



# National Disclosure Summit

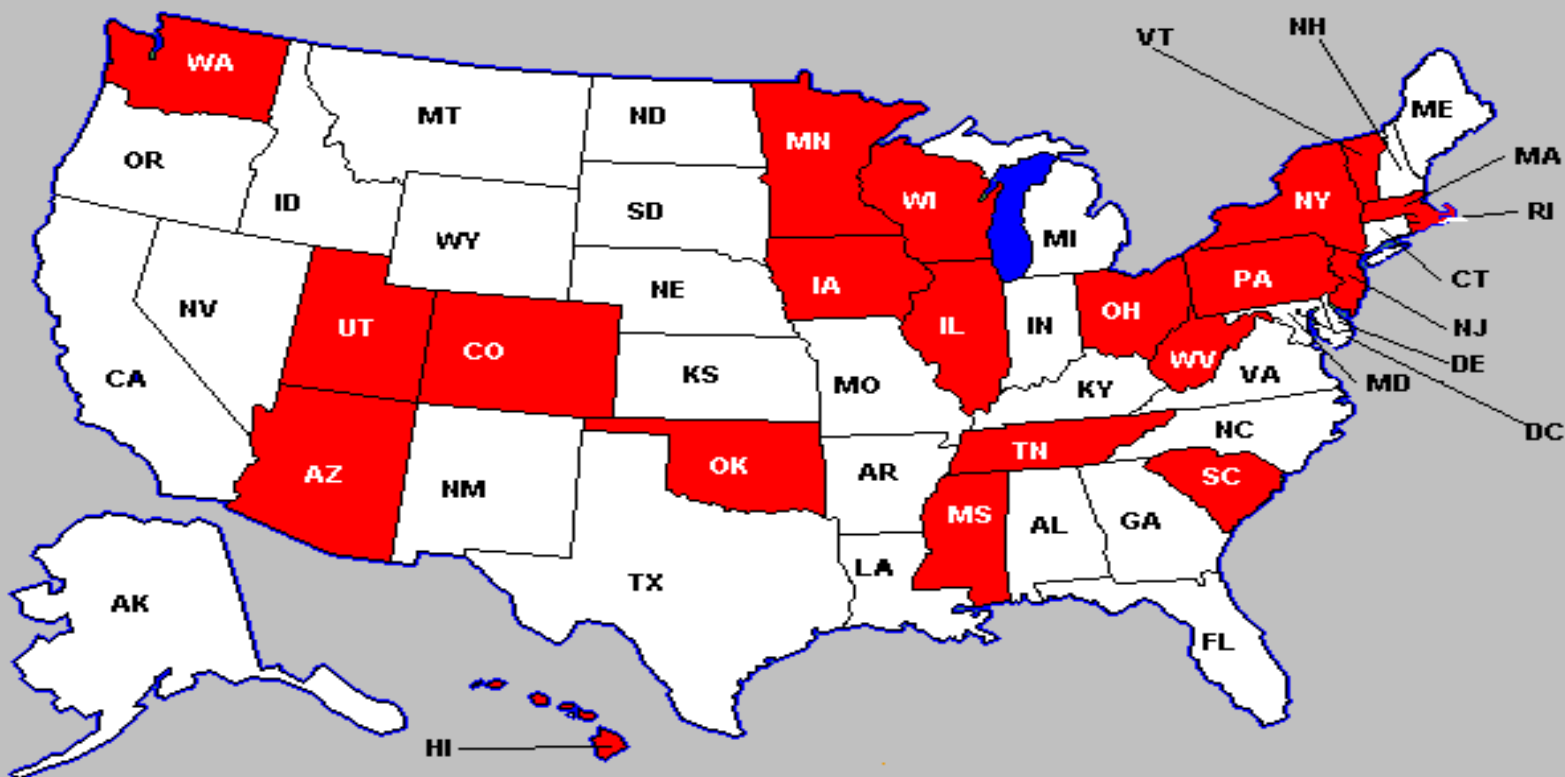
*Presented By:*

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# States that have introduced legislation during 2010 Legislative Session



Legislation is pending in one or more of the following areas:

- ❖ Drug Pricing
- ❖ Marketing Disclosures/Limitations
- ❖ Prescriber Data
- ❖ Clinical Trial Disclosure/Registration

# Federal Disclosure Legislation

**America's Affordable Health Choices Act of 2009**

**H.R. 3962, 111<sup>th</sup> Cong. (2009)**

**Patient Protection and Affordable Care Act of 2009**

**H.R. 3590, 111<sup>th</sup> Cong. (2009)**



# Threshold for Reporting

❖ **Transfers less than the reporting threshold are not subject to reporting.**

## **H.R. 3962**

**Any transfer of anything of value that does not exceed \$5.**

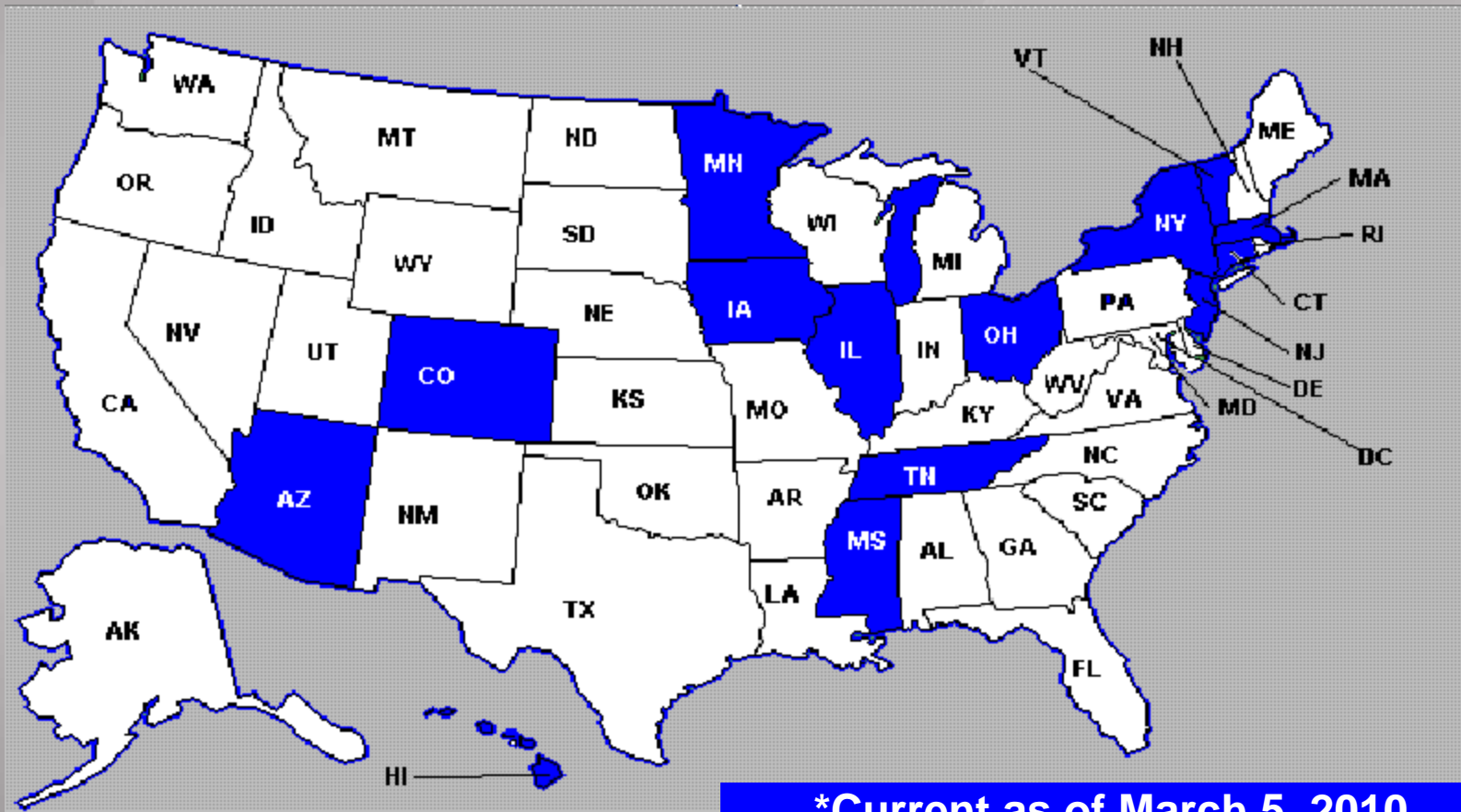
## **H.R. 3590**

**Any transfer of anything of value that is less than \$10, unless the aggregate amount transferred to a covered recipient exceeds \$100 for the calendar year.**

# Recipients Triggering Disclosure

	H.R 3962	H.R. 3590
Physician	X	X
Physician Medical Practice	N/A	N/A
Other Prescriber	X	N/A
Pharmacy or Pharmacist	X	N/A
Pharmacy Benefit Manager	X	N/A
Hospital	X	X *
Medical School	X	N/A
Sponsor of CME program	X	N/A
Patient Advocacy or Disease Specific Group	X	N/A
Organization of Healthcare Professionals	X	N/A
Physician Group Practice	X	N/A
Health Insurance Issuer, Group Health Plan, Entity offering Health Benefits Plan	X	N/A
Biomedical Researcher	X	N/A
Group Purchasing Organization	X	N/A
* Teaching Hospital		

# States with Pending Marketing Disclosure and/or Limitation Legislation



# State Disclosure Laws: Vermont

## SAMPLES

- ❖ Free samples of prescription drugs (both chemical compounds and biologics) need not be reported
- ❖ Free samples of medical devices and combination medical devices and prescription drugs must be reported

# Recipients Triggering Disclosure

	DC	ME	MA	MN	VT	WV
Physician	✓	✓	✓	✓	✓	✓
Other Prescriber	✓	✓	✓	✓	✓	✓
Pharmacist	✓	✓	✓		✓	*
Hospital/ Clinic	✓	✓	✓		✓	

\* **"pharmacist"** (pursuant to West Virginia's emergency Rule) does not trigger disclosure, but the licensed "pharmacy" does

# State Law: Disclosures & Limitations Law Overview

	DC	ME	MA	MN	VT	WV
<b>Reporting Fees</b>						
<b>Filing Fees</b>	<b>\$2,500</b>	<b>\$1,000</b>	<b>\$2,000</b>	<b>None</b>	<b>\$500</b>	<b>None</b>
<b>Types of Payments Reported</b>						
<b>Educational Program</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
<b>Food</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<b>Travel</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<b>Consulting Fees</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<b>Gifs</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<b>Advertising / Marketing Cost</b>	<b>X</b>	<b>X</b>	<b>X</b>			<b>X</b>
<b>Clinical Trials / Bona Fide Research Payments</b>				<b>X</b>		
<b>Compensation &amp; Benefits for Employees / Contractors engaged in promotion</b>	<b>X</b>	<b>X</b>				
<b>Reporting Threshold</b>						
<b>Payment Over</b>	<b>\$25</b>	<b>\$25</b>	<b>\$50</b>	<b>\$100</b>	<b>\$0</b>	<b>\$100</b>

# Lobbying: Connecticut

*New Lobbying Advisory Opinion: dated February 26, 2009*

The Connecticut Citizen Advisory Board concluded that in communicating with members of the **P&T Committee** to get a drug placed on the preferred-drug list, the **drug maker** is influencing administrative action.

*Therefore, the drug maker is “lobbying” unless, the communication falls under one of the statutory or regulatory exceptions.*

# Lobbying: Connecticut

- ❖ Pharmaceutical companies who communicate with members of the P & T committee to get drugs placed on the preferred drug list must register as a **“client lobbyist”**
- ❖ A pharmaceutical representative who is compensated by the pharmaceutical company may also be required to register as a **“communicator lobbyist”**
- ❖ Registration is required only if there are expenditures totaling or an agreement to spend \$2,000 or more on lobbying in a calendar year

## Reporting Deadline:

- ❖ Client lobbyists (Pharmaceutical Companies) must file financial reports on a **quarterly basis**
- ❖ Communicator lobbyists (Pharmaceutical Representatives) must file financial reports **annually**

# Lobbying: Louisiana

## *Revised Lobbying Law: effective January 1, 2009*

- ❖ Applies to drug company representatives who lobby any member of the **Medicaid Pharmaceutical and Therapeutics Committee** for inclusion of a product on the formulary
- ❖ Lobbyists are required to register “as soon as possible after employment as a lobbyist or after the first action requiring his registration as a lobbyist, whichever occurs first, and in any event not later than five days after employment as a lobbyist or not later than five days after the first action requiring his registration as a lobbyist, whichever occurs first.”
- ❖ Lobbyists must file disclosure reports detailing “expenditures,” including “**the gift or payment of money or anything of value for the purchase of food, drink, or refreshment.**”

As of January 1, 2009, lobbyists must file **electronic monthly** disclosure reports. The report for each month must be filed by the 25th day of the following month.

# Lobbying: Louisiana

## *Revised Lobbying Law: effective January 1, 2009*

- ❖ **Beginning on January 1, 2009, each lobbyist registered as an executive branch lobbyist is required to receive a minimum of one hour of education and training on the provisions in the Executive Branch Disclosure Act and the Code of Government Ethics.**
- ❖ **The law specifies that the training may be in person or via the Internet. The Board has scheduled both live and online seminars.**

A listing of training sessions is available at [www.ethics.state.la.us](http://www.ethics.state.la.us). According to the website, participation in one of the listed seminars will fulfill a lobbyist's mandatory training requirement.

# Lobbying: Louisiana

- ❖ Under Louisiana's Code of Governmental Ethics, a public employee or elected official is prohibited from accepting **anything of economic value** as a gift or gratuity.
- ❖ Public employees may also not accept food, drink or refreshment at a **single event** where the total value **exceeds \$50**.

**Note: The \$50 limitation on food, drink, and refreshment does not apply to gatherings held in conjunction with a meeting related to a national or regional organization or a meeting of a statewide organization of governmental officials or employees.**

# Lobbying: Kentucky

- ❖ The Executive Branch Ethics Commission issued an Advisory Opinion stating that any pharmaceutical manufacturer employee attempting to influence members of the T&P committee must register as a lobbyist.
- ❖ Drug company representatives and their employer must register as **“Executive Agency Lobbyists”** within 10 days of engaging in lobbying activity.
- ❖ Each lobbyist and its employer must file a statement annually disclosing the total amount of expenditures made during the reporting period.
- ❖ Reportable expenditures include, but are not limited to:
  - A payment, distribution, loan, advance, deposit;
  - Gift of money, real estate;
  - Food, beverages, entertainment, lodging, transportation; and
  - The purchase sale or gift of service or any other thing of value.

**Executive agency lobbyists must send a copy of the expenditure statement to each executive branch official or employee on whose behalf the expenditures were made at least ten days prior to the date the report is filed with the Kentucky Executive Branch Ethics Commission.**

# Lobbying: Miami-Dade County

- ❖ Register “within 5 business days of being retained as a lobbyist or **before engaging in any lobbying activities**, whichever shall come first.”
- ❖ Lobbyist shall be subject to fines of “\$50 per day” and may be suspended from lobbying if they fail to register as a lobbyist.
- ❖ Disclose “signed statement under oath” to Board of County Commissioners, listing all **lobbying expenditures exceeding \$25** for preceding calendar year.
- ❖ **Disclosure reports due on July 1<sup>st</sup> even if there have been no expenditures during the reporting period.**

## Expenditures may include:

- ❖ Food/beverages
- ❖ Research
- ❖ Entertainment
- ❖ Communication
- ❖ Travel and lodging
- ❖ Special events

# Questions/Comments



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