



# **3rd Annual Summit on Disclosure, Transparency and Aggregate Spend**

## **Introduction to Marketing and Disclosure Laws for Pharmaceutical, Biotechnology and Medical Device Manufacturers**

Preconference  
March 9, 2011

Sarah K. Giesting

**EPSTEINBECKERGREEN**

# TOP 10 THINGS TO KNOW ABOUT STATE MARKETING & DISCLOSURE LAWS

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1

Currently there are 11 state laws that relate to marketing and/or disclosure for pharmaceutical and medical device companies

- California, Colorado, Connecticut, District of Columbia (2 laws), Maine, Massachusetts, Minnesota, Nevada, Vermont, West Virginia

2

Of the 11 current state laws, all are applicable to drug companies and 6 are applicable to medical device companies

- The definition of “manufacturer” varies for each state law
- Some state laws, such as Nevada, have a very broad definition of “manufacturer”
  - OTC products, veterinary products, chemicals, appliances

# TOP 10 THINGS TO KNOW ABOUT STATE MARKETING & DISCLOSURE LAWS

3

Two state laws, California and Connecticut, require companies to adopt a corporate compliance programs

- OIG Voluntary Guidance, industry codes

4

Four state laws -- Connecticut, DC, Massachusetts and Nevada -- require manufacturers to adopt a corporate compliance programs

- CT, NV - industry codes
- DC, Mass. – codes developed by regulatory agency
- Policies, procedures, training, auditing and monitoring

5

Five state laws -- California, DC, Massachusetts, Minnesota and Vermont -- impose limits on “gifts” and other items that can be provided to HCPs

# TOP 10 THINGS TO KNOW ABOUT STATE MARKETING & DISCLOSURE LAWS

6

Six state laws -- DC, Maine, Massachusetts, Minnesota and Vermont -- require manufacturers to file an annual report with the state regarding gifts and other items provided to HCPs

- Reporting requirements vary by state, but examples of items that companies may need to report include:
  - Compensation for speaking, consulting, research
  - Grants for CME, third-party meetings, research, studies
  - Food, articles, journals, educational items
  - Charitable donations
  - DTC advertising expenses
  - Product samples

7

Nine state laws require companies to file annual reports and/or annual certifications of compliance

# TOP 10 THINGS TO KNOW ABOUT STATE MARKETING & DISCLOSURE LAWS

8

The definition of “health care professional” varies by state, but may include MDs, DOs, NPs, PAs, RNs, pharmacists, hospitals, nursing homes, dentists and others

9

Additional requirements likely

- New state laws
- Updates to current state laws

10

It does not appear that any current state law will be preempted in whole by Federal legislation

- Preemption analysis and challenges

# OVERVIEW OF FEDERAL AND STATE MARKETING AND DISCLOSURE LAWS

	Applicable to Drug Companies	Applicable to Device Companies	Compliance Program	Code of Conduct/ Ethics	"Gift" Limits	Annual Report	Annual Certification
Federal	X	X				X	
California	X	X	X		X		X
Colorado	X	X				X	
Connecticut	X	X	X	X			
DC (2 laws)	X			X	X	X	X
Maine	X					X	
Mass.	X	X		X	X	X	X
Minnesota	X				X	X	
Nevada	X	X		X			X
Vermont	X	X			X	X	
West Virginia	X					X	



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