

Thought Leadership

Sales and Marketing Compliance



PORZIO
BROMBERG & NEWMAN P.C.

Volume 2, Issue 7 Summer 2007

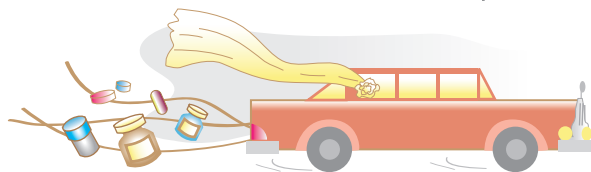
"I Take Thee to Be My Lawfully Authorized Distributor of Record"

By Rhonda Sobral O'Toole, Director of Compliance, StayinFront, Inc.



Rhonda Sobral O'Toole

There's an age old adage that is well-ingrained in the pharmaceutical industry - "Try it, you'll like it." Each day, millions of dollars of free pharmaceutical samples are given to physicians in the hopes that the drugs will be prescribed and ultimately purchased by patients. Usually, these pharmaceutical samples are distributed "door-to-door" through pharmaceutical sales representatives. However, there are times when it is more efficient and/or cost-effective for manufacturers to retain wholesale distributors to accomplish this task. In effect, the wholesale distributor replaces the sales representative as the conduit for providing samples.



Here are a few simple ground rules to make this a successful "union:"

Rule 1: I like you, but are we a compatible?: Picking the right wholesale distributor is the most important step to a good relationship. And just like picking a mate, there are some key factors that every manufacturer needs to consider:

- Does the wholesale distributor have sufficient staff and facilities to assure that samples will be safely stored/distributed? Can the distributor handle the size of the distribution program in issue?
- Does the distributor have a secure warehouse facility that can handle both controlled and non-controlled substances? What special safeguards are in place to protect controlled substances?
- Does the distributor have an inventory system that can effectively monitor the number of samples that are received, shipped, quarantined and destroyed?

d) Is the distributor licensed to distribute pharmaceutical samples in the States where samples are being shipped?

Step 2: What do others think?: When making a choice, it's always nice to get a second opinion from an objective party. Luckily, the National Association of Boards of Pharmacy® (NABP®) serves just this role in helping manufacturers select wholesale distributors. Through its Verified-Accredited Wholesale Distributors® program (VAWD®), NABP subjects wholesale distributors to rigorous scrutiny. Only distributors who meet these high standards are awarded prestigious VAWD accreditation.

Obtaining the VAWD "seal of approval" is a significant achievement because some VAWD standards are stricter than those imposed by the FDA. For example, Part 203.37(b) of the PDMA¹ requires that "significant loss" and known theft be reported to the FDA within 5 business days. However, VAWD requires that wholesale distributors report these events within 3 days to both the FDA and the appropriate state regulatory agency.

Step 3: Will you honor and protect me from trouble with the FDA?: By law, pharmaceutical samples can only be distributed to physicians who are properly licensed. The PDMA requires that either the manufacturer or the authorized distributor of record verify physician licenses before providing samples². While CRM software assists a sales representative in verifying a physician license around the time of the face-to-face visit, this is no guarantee that the physician will be validly licensed months later. Using a wholesale distributor who can do last minute license checks before shipping samples helps keep everyone out of hot water with the FDA.

Step 4: Tying the knot.: It always a good idea to have a written agreement between two parties. When it comes to wholesale distributors, the

agreement should establish that the distributor is the manufacturer's "authorized distributor of record." Having "authorized" status simplifies drug sampling process somewhat because "authorized distributors of record" are not required to provide a drug "pedigree."³ However, manufacturers are required to keep up-to-date lists of their "authorized distributors of record" and the products they are authorized to distribute available for inspection and copying⁴.

To assure the wholesale distributor's status as an "authorized distributor of record," the agreement between the parties should contain 3 key elements:

- A statement that all samples are being sent to the distributor directly from the manufacturer;
- A statement setting forth either the time period during which the distributor will be distributing the samples or the number of shipments the distributor will receive from the manufacturer⁵; and
- A statement establishing the scope of the samples that will be distributed. If the distributor is not being authorized to distribute the manufacturer's entire product line, the agreement should identify the following items relating to the authorized products:
 - The name of each drug,
 - The NDC number for each drug,

¹See 21 CFR 203.50 (a)

²1 CFR 203.50 (b)

³See 21 CFR 203.3 (a)

Inside This Issue

"I Take Thee to Be My Lawfully Authorized Distributor of Record"

Navigating through the Disparities of State Marketing Tracking and Disclosure Laws

What is the Verified-Accredited Wholesale Distributors (VAWD®) program

iii) Dosage form of the drug (*i.e.*, liquid, tablet, injectable, etc.); and

iv) Strength of the drug⁶.

Step 5: That's my stuff. Hands off.: All records relating to the distribution of pharmaceutical samples must be retained by both the manufacturer and distributor for 3 years⁷. Both parties must have appropriate retention policies and fast retrieval systems in place since FDA regulations require that such records be available for inspection and copying within 2 business days⁸.

Step 6: Can I get you anything, Honey?: As is true with any successful union, the manufacturer and distributor need to work together as a team. Information and documentation must be exchanged seamlessly. Manufacturers need to provide sufficient information to distributors who are not "authorized distributors of record" so that they can supply a proper drug pedigree. Manufacturers also need to provide distributors with a sufficient number of package inserts and product instructions so that the distributor can provide the physician with one for each sample shipped.

Hopefully, following these basic guidelines should allow the manufacturer/wholesale distributor relationship to continue "happily ever after."

Navigating through the Disparities of State Marketing Tracking and Disclosure Laws

Garineh S. Dovelian, Counsel with Porzio, Bromberg & Newman, P.C. and serves as Director of Quality Control for Porzio Pharmaceutical Services, LLC

Christopher R. Corallo, Senior Regulatory Analyst with Porzio Pharmaceutical Services, LLC



Garineh S. Dovelian



Christopher R. Corallo

A growing number of states are requiring pharmaceutical companies to track their annual expenditures relating to

marketing activities to comply with annual spending limits and state reporting requirements. Since the passage of Minnesota's marketing disclosure law in 1993, several other states such as California, Maine, Vermont, West Virginia, as well as the District of Columbia, have enacted laws imposing varying expense limitations and disclosure requirements on companies that market prescription products in those states. Additionally, currently there are bills pending in approximately nine states that, if passed, would impose further expense tracking or disclosure requirements on

companies. On their face, these statutes appear to require tracking and disclosure of many of the same categories of expenses. A closer look, however, reveals a multitude of differences between how each state's legislature and the agency authorized to enforce the statute choose to define and interpret the requirements. In application, those differences are presenting significant challenges for companies in compiling, evaluating, and ultimately reporting marketing expenses. The



prospect of more states passing similar legislation only compounds those challenges. The following is an overview of some of the distinctions in the tracking and reporting requirements under the various state laws.

Who Must Comply?

When evaluating a company's obligations under a state marketing law, a company's first step should be to determine whether its marketing activities within a state trigger any tracking or disclosure requirements. This determination turns upon the type of product that the company markets within the state and the nature of the company's business. Simply because a company's business implicates one state's law does not necessarily mean that the company's business triggers tracking or reporting obligations in other states.

For example, California requires "pharmaceutical companies" to adopt a Comprehensive



Compliance Program that, among other things, requires pharmaceutical companies to establish a specific annual limit on marketing expenses directed to healthcare professionals ("HCPs").¹ The statutory definition of "pharmaceutical company" broadly covers not only a manufacturer of "dangerous drugs," but also any entity involved in packaging, labeling, distribution, detailing or marketing.² In turn, the definition of "dangerous drugs" includes both prescription drugs and devices.³

Minnesota prohibits a "manufacturer" or "wholesale drug distributor," or its agent, from offering gifts to an HCP with a combined annual value greater than \$50.⁴ Unlike California, the Minnesota limitation on gifts expressly exempts a medical device manufacturer that distributes drugs "as an incidental part of its device business."⁵ In addition to the gift prohibition, Minnesota's wholesale drug distributor licensing statute requires "wholesale drug distributors" to file annual reports disclosing payments and compensation to HCPs.⁶ For purposes of this statute, the term "wholesale drug distributor" extends beyond the common understanding of the term and encompasses "manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution."⁷

Both Maine's and D.C.'s disclosure laws impose disclosure requirements on a "manufacturer or labeler of prescription drugs dispensed in the [State or District] that employs, directs or utilizes marketing representatives in the [State or District]."⁸ For purposes of those laws, a "manufacturer" includes not only the manufacturer of the prescription drug, but also its "affiliate" or "subsidiary."⁹ A "labeler" is an entity or person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.¹⁰

Notwithstanding the virtually identical statutory language in Maine and D.C., the universe of affected companies that fall within the scope of each statute differs. Maine's statute applies to "any product dispensed with a prescription and

¹ Cal. Health and Safety Code § 119402(d)(1).

² Cal. Health and Safety Code § 119400(c).

³ Cal. Health and Safety Code § 119402(a).

⁴ Minn. Stat. § 151.461 (1993).

⁵ Id.

⁶ Minn. Stat. § 151.47(1)(f).

⁷ Minn. Stat. § 151.44(f).

⁸ Me. Rev. Stat. Ann. tit. 22, § 2698-A (2005); D.C. Code § 48-833.01 (2004).

⁹ Me. Rev. Stat. Ann. tit. 22, §§ 2697(1), 2698-A(2)(b) D.C. Code § 48-831.02(12).

¹⁰ Me. Rev. Stat. Ann. tit. 22, §§ 2697(1), 2698-A(2)(A) D.C. Code § 48-831.02(11).

covered by a State of Maine pharmacy benefit."¹¹ Accordingly, a manufacturer or labeler need not report expenses that are clearly related exclusively to a prescription product that is not covered by a State of Maine pharmacy benefit, but does need to report marketing expenses relating to over-the-counter products if such products are covered.¹² The D.C. law does not have a similar limitation, although the definition of "drug" expressly excludes medical devices and their components, parts, or accessories.¹³



Similarly, in West Virginia, manufacturers and labelers of prescription drugs dispensed in the state that employ, direct or utilize marketing representatives must report advertising costs for prescription drugs. The statutory definition for "drug manufacturer" and "pharmaceutical manufacturer" expressly excludes a wholesale distributor of drugs and a retail pharmacy licensed under state law.¹⁴

Vermont's disclosure law requires registration and financial disclosure by "pharmaceutical manufacturing companies" and "pharmaceutical marketers."¹⁵ "Pharmaceutical manufacturing company" means any entity that is engaged in the production of prescription drugs, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. A "pharmaceutical marketer" refers to a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in the state to an HCP. The definitions of both terms expressly exclude a wholesale drug distributor.¹⁶

What Expenses is a Company Required to Track?

Upon concluding that the company's business triggers a state marketing law, the company must then identify which of its expenditures it must track

or disclose under that state's law. Companies must determine, among other things, the type of recipients and expenses covered by the law and the type of expenses expressly exempt. Undertaking this exercise quickly reveals the challenges that companies face in implementing a homogenous set of procedures for compiling the necessary information.

For example, not every interaction with a person or entity involved in the healthcare industry will trigger tracking or reporting requirements under the applicable state law. California requires companies to track gifts and incentives provided to "medical or health professionals." The term "medical or health professional" is limited to: (1) a person licensed by state law to prescribe drugs for human patient; (2) a medical student; and (3) a member of a drug formulary committee.¹⁷ Similarly, West Virginia focuses on interactions with "prescribers," — physicians and other health care professionals licensed under state law to prescribe drugs¹⁸ — and Minnesota focuses on interactions with "practitioners," — individuals licensed to practice medicine, dentistry, optometry, and podiatry, veterinarians, and mid-level practitioners authorized to prescribe, dispense and administer prescription drugs.¹⁹ Conversely, D.C., Maine, and Vermont's laws are not limited to individuals but also include interactions with entities such as health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care.²⁰

Within the general category of marketing interactions with HCPs, the types of expenses that a company must track or disclose differ from state to state. For example, California requires companies to implement an annual dollar limit on the aggregate value of gifts, promotional materials, and "items or activities" to individual HCPs, but expressly excludes from that limit payments for "legitimate professional services" as long as the payments reflect fair market value.²¹ District of Columbia, Maine, Minnesota, and Vermont, however, all require companies to itemize consulting fees paid to HCPs by name of recipient, total amount of payment, and descriptions of nature of payments. Companies in West Virginia must track "gifts, grants or payments of any kind" given to West Virginia prescribers, but need only disclose the total number of prescribers receiving such

What is the Verified-Accredited Wholesale Distributors (VAWD®) Program?

Each state has its own Board of Pharmacy or similar agency responsible for overseeing licensing requirements relating to pharmaceutical products. The boards of pharmacy for all 50 States are members of National Association of Boards of Pharmacy® (NABP®) - an independent, impartial, professional association.

NABP assists its members in developing, implementing, and enforcing uniform standards in cooperation with State and Federal Agencies for the purpose of protecting the public health. NABP designed the Verified-Accredited Wholesale Distributors® (VAWD®) program to help address incidences of counterfeit drugs reaching the public. As NABP President Oren M. Peacock, Jr. noted, "By requiring wholesale distributors to undergo an objective, third-party audit of their facilities' practices and procedures, VAWD accreditation provides an added level of security."

VAWD applicants undergo close scrutiny concerning numerous factors, including:

- > Comprehensive compliance review
- > Licensure verification (including DEA registration)
- > Verification of insurance coverage and secured monetary funds
- > Criminal background checks for designated representatives and other responsible persons
- > On-site inspections to determine, among other things, whether the storage facility:
 - is of suitable construction, secure and properly maintained
 - has appropriate inventory controls in place
 - has appropriate policies and procedures in place to assure the safe handling, storage and disposal of pharmaceutical products
 - has a secure area designated for the storage and handling of controlled substances
 - has appropriate quarantine area for controlled and non-controlled substances

Since only entities satisfying these rigorous requirements can become VAWD accredited, manufacturers who use VAWD accredited distributors can rest assured that their pharmaceutical products will be properly handled and distributed.

Redi-Mail Direct Marketing is a member of an elite group of pharmaceutical distributors that have received VAWD accreditation from the NABP. To learn more about the VAWD process please visit, www.nabp.net.



¹¹ 275 Me. Code R. § 2.01 (emphasis added).

¹² Letter Guidance from Maine Department of Health and Human Services (June 13, 2007).

¹³ D.C. Code § 47-2885.02(3)(D).

¹⁴ W. Va. Code § 5A-3C-3(4)(2004).

¹⁵ 33 V.S.A. § 2005 (2004).

¹⁶ 33 V.S.A. § 2005(c)(6).

¹⁷ Cal. Health and Safety Code § 119400(b).

¹⁸ W. Va. Code R. § 206-1-2.

¹⁹ Minn. Stat. § 151.01(23).

²⁰ Me. Rev. Stat. Ann. tit. 22, § 2698-A(4)(B); D.C. Code § 48-833.03(a)(2). Vermont's disclosure law applies to interactions with to "any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state." 33 V.S.A. §2005(a)(1).

²¹ Cal. Health and Safety Code § 119402(d)(1).

items of value, broken down by the range in which their annual aggregate receipts fall. Companies in D.C., Maine, and Vermont, however, must itemize on their disclosures all expenses associated with food, entertainment, and gifts exceeding \$25.²²

Although some states limit their focus on expenditures relating to HCPs, other states also require disclosure of direct-to-consumer advertising ("DTC") expenses directed to residents of that state.²³ But even among the states that impose such a requirement, there is divergence in application. Maine, for example, expressly excludes expenses associated with DTC advertising purchased for a regional or national market that includes advertising within the State. Conversely, West Virginia requires companies engaging in national or regional DTC to report the proportionate share of the amount spent on advertising in West Virginia by using population statistics reported by the U.S. Census Bureau.²⁴ Finally, D.C.'s approach appears to fall in the middle, exempting national or regional costs if the portion of the cost attributable to D.C. cannot be reasonably allocated.²⁵

Maine and D.C. also require companies to disclose the aggregate cost of all employees and contractors engaged in direct or indirect advertising or promotion within the respective jurisdiction.²⁶ Both Maine and D.C. impose this reporting requirement based on virtually identical statutory language. But Maine's Department of Health and Human Services has provided further instructions on calculating aggregate employee and contractor costs,²⁷ whereas to date the D.C. Department of Health has not.

In addition to differing disclosure requirements, some states implement minimum monetary thresholds for expenses that companies must track or disclose. District of Columbia, Maine, and Vermont all exempt from disclosure, expenses of \$25 or less. Neither California nor West Virginia, however, expressly exempt items of nominal value from their respective tracking or disclosure requirements. Similarly, Minnesota does not exclude items of nominal value from its annual \$50 cap on gifts to practitioners. Under its disclosure law, Minnesota, however, does not require reporting of payments to HCPs that are less than \$100.

Is There Any Common Ground?

In light of all the differences between state tracking and disclosure requirements, companies may be wondering if there is any uniformity among the current state tracking or disclosure laws. All six states unanimously exempt drug samples intended for free distribution to patients.²⁸ With the exception of Minnesota, the remaining states exempt scholarships and other support for medical students, residents and fellows to attend educational or scientific conferences or seminars if the association sponsoring the conference or seminar selects the scholarship recipient. Finally, these five states also exempt the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials.²⁹

Conclusion

The foregoing is only a sample of the disparities between the state expense tracking and disclosure laws that are currently in effect. With new legislation potentially on the horizon, reconciliation of the differing tracking and disclosure requirements may become even more complicated. Companies should be mindful of the changing climate regarding state tracking and reporting initiatives and focus on state law compliance, not only in the handful of states that currently require it, but also on the national level. Any procedure or system that a company ultimately implements to track relevant expenses should be flexible enough to address the current inconsistencies and accommodate future ones as regulation on a state level becomes more prevalent.

About StayinFront, Inc.

StayinFront, Inc. is a leading global provider of enterprise-wide customer relationship management (CRM) applications, decision support tools, data services and eBusiness systems. StayinFront offers rapidly configured and implemented solutions to manage and integrate all points of customer interaction including sales, marketing, customer support applications and the web. StayinFront has been chosen globally as a strategic CRM partner for more than seventy pharmaceutical companies and StayinFront solutions have been implemented in over twenty countries in twelve languages.

Headquartered in Fairfield, NJ, StayinFront has offices in Illinois, the United Kingdom, India, Ireland, Belgium, Australia, Singapore and New Zealand. The Company can be contacted via the web at stayinfront.com. 107 Little Falls Road, Fairfield, NJ 07004 Ph: 973.461.4800 Fax: 973.461.4801

About Redi-Mail Direct Marketing, Inc.

As a leading industry provider of marketing support services, Redi-Mail Direct Marketing combines world-class technology with custom web application development and hosting, database management, lettershop and fulfillment capabilities to deliver true turnkey solutions to direct marketing and fulfillment requirements. As a licensee of the American Medical Association (AMA) Physician Masterfile database, Redi-Mail offers online physician counts and targeted direct mail lists on over 800,000 US based physicians through Redi-Mail Data™ our interactive medical database system.

Redi-Mail Direct Marketing is a member of the Redi-Direct family of companies. Headquartered in Fairfield, NJ, Redi-Mail occupies over 170,000 square feet of secure, state of the art data management and production facilities. The Redi-Mail facilities include an in-house post office and Redi-Mail is an active member of the U.S. Postal Customer Council. The Company can be contacted via the web at redimail.com. 5 Audrey Place, Fairfield, NJ 07004-3401 Ph: 973.808.4500 Fax: 973.808.5511

About Porzio, Bromberg & Newman, P.C.

Porzio, Bromberg & Newman, P.C. ("Porzio") is committed to serving the needs of the pharmaceutical industry, from regulatory compliance counseling to governmental affairs, from litigation to real estate and corporate. During the past five years, Porzio has provided more services to the pharmaceutical industry than to any other industry.

Porzio's dedication to the pharmaceutical industry is evidenced by its active participation in the HealthCare Institute of New Jersey, an association of research-based pharmaceutical and medical technology companies dedicated to advancing the development and implementation of sound public health and business policies.

To find out more about the various services that Porzio provides, please visit our website at www.pbnlaw.com or contact us at our Morristown, NJ location. Ph: 973-538-4006 Fax: 973-538-5146.

About Porzio Pharmaceutical Services, LLC

Porzio Pharmaceutical Services, LLC ("PPS"), is dedicated to helping the pharmaceutical industry remain compliant with the growing body of federal and state regulations governing pharmaceutical marketing and sales. "PPS provides companies with easily accessible, highly efficient information resources, such as Porzio Pharmaceutical Digest, Porzio Compliance Modules, Porzio EXP, and ePorzio."

To find out more about the various services that PPS provides, please visit our website at www.porzioharma.com or contact us at our Morristown, NJ location. Ph: 973-538-1690 Fax: 973-538-5146.

Additional copies of this publication can be requested through any of the contact information listed above.

²² Me. Rev. Stat. Ann. tit. 22, § 2698-A (4)(B)(2); D.C. Code § 48-833.03(a)(2); 33 V.S.A. § 2005(a)(4)(C).

²³ Me. Rev. Stat. Ann. tit. 22, § 2698-A (4)(A); D.C. Code § 48-833.03(1); W. Va. Code R. § 206-1-3(3.3).

²⁴ W. Va. Code R. § 206-1-3(3.3).

²⁵ D.C. Rule 1801.2(d).

²⁶ Me. Rev. Stat. Ann. tit. 22, § 2698-A (4)(C); D.C. Code § 48-833.03(a)(3).

²⁷ 275 Me. Code R. § 2.04-3.

²⁸ Cal. Health and Safety Code § 119402(2); D.C. Code § 48-833.03(a)(2)(D); Me. Rev. Stat. Ann. tit. 22, § 2698-A(4)(B)(4); Minn. Stat. § 151.461(1); 33 V.S.A. § 2005(a)(4)(A); W. Va. Code § 5A-3C-13(c)(1).

²⁹ Cal. Health and Safety Code § 119402(3); D.C. Code § 48-833.03(b); Me. Rev. Stat. Ann. tit. 22, § 2698-A(5); 33 V.S.A. § 2005(a)(4); W. Va. Code § 5A-3C-13(c)(2). Although California does not specifically address clinical trials, it generally exempts all payments to HCPs for "legitimate professional services" as long as the payment does not exceed fair market value.

We hope the information provided in this newsletter is helpful. If you have a perspective or opinion on state regulation and compliance you would like to share, or other contributions and comments, please contact:

*Sam Barclay at sbarclay@stayinfront.com or
John Oroho at jporoho@pbnlaw.com*