

State Marketing Law Compliance: Implications of Federal Sunshine Act Preemption

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Health / United States



Agenda

- Types of state marketing laws
- State-specific requirements
- Impact of federal preemption

Types of State Laws

- **Code of Conduct Laws** (require companies to adopt policies/procedures or marketing codes of conduct)
 - **California** (2005 pharma & device(?))
 - **Nevada** (2008 pharma & device)
 - **Massachusetts** (2009 pharma & device)
 - **Vermont** (2009 pharma & device)
 - **Connecticut** (2010 pharma & device)
 - Also: **District of Columbia SafeRx** (2008 pharma only)
 - Does not regulate companies; requires pharmaceutical detailers in DC to be licensed and follow a statutory code of conduct

Types of State Laws

- **Marketing Practice Laws** (limit the amount and/or type of expenditures that can be made on health care practitioners)
 - **Minnesota** (1994 pharma)
 - **California** (2005 pharma & device(?))
 - **Massachusetts** (2009 pharma & device)
 - **Vermont** (2009 pharma & device)

Types of State Laws

- **Disclosure of “Sales and Marketing” Expenditure Laws**
(require annual disclosure of certain expenditures)
 - **Minnesota** (1994 pharma only)
 - **Vermont** (2004 pharma only); (2009 pharma & device)
 - Also Samples disclosure
 - **District of Columbia** (2007 pharma only)
 - **West Virginia** (2008 pharma only)
 - **Massachusetts** (2009 pharma & device)

Which state laws apply to your company?

- Laws typically apply to **manufacturers**, labelers, or other entities engaged in the production, preparation, processing, packaging, repackaging, labeling, relabeling, or distribution of “**prescription drugs**” or “**medical devices**”
 - DC, MN & WV: Laws apply to pharmaceutical companies only
- **Once manufacturer makes approved product, laws typically apply**
 - States differ on how to treat company affiliates
- **Some states have additional “nexus” requirements**
 - DC & NV: “Employs, directs or utilizes marketing representatives” in the state
- A few state laws apply to additional/different entities
 - CA: Also applies to anyone who markets on behalf of a company
 - MN: Marketing restriction applies to manufacturers and wholesale drug distributors; however, disclosure is limited to licensed distributors only

When are your interactions subject to a state's law?

- Certain state laws apply to interactions with HCPs licensed or practicing in a state even if the interaction occurs outside the state
 - Minnesota-licensed physician at a conference in Arizona
- Interactions with certain HCP may be subject to laws of more than one state
 - Massachusetts-licensed physician who primarily practices in Vermont

So what are these state-specific requirements?

- No filings: CT & CA
- Filing does not require marketing activity disclosure: NV
- The kitchen sink: MA & VT
- Clearly pharma only: DC, MN & WV

Connecticut (Code of Conduct: Pharma & Device)

- Manufacturers must adopt a “Comprehensive Compliance Program” (CCP) in accordance with the OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers
- Manufacturers must adopt and implement a code that contains all of the requirements prescribed in the PhRMA/AdvaMed Code

California (Code of Conduct: Pharma & Device(?))

- Pharmaceutical companies must develop a CCP that is in accordance with OIG Compliance Program Guidance for Pharmaceutical Manufacturers and includes policies for compliance with the PhRMA Code
 - Pharmaceutical companies defined to include entities that produce or market “any drug or device that, pursuant to federal or state law, may be dispensed only by prescription.”
- CCP must include a **specific annual dollar limit** on “gifts, promotional materials, or items or activities” the manufacturer gives or provides to “medical or health care professionals”
 - Medical and health care professionals include licensed prescribers, medical students and members of drug formulary committees
- Manufacturers must declare annually in writing that they are in compliance with the provisions of the law and their CCP
- CCP and declaration must be available on company website

Nevada (Code of Conduct: Pharma & Device)

- Manufacturers must adopt a marketing code of conduct, a program to provide regular training to appropriate employees; and policies for investigating instances of noncompliance with the marketing code of conduct
- Manufacturers must also:
 - identify a compliance officer responsible for monitoring the company's marketing code of conduct
 - conduct annual audits to monitor compliance with the company's marketing code of conduct
- Manufacturer must make an annual submission to the NV Board of Pharmacy certifying that the company has conducted its annual audit and is in compliance with its marketing code of conduct

Massachusetts (Code of Conduct, Gift Ban & Disclosure Law: Pharma & Device)

- Obligations on the company include: adoption of a marketing code of conduct, and reporting instances of noncompliance to appropriate state authorities
- Code of Conduct restricts interactions with Massachusetts health care practitioners, even if the interaction takes place outside of Massachusetts.
- Practitioners includes:
 - MA-licensed prescribers
 - any officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals (e.g., nurses and office staff)

Massachusetts Continued

- Code required by Massachusetts is generally consistent with PhRMA & AdvaMed Codes but some differences:
 - No meals directly to practitioners at educational conferences, even if permitted by conference sponsor
 - “Snacks and refreshments” at conference booths are okay
 - Business courtesy meals may only be provided only if the primary purpose of the meeting is to educate and inform health care practitioners about the benefits, risks and appropriate on-label uses of the company’s products, related disease states or other scientific information

Massachusetts Continued

- Company must disclose the **value, nature, purpose, and recipient** of any fee, payment, subsidy or other economic benefit with a value of \$50 or more provided directly or through its agents to a **covered recipient** in connection with its **sales and marketing activities**
 - "Covered recipients" include not only practitioners but also some other health care professionals and entities (e.g., hospital, nursing home, pharmacy)
 - "Sales and marketing" includes the provision of any payment or other economic benefit with a value of at least \$50 to a covered recipient with very limited exceptions
- Additional quarterly disclosure requirements for meals outside a hospital or office setting unless it is part of a CME event.
- The content of disclosure reports are posted on a public website

Vermont (Code of Conduct, Gift Ban & Disclosure Law: Pharma & Device)

- Prohibits manufacturers from offering or giving any gift to persons authorized to prescribe or recommend prescribed products ("health care professionals"), their employees, agents, or contractors, and certain health care entities (e.g., hospital, nursing home)
- “**Gift**” is defined as "**anything of value** provided to a health care provider for free;" **or** "any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider" unless:
 - it is an "allowable expenditure" or
 - the health care provider reimburses the cost at FMV
- No *de minimis* exception
- Statute also sets forth other items and activities not subject to gift ban

Vermont Continued

- Prohibited gifts include:
 - **Business courtesy meals regardless of the location of such meals**
 - Educational grants and charitable donations to Vermont health care providers
- Allowable expenditures (i.e., items/activities excluded from definition of gift) are specifically identified and include:
 - Support for some independent medical education
 - Payments for bona fide clinical trials and other research projects
 - Other FMV fees, payments subsidies (e.g., for consulting meetings)

Vermont Continued

- Permitted gifts that are statutorily excepted from gift ban include:
 - Demonstration or evaluation units
 - Peer-reviewed academic, scientific, and clinical articles
 - Samples
- Annually must disclose, with limited exceptions, value, nature, purpose, and recipient of any allowable expenditure or permitted gift made to Vermont health care provider as well as any academic institution and any professional or patient organization representing or serving Vermont HCPs or patients.

Remember: VT separately requires the reporting of samples (including starter packs and vouchers)

- Reports are publicly available

Minnesota

(Gift Ban & Disclosure Law: Pharma)

- Gift ban prohibits drug manufacturers from giving "any gift of value" to practitioner. Prohibition generally applies to meals and textbooks.
- Limited exceptions include:
 - Items with total combined retail value of not more than \$50 per year
 - Salaries / benefits to employees
 - ****Payments to conference sponsor or for other educational programs****
 - ****Reasonable honoraria/expenses for faculty****
 - ****Compensation for substantial professional or consulting services****
- Licensed wholesale drug distributors must report nature, value, and recipient of permitted gifts noted "***" above
- Company reports are posted, as is, on the MN Board of Pharmacy website

District of Columbia (Disclosure Law: Pharma)

- Report value, nature, purpose, and recipient (persons/entities licensed to provide health care in state) of expenses associated with educational or informational programs (defined broadly to include direct/indirect expenditures for advertising and promotional activities). Reporting includes:
 - Expenses for food, entertainment, gifts greater than \$25
 - Payments for IME or CME; charitable grants
 - Printing, design, production costs for patient education materials
 - Consulting fees, speakers bureaus, market research
- Report DTC expenditures directed at state residents
- Report aggregate cost (including all forms of payments) of employees or contractors who directly or indirectly engage in reportable activity
- State will make public disclosure of aggregate data

Remember: DC also requires licensing of detailers

West Virginia (Disclosure Law: Pharma)

- Must report total number of West Virginia prescribers to whom the company provides "gifts, grants, or payments of any kind in excess of \$100 for the purpose of advertising prescription drugs" by dollar-amount categories (e.g., \$100-2500, \$2501-\$2500)
- For DTC advertising, must report the total expenditure
 - Rule sets forth specific calculation for DTC expenditures by population
- Must report aggregate amount spent for advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups in West Virginia
- State will make public disclosure of aggregate data

Preemption by Federal “Sunshine” Law?

- CMS Position
 - Requests that manufacturers continue to report to states until the federal Sunshine requirements take effect on August 1, 2013
 - After federal reporting takes effect many state laws will still apply.
 - Does not preempt state code of conduct or marketing practice laws
 - Does not preempt different state law disclosure requirements
 - Different recipient types
 - Transfers of value excluded from federal reporting
 - Does preempt disclosure for payments and transfers of value required to be reported AND those excluded from federal reporting based on the minimum dollar threshold

Preemption by Federal “Sunshine” Law?

- Range of responses from the states to date
 - **Minnesota:** Announced no reporting for calendar year 2012 and will ask the Minnesota legislature to repeal the existing reporting law. Keeping marketing restrictions.
 - **Vermont:** Cautioned that manufacturers must take care to make all non-preempted disclosures and affirmed that the AG would accept preempted disclosures. Noted no preemption of gift ban or samples disclosure.
 - **Massachusetts Two-Step:**
 - Originally proposed repealing disclosure requirements and accepting Sunshine compliance as sufficient for quarterly meal reporting.
 - Adopted rule plainly stating “no pharmaceutical or medical device manufacturing company is required to disclose information to the Department that has been disclosed” pursuant to federal law.

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