

# Pharmaceutical Compliance Congress: “State of the States”



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# Overview

- Types of State Laws Potentially Affected by the “Sunshine Act”
  - Limits or Prohibitions on Gifts to Prescribers
  - Marketing Cost Reporting Requirements
  - Code Compliance/Licensing of Representatives
  - Prescriber Data Restrictions
  - Counterdetailing Programs
- Compliance Challenges
- Next Steps/Where Will It Go From Here?
- Specifically not going to address state price reporting or clinical trial registry laws



# Gift Limits

- Minnesota
- California



## Minnesota

- **Statute generally prohibits a manufacturer or wholesale drug distributor from “giv[ing] any gift of value” to a practitioner with certain exclusions including:**
  - Aggregate annual value <\$50
  - Samples
  - Certain meeting and CME sponsorships
  - Bona fide consulting or research fees



# California

- Manufacturers must declare annual spend limit per health care provider
  
- Not included in the limit:
  - Samples
  - Bona fide consulting
  - CME



## Marketing Cost Reporting Requirements

- District of Columbia
- Maine
- Massachusetts
- Minnesota
- Vermont
- West Virginia



# District of Columbia

- **Must track per HCP:**
  - Expenses associated with educational or informational programs/materials
  - Remuneration for promoting or participating in educational or informational sessions
  - Expenses associated with food, entertainment, or gifts valued at more than \$25
  - Anything provided to a health care professional at less than FMV
  - Expenses associated with trips and travel
  - Expenses associated with product samples (except free samples for patients)
- Expenses for DTC
- Costs for reps



# Maine

- **Per HCP:**
- Educational or Informational Program expenses
  - Support for IME or CME;
  - Printing, design and other production costs for patient education and disease management materials;
  - Direct or indirect payments for consulting fees, speakers bureaus, writing or publishing articles, and market research surveys; and
  - Charitable grants, even if unrestricted.
- Expenses associated with food, entertainment, or gifts valued at more than \$25 per day.
- Anything provided to a health care professional for less than fair market value.
- Expenses associated with trips and travel.
- Expenses associated with product samples (except free samples for patients)





# Maine

- Also track DTC expenses
- Costs associated with reps



## Massachusetts

- Must report the value, purpose, nature and recipient of any fee, payment, “other economic benefit” valued at >\$50
  - No exceptions for samples, clinical research payments, etc.
- Reported information to be disclosed on a publicly available web site



## Minnesota

- Total spend per HCP
- Scholarships
- Honoraria and expenses for faculty
- Consultants over \$100



## Vermont

- Must report the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, with certain exceptions:
  - Samples
  - Gifts <\$25
  - Certain scholarships and CME



## West Virginia

- Spend per HCP except for
  - Samples
  - Clinical research
  - Certain scholarships
- DTC costs
- Spend to disease advocacy groups >\$10,000



# Code Compliance/Licensing of Representatives

- Ethics Code Compliance
  - California
  - Nevada
  - Massachusetts (through rulemaking)
  - District of Columbia (through rulemaking)
- Licensing of Representatives
  - District of Columbia
  - Vermont (bill pending)



## California

- Manufacturers must have a written Code of Conduct/Compliance Plan
- Manufacturers must certify compliance annually on Company website
- Certification of Compliance must be available through toll-free number



## Nevada

- Must adopt a Compliance Plan
- Annual report to include:
  - Copy of Healthcare Compliance Plan
  - Description of training program
  - Description of investigation policies
  - Contact information for compliance officer
  - Certification that audit has been done and company is in compliance.





## Massachusetts

- Commonwealth to promulgate a “Marketing Code of Conduct” with which manufacturers must comply
- Annual report to include:
  - Description of training program
  - Description of investigation policies
  - Contact information for compliance officer
  - Certification that audit has been done and company is in compliance.



## District of Columbia

- SAFERx Regulations Require Detailers to Comply with Marketing Code as Condition to Maintaining their License
  - Detailers Must Sign “Affidavit to Abide By Code of Ethics”
  - PhRMA Code Is Minimum Standard
  - Additional Provisions Outlined on Affidavit Form and in DC Regulations



## District of Columbia

- Licensing of “Pharmaceutical Detailers”
- Requirements
  - College degree, unless waiver approved
  - Compliance with Ethics Code
  - Continuing Education
  - Payment of Licensing Fees
- Penalties



## Vermont

- HR 887 – Pending, but not acted upon in 2008
- Requirements for License:
  - Unless Experience Requirement Satisfied, Bachelors in Pharmacy or a Chemical, Physical or Biological Science
  - Payment of \$300 Fee to Fund “Evidence-Based Information” Program (every two years)



# Restrictions on Sale of Prescriber Data for Promotional Purposes

- New Hampshire
- Maine
- Vermont



## New Hampshire

- **Prohibits license, transfer, use, or sale of prescriber-identifiable data for commercial purposes**
  - Excludes use of prescriber-identifiable data for formulary management, pharmacy reimbursement, or research purposes
- Struck Down by District Court
- On Appeal to First Circuit



# Maine

- **Prohibits license, use, sale, transfer or exchange for value of prescriber-identifiable data for any “marketing” purpose for those physicians who have filed a confidentiality application.**
  - “Opt Out”
  - Marketing Broadly Defined
- Struck Down by District Court
- Appeal Stayed Pending Outcome of New Hampshire Case



# Vermont

- **Prohibits License, Sale, Transfer or Use of Prescriber Identifiable Data for commercial purposes for all Physicians in the State unless Physician Consented to Use**
  - “Opt In”
  - Broad Marketing Definition
  - Broad Carve Outs for Insurers, PBMs and the State
- Case Tried in July
- District Court Decision Pending





## Counter-Detailing

- Pennsylvania
- Maine
- Massachusetts
- Vermont
- West Virginia



# Pennsylvania

- PACE Program -- 2005
  - Developed in Conjunction with Jerry Avorn (Harvard Medical School)
  - Funded by PA Department of Aging
  - Provide Scientific and Cost Information about Commonly Prescribed Products



# Maine

- Effective January 1, 2008, ME shall establish “a prescription academic detailing program”
  - to enhance the health of residents
  - to improve the quality of decisions regarding drug prescribing,
  - to encourage better communication between the department and HCPs participating in publicly funded health programs, and
  - to reduce the health complications and unnecessary costs
- Provide outreach and education about “therapeutic and cost effective drugs”
- For HCPs in publicly funded programs



## Massachusetts

- The department shall . . . develop, implement and promote an evidence-based outreach and education program about the therapeutic and cost-effective utilization of prescription drugs. . .



# Vermont

- Act 80, Section 14 (2007)
  - The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs.



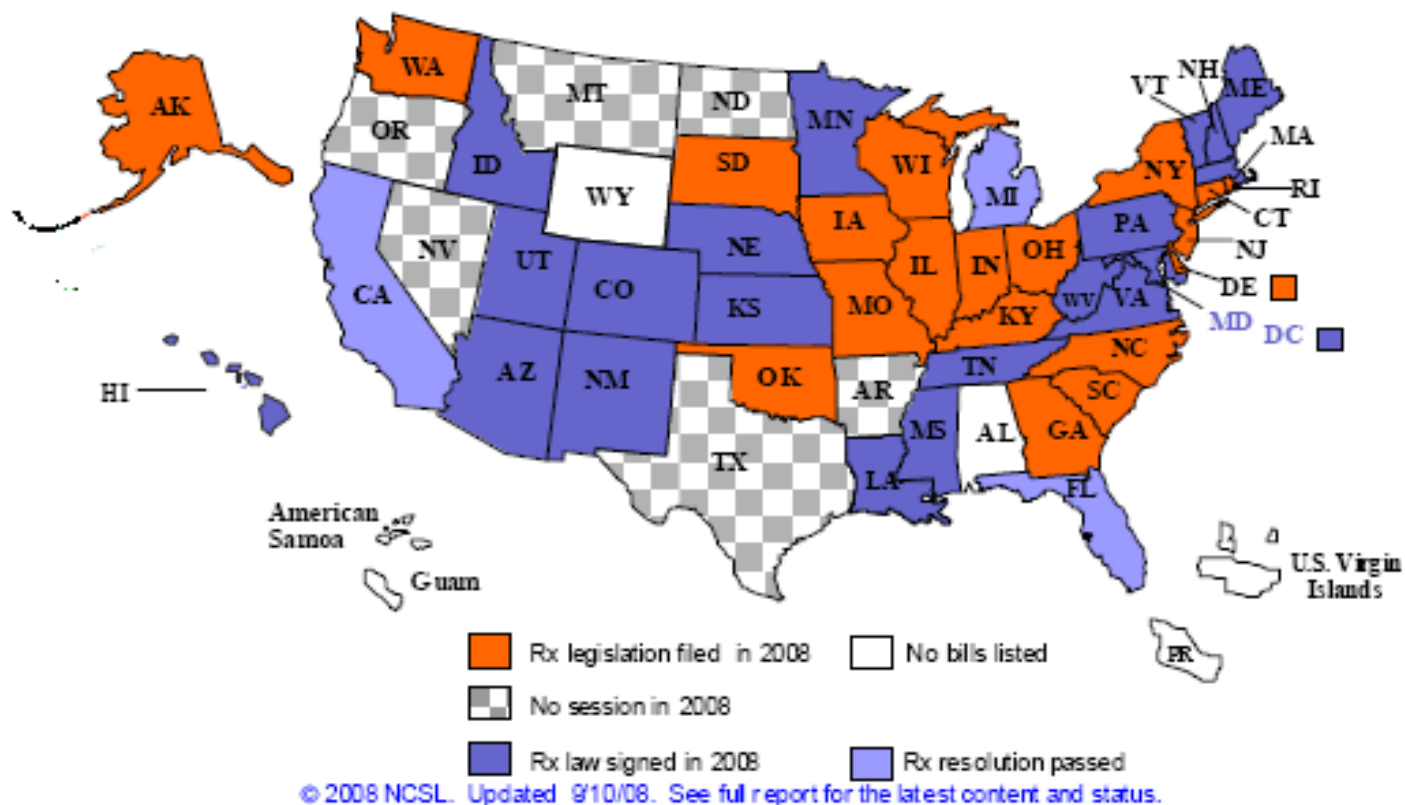
## West Virginia

- Code Provision establishes “counter-detailing programs aimed at educating health care practitioners authorized to prescribe prescription drugs about the relative costs and benefits of various prescription drugs, with an emphasis on generic substitution for brand name drugs when available and appropriate; prescribing older, less costly drugs instead of newer, more expensive drugs, when appropriate; and prescribing lower dosages of prescription drugs, when available and appropriate.”



# Other Initiatives

## 2008 Prescription Drug State Legislation



# Compliance Challenges

- Keeping Up!
- Establishing Compliance Mechanisms and Controls
- Ensuring Timely Reporting
- Nuances
  - “other economic benefit”
  - “directly or indirectly”





## Next Steps

- Impact of a Potential Federal “Sunshine” Law on State Activity?
- Impact of the 2008 Revision to the PhRMA Code on State Activity?



# Questions?

