

The Transparency and Disclosure Field Guide Navigating a Compliant Pathway

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Health / United States



Agenda

- Types of state marketing laws
- Keys to understanding when a state law applies
- State-specific requirements
- Navigating a compliant pathway

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 starting in 2011
 - **District of Columbia** (2007 pharma only)
 - **Maine** (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, ME & 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, ME & 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 HCPs 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?

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

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
- Companies 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 (which may be AdvaMed/PhRMA Code), 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 Code but some differences:
 - Business courtesy meals may only be provided in practitioner's office or "hospital setting"
 - Restriction not limited to field sales reps and managers
 - A “hospital setting” includes a “specialized training facility”
 - No meals directly to practitioners at educational conferences, even if permitted by conference sponsor
 - “Snacks and refreshments” at conference booths are okay

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
- 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) beginning with samples dispensed in 2011

- 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 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 and Maine (Disclosure Laws: 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-\$5000)
- 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

Federal Physician Payments “Sunshine” Law (Disclosure: Pharma & Device)

- Effective January 2012 manufacturers must track payments in all states for federal disclosure requirements.
- Statute requires disclosure of value, form, nature, and recipient of any “payment or other transfer of value” by manufacturer to any “covered recipient.”
 - “Payment or other transfer of value” includes meals and gifts and also include in-kind items or services, certain ownership and investment interests, travel, honoraria, research, and certain consulting and educational payments
 - “Covered recipient” defined to mean physicians and teaching hospitals.
- The U.S. Department of Health and Human Services is expected to issue regulations clarifying the scope of the federal reporting obligation.
- Even after federal reporting takes effect many state laws will still apply.
 - Only preempts the “same” state law disclosure requirements.
 - Does not preempt state laws that require disclosure of different information, impose a gift ban, or require a code of conduct.

Navigating a Compliant Pathway

State marketing practice and disclosure laws are far-reaching; compliance efforts should be too!

Efforts must reach:

- Activities throughout company's operations
- Interactions across customer types
- Wide range of interactions

No one-size-fits-all solutions – highly dependent on size of company, types of customers, types of interactions

Navigating a Compliant Pathway: Operations

- Marketing restrictions and disclosure laws impact operations company-wide
 - **Sales and Marketing** (in-office meetings, speaker programs, promotional "giveaways," sample devices)
 - **Medical/Clinical Affairs** (education and training, advisory boards, research publications)
 - **Product development** (grants, consultants, licensing)
 - **Vendors** (program logistics, travel and expense reimbursement, consultants), **distributors** and **independent sales agents**
 - **Anyone else that interacts with HCPs**

Charting Your Pathway

- Company-wide education on state law compliance (not just sales reps)
- Adopt systems (including tracking and disclosure) for activities and expenses throughout the company

Navigating a Compliant Pathway: Customers

- Relevant “recipient” varies from state to state.
 - CA: Applies to interactions with an **individual licensed to prescribe**, as well as **medical students** and **members of formulary committees**
 - DC & ME: Applies to interactions with **persons and entities licensed to provide health care** in the state, including health plans, PBMs, pharmacies, physicians and hospitals
- Within a state the code of conduct/marketing restrictions may apply to different parties than the disclosure obligation
 - MA: **Code of Conduct** applies to health care practitioners licensed and authorized to prescribe in Massachusetts and their employees. **Disclosure obligation** also applies to other individuals or entities authorized to prescribe, dispense, or purchase (e.g., pharmacists, hospitals)

Charting Your Pathway

- Develop and maintain a comprehensive list of customers and related individuals
- Develop systems for tracking interactions with individuals and organizations

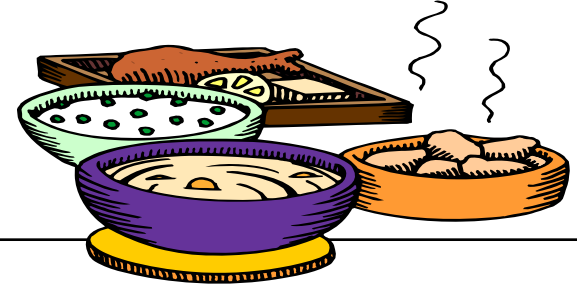
Navigating A Compliant Pathway: Interactions

- Several states require compliance with PhRMA/AdvaMed Codes, some states impose greater marketing restrictions
- Disclosure laws have varying dollar thresholds
 - VT: no *de minimus* exception.
 - WV: in excess of \$100
- Exceptions to disclosure requirements also vary
 - DC, ME, MA & WV: Each exempt some payments for research; however, definition of research is state-specific

Charting Your Pathway

- Before evaluating under state laws, ask: Does this interaction present an FDA, Kickback or AdvaMed / PhRMA Code problem? If it does, state disclosure laws may highlight risky conduct.
- Engage legal, business, and compliance to arrive at workable solutions for all HCP-interactions.
- Capture granular information about interactions; it's easier to aggregate or set aside data than to chase information after the fact.

Navigating Business Courtesy Meals



- PhRMA/AdvaMed Code permit modest, occasional meals for HCPs with a bona fide interest in the informational discussion that is the purpose of the meeting in a setting conducive to that discussion (in-office only for pharma sales reps)
- Some states are more restrictive than PhRMA/AdvaMed Code
 - VT: No business courtesy meals for HCPs regularly practicing in Vermont
 - MA: No out-of-office business courtesy meals for HCPs licensed in MA
 - CA & MN: Dollar limits apply to meals for HCPs
- Meals reporting is required in several states
 - DC, ME, MA, and WV

Charting Your Pathway

- Always ask customers in which state(s) they are licensed and practice before providing any meal
- Consider developing a Meals Reporting Form for in-office meals and speaker programs

Navigating Promotional Reprints



- FDA permits dissemination of reprints provided they meet the requirements of FDA's Good Reprints Guidance. PhRMA Code and AdvaMed Code permit giving an HCP a reprint.
- State laws appear to permit manufacturers to provide reprints
 - MA: Dept. of Public Health FAQ (Apr. 20, 2009): “The provision of educational items consistent with the [PhRMA and AdvaMed Codes] . . . is permitted.”
 - MN: Statutory exception to gift ban for “publications and educational materials.” But Minnesota Dept. of Pharmacy FAQ indicates that the “publications and educational materials” **exception only applies to materials** used by a manufacturer “**to market a specific product** (e.g., reprints of journal articles, marketing brochures and related materials, and instructional materials intended for use in educating patients . . .).”
 - What about reprints regarding off-label use in response to an unsolicited request?

Navigating Promotional Reprints

- Some states require the disclosure of reprint expenses
 - DC and ME : Disclosure includes all expenses associated with educational or information programs, materials and seminars including “printing costs of patient education materials.”
 - VT: Disclosure is required for any permitted gift to an HCP.
 - Report the fair market value (i.e., cost to the practitioner) of the reprint and the identity of the recipient
 - For gifts that are not banned but are of fair market value below \$25, Vermont guidance indicates that manufacturer may elect to report the expenditures for all Vermont prescribers or institutions in the aggregate (not by individual HCP name)

Charting your Pathway

- Evaluate whether dissemination of items is permissible
- Develop systems to capture and report reprint expenses that allow for the different disclosure requirements in the relevant states

Navigating a Compliant Pathway

Remember, timing is (almost) everything!

- **West Virginia** – Report April 1 for prior calendar year
- **Minnesota** – Report May 1 for prior calendar year
- **Nevada** – Report and annual certification June 1
- **D.C.** – Report July 1 for prior calendar year
- **Maine** – Report July 1 for prior calendar year
- **Massachusetts** – Report July 1 for prior calendar year
- **Vermont** - Report October 1 for FY ending June 30 (e.g., October 1, 2011 for July 1, 2010 to June 30, 2011)
 - Note: Fee due July 1
- **California** – Annual declaration

Questions?

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