



# Overview

## *GLOBAL TRANSPARENCY & DISCLOSURE REQUIREMENTS*

*September 2011*

# Current Global Regulatory Trends



Type of Regulations/ Guidance	Company's obligations	Scope	Sanctions/ Penalties
State Laws	Promotional spend reporting and public disclosure	U.S.	Financial penalties
Federal Law (PPACA 6002)	Promotional spend reporting and public disclosure	U.S.	Financial penalties
ABPI (UK Pharma Assoc.)	Speaker, consultant, ad board fees reporting	UK	Self regulation
France Law Fall 2011	Spend data reporting and public disclosure	France	TBD
CGR/Netfarma (Dutch Pharma. Association)	Spend data reporting and public disclosure	Netherlands	Self regulation
JPMA (Japan Pharma Assoc.)	Spend data reporting and public disclosure	Japan	Self regulation
Australia (Medicines Australia Assoc.)	Spend data reporting and public disclosure	Australia	Self regulation
UK Bribery Act	Adequate anti-bribery preventive measures	Global	Financial penalties / civil and criminal prosecution
Foreign Corrupt Practices Act (FCPA)	Clean Books of records Anti-bribery measures	Global	Financial penalties / civil and criminal prosecution

# U.S. States

## Transparency, Disclosure, Compliance Program Laws



### Pending Legislation

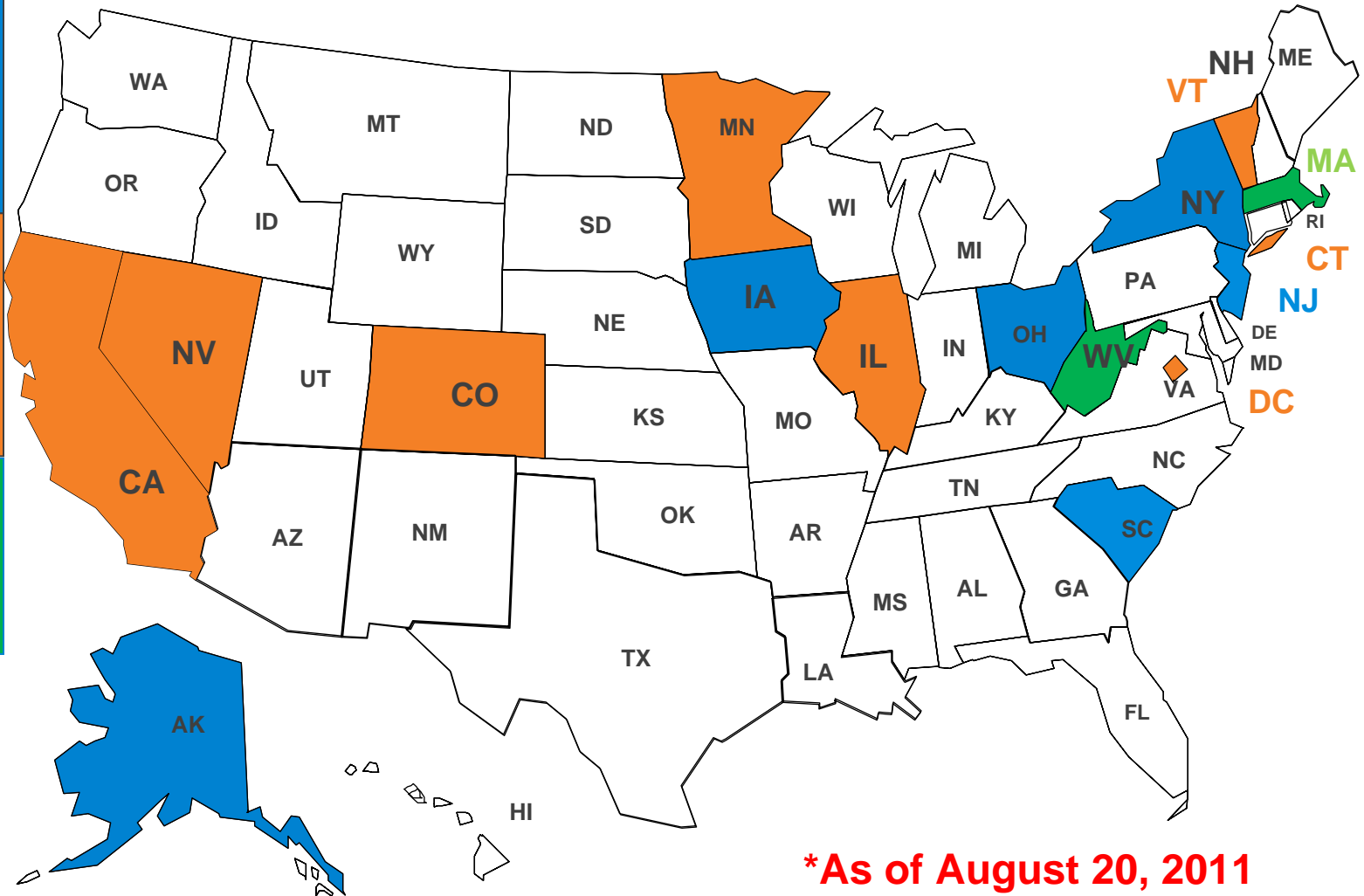
Alaska,  
Iowa,  
New Jersey,  
New York,  
Ohio &  
South Carolina,

### Enacted Legislation

California, Colorado,  
Connecticut  
District of Columbia,  
Illinois  
Minnesota,  
Nevada,  
Vermont

### Enacted & Pending Legislation

Federal,  
Massachusetts,  
West Virginia



**\*As of August 20, 2011**



## → 8 States with Pending Legislation

## → 10 States with Enacted Legislation

- Compliance Program Requirements:
  - California
  - Connecticut
  - Nevada
- Disclosure Requirements:
  - Washington, DC
  - Illinois
  - Minnesota
  - Vermont
  - West Virginia
- Disclosure and Compliance Program Requirements:
  - Massachusetts

## → Disclosure requirements range from:

- Employee costs
- R & D expenses
- Sales / Marketing expenses
- Gifts
- Grants
- Honoraria
- Consulting
- Education
- Samples
- Etc.
  - Aggregated Totals and Individual Transactions

## → Annual Fees

## → Financial Penalties for non-compliance



## → Reporting to Federal Government (PPACA Section 6002)

- Individual Payments to Physicians and Teaching Institutions (Hospitals)
  - Consulting fees, honoraria
  - Gift, entertainment, food
  - Travel (including the specified destinations)
  - Education , research
  - Charitable contribution, grant
  - Royalty or license;
  - Current or prospective ownership or investment interest;
  - Direct compensation for serving as faculty or as a speaker for a medical education program

→ **\$10 & Greater or >\$100 in Total**

→ **2012 Data Reported in 2013**

→ **Final Report Template Not Provided Yet by Federal Government**

→ **Financial Penalties**

→ **Drug Samples Also Required to be Reported to Federal Government Starting in 2012 (PPACA Section 6004)**

# First European Disclosure Measure



## ABPI Transparency Reforms (UK)

- **Declaration of payments made by any affiliate , head office or third party to UK healthcare professionals and organisations**
  - Speaker fees
  - Advisory positions
  - Market research
  - Meeting sponsorship / travel / accommodation
  - Patient groups
- **First declaration to be made in March 2013 for 2012 payments**
  - Total amount plus number of recipients
  - ***Must collect spend at individual doctor level to create report***
- **Nominative market research declaration March 2014 for 2013 payments**

# Netherlands



- **Public Disclosure of all financial relationships under service and sponsorship contracts between pharmaceutical companies and physicians and organizations**
- **Must included nature and duration**
- **Starting with 2012 data to be reported Q1 2013**
- **Disclosure takes place from a total of €500, - per year.**
- **Final reporting format still unclear**



- **On August 1, 2011 the French Council of Ministers reviewed new health and safety draft legislation**
- Enforce transparency between **hospitals, patient associations, medical students, scientific societies**, the **media**, and medical device and pharmaceutical companies
  - Apply to all **health products**
  - Accelerated legislative procedure with Parliamentary votes scheduled before the 2012 elections. All reforms are scheduled to be enforced by **July 31, 2012**, although decrees will be necessary before implementation.





## → Key reforms include the following:

### ■ **Disclosures Related to Marketing, Health Professional Interactions**

Drug and device companies will be required to disclose all marketing efforts, services associated with products, and cash benefits made to health care professionals and institutions.

Furthermore, meetings of committees, advisory commissions, boards and bodies will be made public and recorded on the Ministry of Health website or through other media yet to be identified

- **Medical experts** will be required to publicly declare prior conflicts of interests before conducting appraisals as part of French committees



## JPMA

### → Spend Data Yearly Tracking

- Total Aggregated Payments for R&D
- Total Aggregated Payments for providing information to Congress / Meetings
- Total Aggregated Payments for Entertainment
- Research Funding & Grants, by Organization
- Manuscript writing fees & Consulting fees, By Individuals.

### → 2012 Data Reported in 2013

### → Doctor Review

### → Disclose on pharmaceutical companies web site after the financial year closing (no obligation to report to JPMA)



## → Disclosure Reporting to Medicines Australia

- 6-month Reporting Period
- Publically Available
- Educational Events Reports
  - Description of Event
  - Duration
  - Venue
  - Types of Professionals
  - Type of Hospitality Provided
  - Total Cost of Hospitality
  - Final Number of Attendees
  - Total Cost of Function

## → All Educational Events Must Abide by the Medicines Australia Code of Conduct

- The provision of gifts to doctors is banned. Entertainment is banned. The provision of lavish hospitality is banned

# Other Global Considerations



## → Reinforced anti-corruption regulations

- **FCPA** (US regulation – 1977) requires all companies to prevent bribery and keep **clean books of records**
- **UK Bribery Act** (new act – 2010) requires all companies to implement **adequate procedures** to prevent bribery globally

# Thank You



William 'Bill' Buzzeo  
VP/GM Global Compliance Solutions  
[william.buzzeo@cegedim.com](mailto:william.buzzeo@cegedim.com)