



Karmen Hanson, MA  
Policy Specialist  
National Conference of State Legislatures

## New State Laws on Promotional Spending Limits, PhRMA Code, and Price Disclosures

### Recent State Legislation

- 25+ states & DC have proposed bills since 2001
- 5+ states & DC have adopted 8 laws since 1993
- Bills have increased since 2001
- 7+ new drafts 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 7 drafts filed as of 1/21/05 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 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.

## 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

- 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 marketing the drugs to consumers and 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."
- MA SD 1137
  - "Pharmaceuticals, Fraudulent Marketing"
- MT Draft 1422
  - "Pharmaceutical Market Reform"
- MS SB 2669
  - "Requirement to disclose gifts, fees, payments or other economic benefit provided to health care providers for promo/marketing activities."
- NH LSR 972 & NH H 0282 R
  - "Relative to pharmaceutical marketers"
  - "Relative to advertisement of prescription drugs and establishing the pharmaceutical marketing disclosure law"

## 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](http://www.ncsl.org/programs/health/pharm.htm)