The Transparency and Disclosure Field Guide

Navigating a Compliant Pathway

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Agenda

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- Types of State Laws
- Key Principles
- Overview of the States
- Putting the Law Into Practice – Reprint Example
- Navigating Compliance, Tracking and Disclosure

Types of State Laws

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- **Disclosure of "Sales and Marketing" Expenditure Laws** (require annual disclosure of certain expenditures)
  - **Minnesota** (1994) – drug
  - **Vermont** (2004) – drug; (2009) – drug, device and biologics
  - **District of Columbia** (2007) – drug
  - **Maine** (2007) – drug
  - **West Virginia** (2008) – drug
  - **Massachusetts** (2009) – drug, device and biologics

Types of State Laws

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- **Code of Conduct Laws** (require companies to adopt policies/procedures or marketing codes of conduct in accordance with industry codes, state laws, or federal guidance)
  - **California** (2005) – drug and device
  - **Nevada** (2008) – drug and device
  - **Massachusetts** (2009) – drug, device and biologics
  - **Vermont** (2009) – drug, device and biologics

Types of State Laws

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- **Gift Bans / Limits Laws** (limit the amount and/or type of expenditures that can be made on health care practitioners)
  - **Minnesota** (1994) – drug
  - **California** (2005) – drug and device
  - **Massachusetts** (2009) – drug, device and biologics
  - **Vermont** (2009) – drug, device, and biologics
- **Laws Relating to State Employees** (state ethics laws that limit amount and/or type of expenditures that can be made to certain state employees)
- **State Licensing / Registration** (for pharmaceutical "detailers" and others interacting with HCPs) – **D.C. SafeRx Act** (2008)

Does this state law apply?

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- Laws apply broadly to manufacturers, labelers, or other entities engaged in, among other things, the production, preparation, processing, packaging, repackaging, labeling, relabeling, or distribution of "**prescription drugs,**" "**biologics**," or "**medical devices**," as those terms are defined by the FDA, or using similar terminology.
- **Once manufacturer makes approved product, laws typically apply**
  - States differ on how to treat company affiliates (local and foreign) and pre-commercial affiliates or divisions within company
- **Additional "nexus" requirements:**
  - "Employs, directs or utilizes marketing representatives" in the state (D.C., Maine, Nevada)
  - "Employs or contracts with a pharmaceutical or medical device manufacturing agent" (Massachussets)

What is subject to disclosure or limit?

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- Typically: **value**, **nature**, **purpose** and **recipient** of expenditures must be disclosed. **"Recipient" varies:**
  - California – "Medical or health care professional" (a person licensed to prescribe drugs to human patients, medical students, or members of drug formulary committees)
  - D.C. and Maine – Persons or entities licensed to provide health care in state (including health plans, PBMs, pharmacies, physicians and hospitals)
- **Expenditures subject to gift limits, codes and disclosure vary greatly**
- **Impact of code of conduct/gift limit may differ from disclosure obligation:**
  - Massachusetts-licensed health care practitioners (MHCPs) – anyone authorized to prescribe and their employees – subject to Code of Conduct. Disclosure obligation applies to MHCPs and other individuals or entities (e.g., hospital) authorized to prescribe, dispense, or purchase.
  - Minnesota gift ban applies to manufacturers or wholesale drug distributors. Disclosure requirement applies only to entities that hold a wholesale drug distributor license.

District of Columbia and Maine
(Disclosure Laws - Drug)

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- Applies to manufacturers or labelers of prescription drugs who employ, direct, or utilize marketing representatives in that state
- Must 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). For example:
    - Support for IME or CME; charitable grants
    - Printing, design, production costs for patient education materials
    - Consulting fees, speakers bureaus, market research
    - Expenses for food, entertainment, gifts greater than $25
- Must 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

West Virginia
(Disclosure Law - Drug)

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- Applies to manufacturers or labelers of prescription drugs who employ, direct, or utilize marketing representatives in that state
- 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

Minnesota
(Gift Ban & Disclosure Law - Drug)

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- Gift ban applies to drug manufacturers and wholesale drug distributors; disclosure applies to entities holding wholesale drug distributor license
- Prohibits giving "any gift of value" to practitioner. The following are not gifts:
  - Free samples, “publications and educational materials”
  - 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****
- Must report nature, value, and recipient of permitted gifts noted "******" above
- Company reports are posted, as is, on the website of Minn. Board of Pharmacy

Massachusetts (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- A number of obligations on the company:
  - adopt a **marketing code of conduct** that complies with the requirements of the Massachusetts regulations
  - establish a **training program** that provides for "regular training of appropriate employees including . . . sales and marketing staff, on the marketing code of conduct"
  - adopt **policies and procedures for investigating noncompliance** with the regulations, **taking corrective action,** and **reporting instances of noncompliance** to appropriate state authorities
  - **make available** to Department of Public Health (DPH), **upon request**, copy of marketing code of conduct, training program, and policies
  - submit to DPH **contact information** of a compliance officer responsible for implementing, monitoring, and enforcing company's code
  - **certify** to DPH that, to best of the company's knowledge, information and belief, it is **in compliance** with the Massachusetts regulations

Massachusetts (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- Restricts company interactions with Massachusetts-licensed health care practitioners, even if those take place outside of Massachusetts.
- Generally consistent with PhRMA and AdvaMed codes. 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”
    - “Snacks and refreshments” at conference booths are okay
  - No meals directly to practitioners at educational conferences, even if permitted by conference sponsor
  - Pharmaceutical manufacturers may only use prescriber data for marketing purposes if prescribers are given opportunity to opt-out

Massachusetts (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- Travel and lodging may not be provided for medical device sales, promotional or other business meetings (e.g., no plant tours)
- For device company-conducted product training and education, may pay or reimburse for reasonable expenses only if:
  - commitment to provide expenses are in written agreement for the purchase of the device between the company and either (1) a purchasing MHCP, or (2) a purchasing facility where the MHCP actively practices and uses, or will use, the products.
  - "contract to purchase a medical device" includes an agreement to purchase a medical device pending an evaluation of the device to assess the appropriate use and functionality of the product
- Essentially codifies industry codes:
  - "bona fide services" characterized by "legitimate need for the services clearly identified in advance"
  - Pharmaceutical company must separate its CME grant-making functions from its sales and marketing departments.

Massachusetts (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- 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 prescribers, but other health care practitioners and some entities (e.g., hospital, nursing home, pharmacy)
  - "Sales and marketing" includes the provision of any fee, payment, subsidy or other economic benefit with a value of at least $50 to a covered recipient. Sales and marketing does not include:
    - demonstration or evaluation units;
    - Certain clinical trials, "genuine research" and market research;
    - in-kind items used for the provision of charity care; and
    - confidential price concessions.
- The content of these disclosure reports are public records and will be posted on a public website

Vermont (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- Prohibits manufacturer of drug or device and any wholesale distributor of medical devices from offering or giving any gift to persons authorized to prescribe or recommend drugs or devices ("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 additional items and activities not subject to gift ban

Vermont (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- Examples of prohibited gifts:
  - Business courtesy meals regardless of the location of such meals
  - Travel and lodging costs for sales, promotional, and other business meetings (e.g., plant tours)
  - Educational grants and charitable donations to Vermont health care providers
- Allowable expenditures (i.e., items/activities excluded from definition of gift) include:
  - Support for some independent medical education
  - Payments for bona fide clinical trials and other research projects
  - Payment or reimbursement for reasonable expenses necessary to attend company-sponsored training (if pursuant to a written agreement)
  - Royalties and licensing fees
  - Other FMV fees, payments subsidies (e.g., for consulting meetings)

Vermont (Code of Conduct, Gift Ban & Disclosure Law – Drugs, Devices and Biologics)

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- Enumerated items statutorily excepted from gift ban include:
  - Samples; demonstration or evaluation units
  - Loan of a medical device for a short-term trial period, not to exceed 90 days, to permit evaluation by a health care provider or patient
  - Peer-reviewed academic, scientific, and clinical articles
- Annually must disclose 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
  - Expenditures for bona fide clinical trials reported at earlier of FDA approval of product or two years after payment
  - For items not customarily sold (e.g., educational brochures), the "value" is the cost of production (attributable to Vermont)
  - For loans of medical devices, only the fact of the loan is reported (no monetary value)
- Reports will be publicly available

Nevada
(Code of Conduct – Drug and Device)

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- Imposes the following requirements:
- Adopt a **written marketing code of conduct** and a training program to provide regular training to appropriate employees and submit this to Nevada Board of Pharmacy
  - A company that **"uses, without modification" the PhRMA Code or AdvaMed Code "as its marketing code of conduct"** is permitted to so indicate on its submission to the Board in lieu of submitting its marketing code of conduct
- Adopt policies for **investigating instances of noncompliance** with the marketing code of conduct
- Conduct **annual audit** to monitor compliance with code of conduct and certify annually to Board of Pharmacy that audit has been completed
- Identify compliance officer responsible for developing, operating and monitoring its marketing code of conduct
- Nevada Board of Pharmacy posts annual listing of companies that are in compliance with requirements

California
(Code of Conduct – Drug and Device(?))

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- Manufacturers must adopt "Comprehensive Compliance Program" (CCP) that includes policies for compliance with the PhRMA Code and OIG's Compliance Program Guidance for Pharmaceutical Manufacturers.
  - Law appears to be geared towards pharmaceutical manufacturers but, by its terms, may apply to medical device manufacturers.
  - Where device manufacturers do comply with California requirements, typically read law as requiring policies for compliance with AdvaMed Code
- 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."
- Manufacturers must declare annually in writing that they are in compliance with the provisions of the law and their CCP.
- CCP and annual written declaration must be available on company website and through a toll-free number.

Federal Physician Payments "Sunshine" Proposals

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- Will require disclosure of value, nature, purpose, and recipient of any "payment or other transfer of value" by manufacturer to any "covered recipient"
- Federal legislation introduced by Sens. Grassley and Kohl as stand-alone; included in both House and Senate health reform bills and White House proposal
- "Covered recipient" may be defined narrowly (physicians and teaching hospitals) or broadly (other prescribers, pharmacists, health insurance issuers, PBMs, hospitals, medical schools, CME sponsors, professional societies, GPOs) depending on which version of legislation is enacted
- "Payment or other transfer of value" includes ownership and investment interests, profit distributions, dividends, and some option grants, in addition to more general gifts and payments for meals, travel, honoraria, research, and certain consulting and educational payments
- 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

Penalties and Certifications

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- **Penalties**
  - Fines for failure to comply (strict liability?)
  - Increased penalties for knowing and willful violations
  - Prohibition against circumvention
- **Certifications**
  - “In compliance”
  - To the best of one’s knowledge and belief
- **Other**
  - False certification?
  - Loss of license

Example: Promotional Reprints

- **FDA permits dissemination of reprints provided they meet the requirements of FDA's Good Reprints Guidance**
  - Among other requirements: (1) must be report of adequate and well-controlled study (no letters to the editor, abstracts, Phase 1 studies, or pubs without substantive discussion) and (2) published in a peer-reviewed journal that is generally available
- **PhRMA Code and AdvaMed Code permit giving an HCP a reprint. Specifically:**
  - Manufacturer may provide occasional item for education of patients and healthcare professionals provided item: (1) is valued at $100 or less (except for textbooks and anatomical models under AdvaMed Code) and (2) does not have value to healthcare professional outside of professional responsibilities
  - E.g., medical textbooks, subscriptions to scientific journals, reprints, copies of treatment guidelines, anatomical models, information sheets and brochures, patient starter kits

Example: Promotional Reprints

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- **State laws permit manufacturers to provide reprints**
- E.g., **Massachusetts** – Dept. of Public Health FAQ (Apr. 20, 2009): "The provision of educational items consistent with the [PhRMA and AdvaMed Codes] . . . is permitted."
- E.g., **Minnesota** – Exception from Minnesota 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 . . .)."
  - General textbooks subject to gift ban
  - Journal subscriptions subject to gift ban
  - What about reprints in response to unsolicited request?

Example: Promotional Reprints

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- **Even where permitted, the value must be tracked**
- E.g., **D.C. and Maine** – State requires disclosure of all expenses associated with educational or information programs, materials and seminars including "printing costs of patient education materials."
- E.g., **Vermont** – Requires disclosure of 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).
  - For items that are not customarily sold (e.g., company-produced educational brochures for patient use), the value to be reported is the manufacturer's cost of production.

Navigating Compliance

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- Recognize that gift bans and codes impact operations company-wide; it is a challenge is to identify where covered expenditures originate
  - **Sales and Marketing** (meals, 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**
- Assess what compliance structure (including tracking and disclosure) is currently in place
- Engage legal, business, and compliance to arrive at workable solutions
- Don't forget to ask the very important question before evaluating under state laws: Is this an FDA / Kickback / AdvaMed / PhRMA Code problem?

Navigating Tracking and Disclosure

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- No one-size-fits-all approach – highly dependent on size of company, types of activities company engages in, existing systems
- Strategies:
  - Determine process for identifying comprehensive list of customers, including health care professionals and health care organizations
  - Develop strategy for tracking interactions
  - Capture granular information from the start so new reporting requirements can easily be generated from existing data

Dates and Fees

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- **California** – Annual declaration. No fee.
- **D.C.** – Report July 1 for prior calendar year. $2500 fee.
- **Maine** – Report July 1 for prior calendar year. $1000 fee.
- **Massachusetts** – Report July 1 for prior calendar year. First report due July 1, 2010 is only for second half of 2009. $2000 fee.
- **Minnesota** – Report May 1 for prior calendar year. No fee.
- **Nevada** – Report June 1; annual certification. No fee.
- **Vermont** – Report October 1 for FY ending June 30 (e.g., October 1, 2011 for July 1, 2010 to June 30, 2011). First report due October 1, 2010 covers entire FY for pharmaceutical manufacturers; only covers Jan. 1, 2010 – June 30, 2010 for all others. $500 fee (due July 1).
- **West Virginia** – Report April 1 for prior calendar year. No fee.

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