine, Minnesota, Vermont, and West Virginia – and the District of Columbia that require drug and device companies to make marketing and advertising disclosures. The passage of Nevada's law marks another chapter in

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pharmaceutical compliance. Transparency is on the rise and companies must adapt to an ever-changing environment as they promote their drugs and medical devices so that they can reach patients who will benefit from them.

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