State Laws: Assessing Challenges, What's Ahead

A Panel Discussion at the Pharmaceutical Compliance Forum, October 28, 2008

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Disclaimer

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This presentation contains time-sensitive information and may be updated for the Panel presentation.

Agenda

- Name that State
- Issues relating to data
  - Aggregating data
  - Allocating spend
  - Confidentiality of data
  - Timelines
- Belated compliance after non-compliance
- Issues needing legal & compliance interpretation under state law
- The new Massachusetts law
- The DC Safe Rx Act
- Has state regulation of Sales & Marketing changed industry practices?

“Name That State”

Panel members will defy the audience to identify specific state laws to which the questions appertain.

Questions will be provided at the session, and participants will be suitably rewarded.

Q&A

Q: How many states have annual reporting requirements due on July 1?

A: 3 (DC, ME and Mass. - Marketing Cost Reporting)

Q: How many states require reporting costs of employees and contractors who directly or indirectly engage in advertising, marketing or promotional activities?

A: 2 (ME and DC)

Q: The laws in how many jurisdictions made the voluntary PhRMA Code not so voluntary:

A: 4 (Nevada, California, Mass. and DC)

Q: Name that state: This jurisdiction's marketing cost disclosure law has a two-step filing process:

A: Vermont

Q: Name the state(s) that consider "grants" to be reportable marketing expenses.

A: Maine, DC, W. Virginia (and potentially Massachusetts pending clarification)

Q: Name that state: If a meal is provided to a prescriber to facilitate an informational presentation, and members of the prescriber's staff are present for the meal, this jurisdiction requires that the cost of the total meal be recorded for the entity/medical group, not the individual prescriber:

A: Maine

Issues Relating To Data:

Aggregating data and allocating spend, and disclosure of data gaps or concerns

- Obtaining data in a resource constrained environment
  - Methodologies employed
  - Systems employed
  - Staffing
  - Time devoted to state reporting

Issues Relating To Data:

Aggregating Data

- Areas of potential data gaps:
  - Multiple affiliates with different business, business rules and systems
  - Home office expenditures (not captured in any event management system)
  - Non-obvious sources of fee for service relationships
  - Expenses in relation to managed care
  - Identity of parties in contracting for services
  - Vendor reporting

Issues Relating To Data:
Allocating Spend

- Different state rules and how they can make compliance a nightmare, even for the best!
- Interpreting the requirements for allocating meal costs:
  - Maine: aggregated by HCP or entity, regardless of licensure, if expenses include provision of meal to a non- licensed practitioner
  - Vermont: Gifts to an office are aggregated and allocated by prescriber; thus a $60 luncheon to an office with 2 prescribers and other attendees is a $30 benefit to each prescriber
  - DC: Reporting per expenditure over $25 a day
  - West Virginia: Aggregate reporting by category
  - Massachusetts: Reporting every expenditure over $50

Issues Relating To Data:
Allocating Spend (cont'd)

- *De minimis non curat lex*: threshold amounts and how they are calculated
  - What does $25 per day mean?
    - What about contract sales organizations
    - What about copromote partners?
  - Do companies address these exceptions with behavioral limits?
- Employee costs
- Material costs
- Grants as "marketing expenses"

How do you address concerns about incomplete data?

- Move to SOX-like certification process
- Disclosure in cover letter
- Disclosure in SEC filings (10-K disclosure)

Certification in Support of
Alpharma Pharmaceuticals' 2008 Report for
Vermont's Pharmaceutical Marketing Disclosure Law
18 V.S.A. § 4632
(Reporting Period: FY/08 - 7/1/07-6/30/08)

In connection with Alpharma Pharmaceuticals' annual report to the state of Vermont in compliance with 18 V.S.A. § 4632, I hereby certify as follows:

- I have reviewed the request for information, conducted a thorough search of all relevant records, databases, etc., and contacted any relevant third-parties for information.

  Select ONE:

  □ Attached to this certification is my submission of all information that is responsive to the request for information.

  or

  □ There are no reportable expenditures to provide.

- I understand that the Vice President and Senior Counsel, Healthcare Law Compliance will rely on this certification in preparing and submitting the report on behalf Alpharma Pharmaceuticals to the state of Vermont.

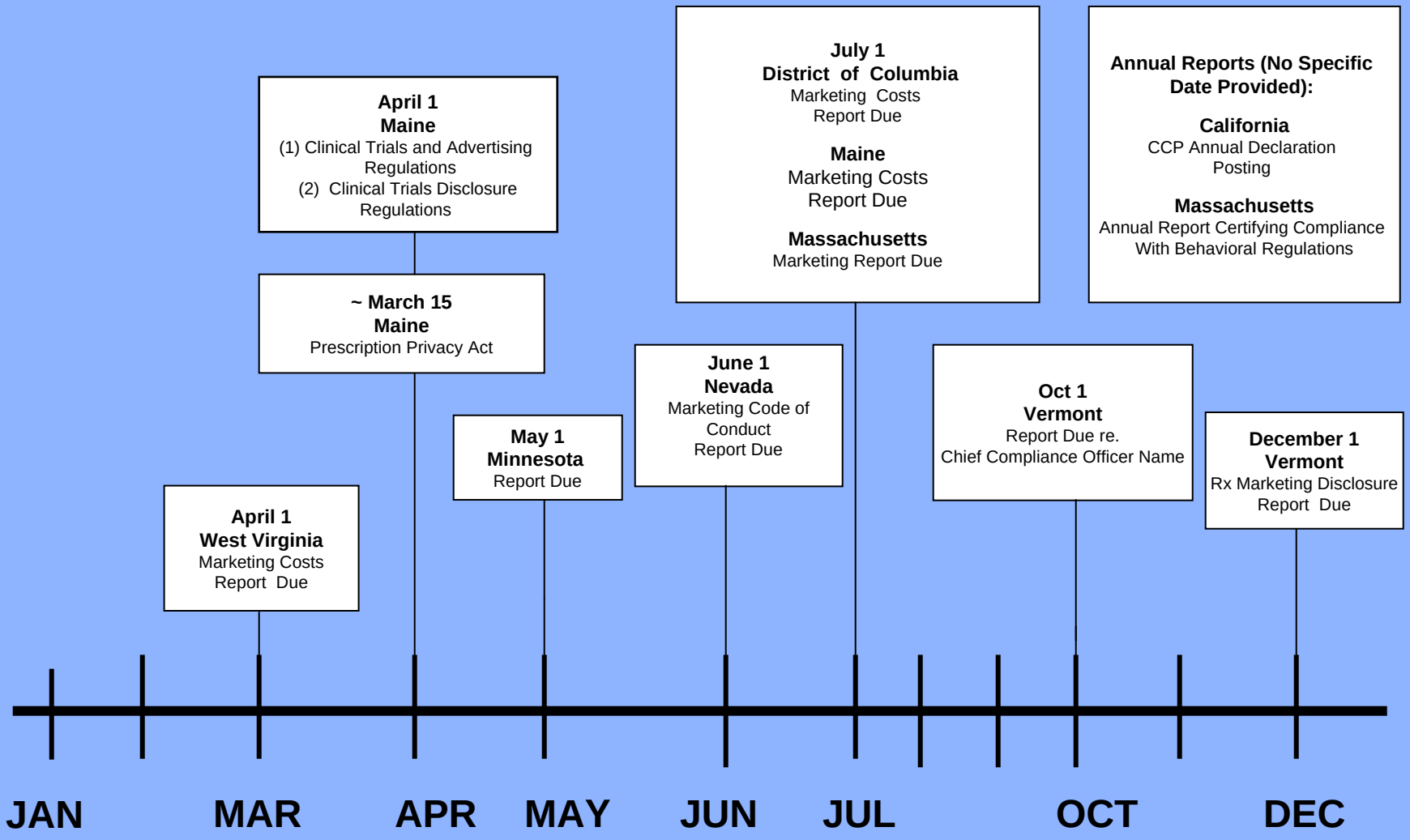
Signature: _____

Printed Name: _____
Title: _____
Department Name: _____
Date: _____

Confidentiality of Data

- After Merck and Lilly: Is there an argument left for confidentiality of data?
- The Federal Sunshine Law: What data will be public?
- Required disclosure: Cephalon CIA and the Device Settlements
- Current states and confidentiality:
  - Minnesota: Data base used for investigative reporting
  - Massachusetts: Anticipated website publication of all payments over $50
  - Other state rules

Issues Related to Data:
State Reporting Timelines



Belated Compliance after Non-compliance

- Should a company account for past non-compliance, and if so, how?
  - Past non-compliance with behavioral regulation
  - Past non-compliance with reporting requirements
    - Ambiguity of entity coverage under the reporting statutes

Legal and Compliance Issues Needing Interpretation Under State Law

Gifts

- Gifts under the new PhRMA Code and state law gift prohibitions
  - Is a gift that is appropriate under the new PhRMA Code subject to the Minnesota gift prohibition?
    - Minnesota states: "... gift does not include: ... 6) publications and educational materials." (Minn. Rev. Stat. § 151.461)
  - Treatment of gifts under other state laws

Gifts: A Comparison

PhRMA Code	Minnesota Gift Statute
• The Code prohibits pharmaceutical companies from making gifts to HCPs that "do not advance disease treatment or education." • The Code permits companies to offer items "designed primary for the education of patients or HCPs" if the items (1) are not of substantial value and (2) do not have value to the HCP outside of his or her practice • These permissible gifts cannot be offered on more than an "occasional basis" (an undefined term in the Code) • Illustrative examples of permitted educational items include: educational brochures; medical text books; subscription to relevant scientific journals; patient tracking and self-assessment tools; anatomical models for exam rooms, and starter kits	The Minnesota Gifts Statute prohibits all gifts to HCPs except for specific enumerated exceptions: • Professional samples provided free to patients • Items provided with a combined value of not more than $50 per year, including meals • Payments to sponsor a medical conference • Reasonable honoraria and expenses for faculty members at educational conferences • Consulting fees in connection with a genuine research project • Publications and educational materials • Salaries and benefits paid to employees

Question for Our Audience

- So, is a medical textbook an item you are permitted to give a healthcare professional under Minnesota Law?

- Yes
- No
- Maybe

Issues Requiring Legal and Compliance Interpretation Under State Law (cont'd)

Meals

- Is there a policy clash between the PhRMA Code, state laws, and other standards?
  - Minnesota: In and out of office meals with practitioners (prescribers) are theoretically permitted: up to a total of $50 a year
  - Massachusetts: New law does not permit any out-of-office meals to practitioners in Massachusetts by anyone employed or under contract with a device or pharmaceutical manufacturer who engages in detailing, promotional activities, or other marketing

Issues Requiring Legal and Compliance Interpretation Under State Law (cont'd)

- AAMC recommendations: No in-office meals at academic medical centers (see Stanford, U. Penn policies)
- Variations in definitions of health care professionals and how that impacts compliance

Question for Our Audience

Market Research

- Market research is permitted under Minnesota law

True

False

Issues Requiring Legal and Compliance Interpretation Under State Law (cont'd)

- What are the reporting rules on market research under different reporting laws?
  - DC
  - Maine
  - Massachusetts
  - Minnesota
  - Vermont
  - West Virginia

Challenges Under State Laws That Require Adoption of Marketing Codes

- Nevada's requirement of an annual audit: How are companies fulfilling this requirement?
  - Companies with Corporate Integrity Agreements
  - Other companies

Challenges Under State Laws That Require Adoption of Marketing Codes

- PhRMA encourages auditing every three years: Impact on state declarations?
- PhRMA Code language: “Companies are encouraged to seek external verification…that the company has policies and procedures in place to foster compliance with the Code. PhRMA will identify on its web site if a company has sought and obtained external verification of its compliance policies and procedures from an external source.” Section 15

Challenges Under State Laws that Require Adoption of Marketing Codes (cont'd)

- When are companies required to comply with the revised PhRMA Code, effective "January 2009"?
  - Nevada statute: "Adoption of the most recent version of the Code…satisfies the requirements…"
  - California statute: "A pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revisions to the ...Code…."
  - DC Safe RX: "Detailers are required to comply with the PhRMA Code, as amended or republished…."

The New Massachusetts Law

Mass. Gen. Laws Ch. 111N, § 1-7

New Code : DPH must promulgate a standard marketing code of conduct for pharmaceutical or medical device manufacturers

- To be no less restrictive than " the most recent update" of the PhRMA Code.
- Requirements are similar to PhRMA Code requirements, except:
  - New code appears to prohibit the provision of *any* meals to healthcare practitioners outside of the health care practitioner's office or hospital setting

Massachusetts Law (cont'd)

The future marketing code will specifically allow for the following activities:

- Distribution of peer reviewed academic, scientific or clinical journals;
- Purchase of advertising in such journals;
- Samples ("prescription drugs") provided for patient use;
- Compensation for substantial professional services in connection with a genuine research project or clinical trial; and
- Payment for technical training on use of a medical device if the expense is part of the vendor's purchase contract for the device.

Massachusetts Law (cont'd)

Reporting Expenditures:

Any "economic benefit" greater than $50 provided, directly or indirectly, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioners, or any other person licensed in Massachusetts to dispense prescription drugs.

Massachusetts Law (cont'd)

Reporting Compliance:

- a description of the company training program
- the name, title, address, telephone number, and e-mail address of its compliance officer; and
- certification that it has conducted an annual audit and is in compliance with its marketing code of compliance

Implementing Regulations:

DPH will issue as emergency regulations with opportunity to comment

DC Safe RX

DC Act 17-282, DC Law 17-131, 55 DC REg.9317

- Who is a “detailer” under the Act, and what are the implications?
  - Final rules issued unchanged October 1, 2008
  - Clarification promised in an FAQ to come
- Definition of “Pharmaceutical Detailing”
  - the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product

DC Safe RX cont'd

Inter alia, requires:

- Licensing of a detailer effective April1, 2009; failure to obtain a license is subject to a $10,000 fine
- Higher education qualifications (with waiver process for current detailers) and continuing education requirements
- Compliance with a code of ethics, including following the PhRMA Code
- Providing information consistent with FDA approved labeling
- Record retention by detailers with respect to their communications with licensed health professionals subject to Board of Pharmacy's authority to collect such records

Has State Regulation of Sales and Marketing Changed Company Practices?

The Pros:

- Promotes more rational spending:
  - Sales and Marketing in Minnesota
- Promotes transparency to management of spending across the organization
- Raises the profile of compliance in the organization
  - State laws, based on regulators' belief that business knows how money is spent, coupled with siloed business practices= opportunity for compliance to take a leading business role

Has State Regulation of Sales and Marketing Changed Company Practices? (cont'd)

- Promotes organizational interest in an aggregate health care provider spend system
  - Increased business awareness to all spend with HCPs
  - Increased efficiency in responding to legal and regulatory inquiries

Has State Regulation of Sales and Marketing Changed Company Practices? (cont'd)

The Cons:

- Is the goal of transparency really furthered by state requirements?
  - Healthcare professional resistance
- Have marketing codes or reporting statutes targeted the right practices to protect the independence of medical judgment?
- Conflicting allocations minimize usefulness of data
- Commitment of enormous resources
- Publication of data has not impacted spending habits

Questions?