



**Summit on Disclosure, Transparency and Aggregate Spend
For Drug, Device and Biotech Companies
March 5, 2009**

Introduction to Existing State Disclosure Laws and Regulations

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OVERVIEW OF STATE DISCLOSURE LAWS

Currently, there are three “types” of state marketing / disclosure laws

1

Laws that require companies to adopt a compliance program and/or marketing code of conduct that affects payments made to healthcare professionals (“HCP”)

- California
- Massachusetts
- Nevada

2

Laws that limit the payments that may be provided to HCPs

- California
- District of Columbia
- Massachusetts
- Minnesota

OVERVIEW OF STATE DISCLOSURE LAWS

Currently, there are three “types” of state marketing / disclosure laws

3

Laws that require certain payments provided to HCPs to be reported on an annual basis

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

OVERVIEW OF STATE DISCLOSURE LAWS

	Compliance Program	Marketing Code of Conduct	Limit on Gifts	Annual Report	Annual Certification
California	X		X		X
District of Columbia			X ¹	X	
Maine				X	
Massachusetts		X	X	X	X
Minnesota			X	X	
Nevada		X			X
Vermont				X	
West Virginia				X	

¹ Title III of D.C. Act 17-282 (2008).

DISTRICT OF COLUMBIA

- Requires annual disclosure of certain marketing costs:
 - Direct to Consumer Advertising
 - Expenses associated with direct or indirect marketing within the state via broadcast & print media, direct mail and telephone solicitation
 - Health Care Provider Marketing
 - Educational and marketing programs and materials
 - Grants, honoraria and consulting fees
 - Food, entertainment and gifts valued at more than \$25 and anything provided at less than fair market value
 - Travel expenses
 - Samples not for free distribution to patients
 - Marketing Personnel Expenses
 - Aggregate costs of all employees & contractors engaged in marketing activities within the state

DISTRICT OF COLUMBIA

- Expenses that are exempt from disclosure:
 - Expenses of \$25 or less per day per HCP entity
 - Reasonable compensation and reimbursement of expenses associated with a bona fide clinical trial
 - Scholarships/reimbursement of expenses for attendance at a significant medical or scientific conference if the recipient is chosen by the sponsoring association
- Information that must be reported:
 - Date of payment/gift
 - Name, type (clinic, physician) and credentials (MD, DO) of the recipient
 - Nature, purpose and monetary value of the payment/gift
- A civil penalty of \$1000 may be imposed for failure to report and for each false report or omission of required information

MAINE

- Requires annual disclosure of certain marketing expenses:
 - Direct to Consumer Advertising
 - Expenses associated with direct or indirect marketing within the state via broadcast & print media, direct mail and telephone solicitation
 - Health Care Provider Marketing
 - Educational and marketing programs and materials
 - Grants, honoraria and consulting fees
 - Food, entertainment and gifts valued at more than \$25 and anything provided at less than fair market value
 - Travel expenses
 - Free or in kind services
 - Samples not distributed free of charge to patients
 - Marketing Personnel Expenses
 - Aggregate costs of all employees & contractors engaged in marketing activities within the state

MAINE

- Expenses exempt from disclosure:
 - Expenses of \$25 or less per day per HCP/entity
 - Reasonable compensation and reimbursement of expenses associated with a bona fide clinical trial
 - Scholarships/reimbursement of expenses for attendance at a significant medical or scientific conference if the recipient is chosen by the sponsoring association
- Information must be reported:
 - Date of payment/gift
 - Name, type (clinic, physician) and credentials (MD, DO) of the recipient
 - Nature, purpose and monetary value of the payment/gift
- A civil penalty of \$1000 plus attorneys fees and cost may be imposed for failure to comply

MASSACHUSETTS

- SB 2863 signed into law on August 10, 2008
 - Effective date was January 1, 2009
 - Draft regulation 105 CMR 970.00 released December 10, 2008
 - Final regulations expected shortly
 - First report due July 1, 2009

MASSACHUSETTS

- Manufacturers must:
 - Adopt a marketing code of conduct developed by the Department that is no less restrictive than the PhRMA and AdvaMed Codes
 - Provide regular training to employees on the marketing code of conduct
 - Conduct annual audits to monitor compliance with the marketing code of conduct
 - Adopt policies and procedures for investigating instances of noncompliance with the code, taking corrective action, reporting noncompliance to state authorities
 - Identify a Compliance Officer responsible for operating and monitoring the marketing code of conduct
 - Submit an annual report and certification to the Board of Pharmacy

MASSACHUSETTS

- Requires annual disclosure of certain information:
 - Description of training program
 - Policies and procedures for investigating noncompliance, taking corrective action and reporting noncompliance
 - Name and contact information for compliance officer
 - Certification that the manufacturer conducted its annual audit and is in compliance with the marketing code of conduct
 - “[V]alue, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50”
- Enforcement
 - Manufacturers and their agents may not “knowingly and willfully” violate the marketing code of conduct
 - Fine of not more than \$5,000 per transaction, occurrence or event
 - Department must “report to the attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the market[ing] code of conduct”

MINNESOTA

- Prohibits manufacturers from offering or giving any gift of value to a prescriber
- “Gift” does not include:
 - Drug samples
 - Items with a total combined retail value of less than \$50 per year
 - Payments to the sponsor of a medical conference, professional meeting or other educational program
 - Honoraria and expenses of a HCP who serves on the faculty at a professional or educational conference or meeting
 - Compensation for substantial professional or consulting services in connection with a genuine research project
 - Publications and educational materials
 - Salaries or other benefits paid to employees

MINNESOTA

- Requires annual disclosure of certain payments totaling \$100 or more:
 - Payments to the sponsor of a medical conference, professional meeting, or other educational program
 - Honoraria and expenses of a practitioner who serves as faculty at a professional or educational conference or meeting
 - Compensation for the substantial professional or consulting services in connection with a genuine research project

VERMONT

- Requires annual disclosure of certain payments to HCPs and institutions:
 - The “value, nature and purpose of any free gift, fee, payment subsidy, or other economic benefit provided in connection with detailing, promotional or other marketing activities”
- What must be disclosed?
 - Fair market value of the payment
 - Description of the nature of the economic benefit (e.g., cash, meal, travel, etc.)
 - Purpose of the payment, including a description of the marketing activity and the drug(s) associated with the payment
 - Name and state license number of the recipient
- Penalty of \$10,000 per violation for failure to comply

VERMONT

- Certain payments are exempt from disclosure:
 - Drug samples
 - Compensation and reimbursement of expenses in connection with clinical trials
 - Any gift, fee, payment, subsidy or other economic benefit the value of which is less than \$25
 - Scholarships for medical students to attend educational conferences if the recipient of the scholarship is selected by the sponsoring medical or professional association
 - Prescription drug rebates and discounts

WEST VIRGINIA

- Requires annual reporting of certain marketing and advertising expenses:
 - “Advertising costs for prescription drugs, based on aggregate national data, must be reported to the state council by all manufacturers and labelers of prescription drugs dispensed in this state that employs, directs or utilizes marketing representatives”
- The following must be disclosed:
 - Total number of HCPs in WV provided gifts, grants, or payments of any kind over \$100.00
 - Rx drugs advertised by DTC advertising reaching/targeting WV
 - Type of advertising used
 - Total amount spent on DTC for each drug
 - Name of any disease-specific patient support or advocacy group operating in WV provided gifts, grants or payments of any kind totaling \$10,000 or more
 - Total amount contributed to each group
 - Name of any pharmacy licensed in WV provided gifts, grants or payments of any kind totaling \$10,000 or more
 - Total amount contributed to each pharmacy

WEST VIRGINIA

- Certain payments are exempt from disclosure:
 - Free drug samples
 - Compensation and reimbursement of expenses for a bona fide clinical trial
 - Scholarships for medical students to attend educational conferences if the recipient of the scholarship is selected by the sponsoring medical or professional association

KEY CONSIDERATIONS

- Definition of “pharmaceutical” or “medical device” manufacturer
- Definition of “drug” and “device”
- Definition of “HCP”
- Definition of “sales” and/or “marketing”



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Appendix

CALIFORNIA

- Requires pharmaceutical manufacturers to adopt a comprehensive compliance program
 - Must be consistent with the OIG Voluntary Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals
- Annual written certification of compliance with the compliance program and California requirements
- Pharmaceutical manufacturers must post the compliance program and annual certification on its website and provide a toll-free telephone number for obtaining written copies

CALIFORNIA

- Compliance program must include a limit on gifts and other payments provided to HCPs
 - Limit is set by each pharmaceutical manufacturer
 - Must be consistent with OIG Guidance and the PhRMA Code
 - Actual payment amounts are not reported
- Certain payments are not included in the limit so long as the payments comply with OIG Guidance and the PhRMA Code:
 - Drug samples
 - Financial support for CME programs
 - Financial support for health education scholarships
 - Legitimate fair market value (“FMV”) payments for consulting and other professional services

DISTRICT OF COLUMBIA

- Title III of DC Act 17-282 (2008) prohibits pharmaceutical companies from offering a gift or remuneration of any kind to a member of a medication advisory committee
- Fine of up to \$1,000 per violation

NEVADA

- Manufacturers must:
 - Adopt a written marketing code of conduct
 - Adopt a training program for employees on the code of conduct
 - Conduct annual audits of the company's compliance with its code of conduct
 - Appoint a Compliance Officer to oversee the compliance program
 - Implement policies and procedures for the investigation of reports of non-compliance with the code
 - Submit an annual report and certification to the Board of Pharmacy