



Karmen Hanson, MA
Senior Policy Specialist
National Conference of State Legislatures

The New California State Law and Other State Laws Targeting Pharmaceutical Sales and Marketing Audioconference

-Recent State Legislation-

- 35+ states & DC have proposed bills since 2001
- 5+ states & DC have adopted 8 laws since 1993
- Bills have increased since 2001
- 48+ new bills for 05 sessions



History of "Disclosure" Legislation

- In 1997, FDA clarified the Rx marketing guidelines, allowing for DTCA in broadcast media
 - some may or may not correlate this action to increases in Rx spending and use of advertised Rx
- NCSL's broad definition of "disclosure" laws include: reporting gifts to Dr. over \$X, honorariums, advertising and marketing expenditures within the state or per Rx, reporting/restricting DTCA, posting drug prices, Rx warnings, any time "sensitive" data may be publicly disclosed and/or otherwise requested by the state.

Recent Legislative History

- 62+ "disclosure" bills in 25+ states and DC during 2003-2004 biennium
 - 5 became laws: CA, DC, ME, VT, WV
- 31+ bills in 13+ states and DC during 2001-2002 biennium
 - 2 became laws: VT, WV
- Few bills prior to 2000
- At least 48 drafts filed as of 4/27/05 for 2005 sessions
- CA (04), ME (03), VT (02, 04) , WV (01, 04) MN (93)
 - All have laws or resolutions affecting Rx marketing

One of the first: MN Law 151.461 (1993)

- It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:
- (1) professional samples of a drug provided to a prescriber for free distribution to patients;
- (2) items with a total combined retail value, in any calendar year, of not more than \$50;
- (3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;
- (4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
- (5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;
- (6) publications and educational materials; or
- (7) salaries or other benefits paid to employees.

Examples of Laws

- CA (SB 1765 of 2004), effective 7/1/05
 - Requires Rx and device companies to:
 - make policies on interactions with health care professionals
 - have limits on gifts and incentives to professionals
 - establish explicitly specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give/provide to a professional, with certain exemptions
 - require a pharmaceutical company to annually declare, in writing, compliance with the Comprehensive Compliance Program and the bill, and make its Comprehensive Compliance Program and written acknowledgment of compliance available to the public on its Web site, and provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written declaration of compliance may be obtained.
 - bill in 2005 to exclude device manufacturers pulled.

DC Law

■ B15-567 of 2004

- Among other things, requires disclosure and reporting of Rx marketing costs by manufacturers, "enabling the District to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services, and furthering the role of the District as guardian of the public interest."

ME Law

■ LD 254/ H 209 of 2003

- Requires full disclosure of Rx marketing costs. (provides the value, nature, purpose and recipient of most expenses)
- A. All advertising expenses.
- B. With regard to all persons and entities licensed to provide health care in this State, the cost of...
 - (1) educational or informational programs
 - (2) food, entertainment, gifts valued at more than \$25;
 - (3) trips and travel; and
 - (4) product samples, except for free patient samples
- C. The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed above, including all forms of payment to those employees within the state
- **Exceptions.** Expenses of \$25 or less; Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment; and Scholarships and reimbursement of expenses for attending a significant educational, scientific or policy-making conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

Vermont Laws

■ VT H 768 of 2004

- (Sec 128b) pharmaceutical marketers are required to disclose prescription drug "AWP" prices to health care professionals, and report gifts and marketing expenditures to the Attorney General

■ VT H 31 of 2002

- Disclosure of gifts and cash payments to doctors- Annually on or before January 1 of each year, every Rx manufacturing company shall disclose to the Vermont board of pharmacy 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, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state.

West Virginia Laws

- WV HB 4084 of 2004
 - Requires reporting of Rx advertising costs
- WV SB 127 of 2001
 - The agency may explore "requiring prescription drug manufacturers to disclose to the state expenditures for advertising, marketing and promotion, as well as for provider incentives and research and development efforts."

2005 Legislation Examples

As reported at: www.ncsl.org/programs/health/rxads.htm

- AR HB 2970
 - Would require disclosure of Rx marketing practices. (*Section pertaining to the marketing of Rx was stricken in amendments.*)
- CA AB 95
 - Would establish Rx manufacturers to pay Medi-Cal or AIDS DPAP a rebate equal to the costs of marketing the chronic condition drugs they promote, and also disclose the costs of marking the drugs to consumers and physicians.
- CA AB 1187
 - Would require every Rx company to adopt a Comprehensive Compliance Program that includes policies related to interactions with health care professionals and limits on gifts or incentives provided to medical professionals.
- CT HB 6183
 - Would require public disclosure of gifts by Rx companies to physicians.
- FL SB 464
 - Requirements and criteria to disclose to the commission expenditures for advertising, marketing, and promotion, based on aggregate national data; not including clinical trial, free sample, or educational material costs.
- HI HB 41 / SB 1440
 - Would require marketing disclosure by Rx manufacturers.

2005 Legislation Examples cont.

- HI HB 32
 - Reporting of gifts over \$25 to persons who prescribe, dispense, or purchase Rx.
- IL HB 656
 - Rx Drug Ethical Marketing Act: would require every Rx manufacturer and labeler that sells in the State to disclose the value, nature, and purpose of any gift, fee, payment, subsidy, or other \$ benefit provided in connection with detailing or promotional or other marketing activities by the company, directly or through its marketers, to any person authorized to prescribe or dispense Rx.
- IA HB 503
 - Would prohibit a Rx marketer from offering or providing to any "practitioner" any gift not otherwise exempt under the bill. Would specify the gifts exempt from the prohibition and direct Rx manufacturing companies on an annual basis to disclose gifts made to the board.
- ME LR 1702/ LD 1541
 - Would limit the pricing information that a manufacturer must report to the Department of Health and Human Services to average manufacturer price and best price as defined by federal law. It eliminates the instructions on calculating other Rx pricing information and the requirement to describe the methodology for calculating pricing information that is reported to the department.

2005 Legislation Examples cont.

- ME LR 1703/ LD 1539
 - Would delay implementation of the deadline for filing reports regarding marketing activities by Rx manufacturers. Would also clarify that the Department of Health and Human Services may disclose that information to an entity that provides services to the department under the laws requiring those reports, but specifies that such disclosure does not change the confidential status of the information.
- ME LD 225
 - Would require registration and continuing education of Rx sales reps or "detailers."
- MA HB 2659
 - Would require disclosure of certain gifts made by Rx companies to persons authorized to prescribe or dispense Rx.
- MA SD 1137
 - Pharmaceuticals, Fraudulent Marketing practices.
- MT HB 532 / HB 563
 - Would require a Rx manufacturer to disclose all of the business costs of advertising the Rx as a % of the total revenue derived from the sale of the Rx in the state.
 - Would require Rx manufactures to disclose gifts over \$25, not including grants for education, clinical trials, or other related research.

2005 Legislation Examples cont.

- MS SB 2669
 - Requirement to disclose gifts, fees, payments or other economic benefit provided to health care providers for promo/marketing activities.
- NV AB 66
 - Would require reporting of certain gifts or other economic benefits provided by wholesalers or manufactures regulated by State Board of Pharmacy.
- NH SB 211 & HB 703
 - Would require pharmaceutical manufacturing companies to disclose to the secretary of state 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, directly or through its pharmaceutical marketers, to any prescriber in the state, or those who dispense or purchase prescription drugs.
 - Would clarify advertisements for prescription drugs. Would also require pharmaceutical manufacturers to disclose certain information on gifts to doctors.
- NM SB 824
 - Would require pharmaceutical manufacturers to report any gift or item pf value given to a doctor over \$25.

2005 Legislation Examples cont.

- NY AB 1027
 - Would prohibit Rx manufacturers and distributors from deducting the costs of advertising drugs to consumers from their personal or corporate income taxes.
- NY AB 2769 & SB 3695
 - Would require manufacturers and labelers of Rx dispensed in this state which engage in marketing activities to annually report marketing expenses to the DOH.
- NY AB 3056
 - Would subject manufacturers of Rx or medical devices who engage in direct-to-consumer-advertising to civil liability where adequate warnings are not provided.
- NY AB 4406
 - Would require manufacturers engaging in direct-to-consumer advertising of Rx to clearly state the primary function of the prescription drug in such advertisement.
- NY AB 4415
 - Would require marketing costs for Rx to be reported to the DOH for the purpose of assisting the state in its role as a purchaser of Rx and an administrator of Rx programs.

2005 Legislation Examples cont.

- NY SB 696
 - Would require Rx manufacturers and wholesalers to annually report to the NY Dept. of Health, for disclosure to the general public, all of its gifts to health care practitioners that prescribe Rx when such gifts have a certain value.
- NY SB 1909
 - Would require manufacturers engaging in direct to consumer advertising of Rx to clearly state the primary function of the Rx in such advertisement.
- NY SB 2258
 - Would require the Commissioner of Rx to conduct a cost benefit analysis of Rx advertising and promotional activities associated with the provision of Rx to citizens in the state.
- OH HB 112
 - Would require Rx manufacturers and labelers to disclose to the state the value, nature, and purpose of certain gifts, fees, payments, subsidies, and other economic benefits they provide in connection with Rx detailing, marketing, or promotion.
- OK HB 1542 / SB 896 / HB 1673
 - Would require the exploration of reporting of certain advertising, promotion and marketing costs by Rx manufacturers.

2005 Legislation Examples cont.

- OR HB 2817
 - Would require Rx manufacturing companies to disclose certain economic benefits provided in conjunction with marketing of Rx, including imposition of civil penalty for failure to disclose.
- PA HB 613
 - Would regulate pharmacies, manufacturers and wholesalers that advertise for sale or sell Rx or devices via the Internet. Provides for powers and duties of the Office of Attorney General.
- PA HR 114
 - Concurrent Resolution would direct the Health Care Cost Containment Council to conduct a study on the impact of Rx advertising and promotion on Rx prices in the state.
- PA SB 320/321
 - Would provide for annual expense reports and for disclosure by Rx marketers.
- RI HB 6141
 - Would require disclosure from manufacturers of Rx regarding gifts given to persons authorized to prescribe and dispense Rx.

2005 Legislation Examples cont.

- TN HB 1093 / SB 1111
 - Would require the commissioner of commerce and insurance to conduct a study of the effects of Rx advertising in the state.
- VT HB 225 / SB 93
 - Would prohibit the advertising of Rx in broadcast media.
- WA HB 1889/ SB 5149
 - Would require the disclosure of gifts made by Rx manufacturers to persons who prescribe Rx.
- WY SF 124
 - Would prohibit payment in exchange for prescribing or recommending Rx and non-Rx medication, medical devices and medical equipment; prohibit receipt of gifts from sellers of Rx and non-Rx medication, medical devices and medical equipment; providing for penalties.

Diverse Approaches

- Legislation varies by:
 - Reporting requirements
 - Some are stand alone requests, others combined with other bills and/or Rx programs
 - Some do/not use the reported information for other reasons

Future Issues?

- Like most Rx issues, this is a constantly moving target
- Check the NCSL Rx page for the latest bill status and information

www.ncsl.org/programs/health/pharm.htm