

States Won't Wait for Feds

The nightmare's coming true—state mandates for costs disclosure are real.

In 2002 it was the PhRMA Code, in 2003 it was the OIG's Guidance for Industry, and in 2004 it was Justice Department enforcement. Now, in 2005, it appears that regulation of the US pharma industry has a new focal point—state legislatures.

Rising costs and shifting public opinion appear to be driving states to take regulation into their own hands rather than wait for movement at the Federal level. The charts on this page summa-

size a sampling of current state laws affecting pharma marketing and sales and describes similar bills being considered in 18 states. States appear to be focused on two areas: codifying existing guidance, such as the OIG Guidance for Industry and the PhRMA Code, and requiring the disclosure of pharmaceutical marketing expenditures.

These laws and pending bills are in a state of constant change; what appears to be on the books today might be completely different tomorrow. So pharma companies should keep close and frequent watch over the developments and waste no time in preparing for the onslaught of requirements to come. ■

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Current Laws

STATE/DISTRICT	DESCRIPTION	COMPLY WITH OIG GUIDELINES	COMPLY W/PHRMA CODE	DISCLOSE AWP WHEN MARKETING	DISCLOSE MARKETING COSTS	GIFT LIMITATIONS	REQUIRED ANNUAL REPORTING	EFFECTIVE DATE
California	Act requires implementation of compliance program and gift limits	✓	✓			✓	✓	July 1, 2005
District of Columbia	Act requires annual disclosure of marketing costs				✓		✓	July 1, 2004
Maine	Act requires annual disclosure of marketing costs				✓		✓	July 1, 2004
Minnesota	Act prohibits certain gifts to physicians					✓		1993
Vermont	Acts require annual disclosure of marketing costs and average wholesale price when marketing			✓	✓		✓	2002 (Mktg.) 2005 (AWP)
West Virginia	Act requires annual disclosure of marketing costs				✓		✓	March 13, 2004

Details on Marketing Disclosure Requirements

STATE/DISTRICT	DTC ADVERTISING COSTS						PURCHASER & PHYSICIAN EXPENSES				AGGREGATE COST OF SALES AND MARKETING EMPLOYEES & CONTRACTORS
	RADIO	TELEVISION	MAGAZINES	NEWSPAPER	TELEPHONE	DIRECT MAIL	EDUCATIONAL	FOOD, GIFTS & ENT.	TRIPS & TRAVEL	SAMPLES	
District of Columbia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Maine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vermont							✓	✓	✓		
West Virginia	✓	✓	✓	✓	✓	✓					

SOURCE: Polaris Management Partners, 2005.

Bills Pending in State Legislatures

State DATE INTRODUCED » Area of Impact

California JANUARY 05 » Disclosure of marketing costs

Connecticut JANUARY 05 » Disclosure of gifts to physicians over \$10

Florida JANUARY 05 » Disclosure of marketing costs

Hawaii JANUARY 05 » Disclosure of gifts to physicians over \$25
JANUARY 05 » Establishment of Pharmaceutical Cost Management Council

Illinois JANUARY 05 » Prescription Drug Ethical Marketing Act

Maine JANUARY 05 » Act to Regulate Pharmaceutical Detailers

Massachusetts JANUARY 05 » Fraudulent marketing

Michigan JANUARY 05 » Ban gifts to prescribers

Montana JANUARY 05 » Pharmaceutical market reform
JANUARY 05 » Pharmaceutical Advertising Act

New Hampshire JANUARY 05 » Disclosure of marketing costs

New Jersey JANUARY 05 » Disclosure of marketing costs

New York JANUARY 05 » Disclosure of marketing costs
FEBRUARY 05 » Bill requiring marketing costs for prescription drugs be reported to the Department of Health

FEBRUARY 05 » Pharmaceutical Drug Manufacturer and Wholesale Disclosure Act, including disclosure of gifts to health-care providers valued over \$75
FEBRUARY 05 » Bill requiring a cost/benefit analysis of pharmaceutical advertising and promotional expenses

Ohio SEPTEMBER 03 » Disclosure of marketing costs

Oklahoma FEBRUARY 05 » Bill proposing Oklahoma Pharmaceutical Availability and Affordability Act, including possible disclosure of marketing costs

Oregon JANUARY 05 » Disclosure of clinical trials

Washington JANUARY 05 » Disclosure of gifts to prescribers