Strafford

presents

Physician Payments Under PPACA's Sunshine Provisions and State Law

Meeting the Challenges of Healthcare Reform's Reporting Requirements

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today's panel features:

Donald H. Romano, Partner, Moderator, **Arent Fox**, Washington, D.C.
Ann DesRuisseaux, Principal, **GlobalComplianceStrategies.com**, Dallas
Kathleen McDermott, Partner, **Morgan, Lewis & Bockius LLP**, Washington, D.C.

Wednesday, October 6, 2010

The conference begins at:

1 pm Eastern
12 pm Central
11 am Mountain
10 am Pacific

You can access the audio portion of the conference on the telephone or by using your computer's speakers.
Please refer to the dial in/ log in instructions emailed to registrants.

For CLE purposes, please let us know how many people are listening at your location by

- closing the notification box
- and typing in the chat box your company name and the number of attendees.
- Then click the blue icon beside the box to send.

For live event only.

- If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.
- If the sound quality is not satisfactory and you are listening via your computer speakers, please dial **1-866-871-8924** and enter your PIN when prompted. Otherwise, please send us a chat or e-mail sound@straffordpub.com immediately so we can address the problem.
- If you dialed in and have any difficulties during the call, press ***0** for assistance.

Morgan Lewis

Stafford's Physician Payments Under PPACA's Sunshine Provisions and State Law

Meeting the Challenges of Healthcare Reform's Reporting Requirements

October 6, 2010
1:00 – 2:30 pm EST

Premise

- Financial conflict of interest in the health industry collaborations, arrangements and services must be managed or eliminated.
- Transparency and disclosure of financial interests are key ingredients to conflict of interest management.
- Trend from self-regulation (Codes of Ethics) to government regulations (U.S. Sunshine Provisions) have become a global trend.

Discussion Agenda

- Transparency Trends
- Self-Regulation via Codes of Ethics v. Mandated Legal Requirements
- Protection of confidential commercial Information and data privacy?
- Impact of anti-bribery enforcement on transparency and conflict of interest management.
- Strategy to reconcile corporate policies, multiple codes of ethics, mandated transparency terms with technology capability, audit process, Information retrieval, and reporting.

U.S. Sunshine Provisions - History

- In 2007, Physician Payment Sunshine Act of 2007 (S.2029) introduced by Senators Grassley and Kohl.
- Senators Grassley and Kohl conducted investigations that revealed potential conflicts of interest in the relationships between physicians and drug and device manufacturers.
- In 2009, the Senators reintroduced the Physician Payment Sunshine Act (S.301).
- The proposed Act was incorporated into both the Senate health reform bill (America's Healthy Future Act of 2009, S.1796, section 4101) and the House-passed health reform bill (Affordable Health Care for America Act, HR.3962, section 1451).

U.S. Sunshine Provisions – Reporting requirement

- Who must report: "Applicable Manufacturer"
  - Manufacturer of a covered drug, device, biological, or medical supply, that is operating in the US
  - "Covered" means for which payment is available under Medicare, Medicaid, SCHIP (or a waiver of such a plan).
- Where to Report: Secretary of HHS
- When to Report:
  - First report due March 31, 2013 for transactions in 2012!
  - 90th day of each calendar year thereafter.
- Secretary to establish procedures for reporting by 10/11. Watch for opportunity to comment to HHS rule-making on transparency implementation.

U.S. Sunshine Provisions – Reporting Requirement

- What to Report: Payments or other transfer of value made in preceding year to "covered recipients."
- Covered Recipients:
  - Covered Physicians defined under SSA (except employee of manu.) and
  - teaching hospitals.
- Includes entity/individual at request or on behalf of covered recipient
- Except if made indirectly through a third, if the applicable manufacturer is unaware of the identity of the covered recipient.

U.S. Sunshine Provisions- Reportable Information

- Name and business address of the **covered recipient** (and specialty and NPI, if the covered recipient is a physician);
- Amount of the **payment or other transfer of value;**
- Dates on which the **payment or other transfer of value** was provided;
- Description of the form of the **payment or other transfer of value**, indicated as:
  - Cash or cash equivalent
  - In kind items or services
  - Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment
  - Any other form of **payment or other transfer of value**;

6. Name of covered drug, device, biological, or medical supply, if applicable; and
7. Any other information as the Secretary may determine appropriate.

U.S. Sunshine Provisions- Core Reportable Activities

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as a faculty or as a speaker for a CME program
- Grant
- **Any other payment or transfer of value. List is not exclusive.**

U.S. Sunshine Provisions- Reporting Exclusions

- A transfer of anything the value of which is less than $10, unless the aggregate amount to a **covered recipient** during a calendar year exceeds $100. For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a **covered device** for a short-term trial period, not to exceed 90 days, to permit evaluation of the **covered device** by the **covered recipient**.
- Items or services provided under a contractual warranty, including the replacement, if the terms of the warranty are set forth in the agreement.
- A transfer of anything of value to a **covered recipient** when the **covered recipient** is a patient and not acting in the professional capacity of a **covered recipient**.

U.S. Sunshine Provisions- Reporting Exclusions

- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.
- In the case of an **applicable manufacturer** who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a **covered recipient** who is a licensed non-medical professional, a transfer of anything of value to the **covered recipient** if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.
- In the case of a **covered recipient** who is a physician, a transfer of anything of value to the **covered recipient** if the transfer is payment solely for the services of the **covered recipient** with respect to a civil or criminal action or an administrative proceeding.

Samples

- Although there is an exclusion from the reporting requirements for samples, there is a separate reporting requirement under Sec. 6004.
- Requires manufacturers and authorized distributors of record to submit to the Secretary by April 1 of each year (beginning with 2012) a report of the identity and quantity of drug samples requested and distributed, aggregated by the practitioner making the request.

U.S. Sunshine Provisions- Confidential Information

- Confidential Commercial Information has limited protection. In the case of information submitted with respect to a **payment or other transfer of value** made pursuant to a product research or development agreement for services furnished in connection with the development of a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply or in connection with a **clinical investigation** regarding a new drug, device, biological, or medical supply, such information shall be made available to the public on the first publication date after the earlier of the following:
  - The date of the approval or clearance of the **covered drug, device, biological, or medical supply** by the FDA; or
  - Four calendar years after the date such **payment or other transfer of value** was made.

U.S. Sunshine Provisions- Limited Pre-emption Protection

- Effective **January 1, 2012**, these transparency provisions will preempt any law or regulation of a state that requires an **applicable manufacturer** to disclose or report the type of information reported hereunder for **payments or other transfers of value** provided by the **applicable manufacturer** to a **covered recipient**.
- **EXCEPTION**: These transparency provisions do not preempt any law or regulation of a state that requires the disclosure or reporting of information -
  - that is not required to be disclosed by these transparency provisions;
  - by any person or entity other than an **applicable manufacturer** or **covered recipient**; or
  - to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.
- The state preemption provisions are not to be construed to limit the discovery or admissibility of information in a criminal, civil, or administrative proceeding.

U.S. Sunshine Provisions- Other Reporting Limitations

- Reporting obligation does not extend to global operations by its terms. Manufacturers and GPOs covered under the statute are those with U.S. based operations: in the United States or its territory, possession or commonwealth .
- A transfer of anything of value does not include a transfer of anything of value that is made indirectly to a **covered recipient** through a third party in connection with an activity or service in the case where the **applicable manufacturer** is unaware of the identity of the **covered recipient**.

U.S. Sunshine Provisions- Penalties

- Failure to submit the required information may result in a CMP of not less than $1,000, but not more than $10,000 for each payment or other transfer of not reported.
- The total amount of CMPs imposed with respect to each annual submission shall not exceed $150,000.
- A knowing failure to submit the required information may result in a CMP of not less than $10,000 but not more than $100,000 for each payment or other transfer of value not reported.
- The total amount of CMPs imposed for knowing failures to report with respect to each annual submission shall not exceed $1,000,000.

U.S. Transparency Requirements

- Federal and State Legislation Focused on specific industry sectors: drugs, device, biologics and medical supply.
- Health reform create new obligations PBMs, GPOs, Nursing homes and hospitals related to financial conflict of interest.
- Government Investigations: DPAs and OIG CIAs. Government mandated sunshine terms as condition of resolving criminal and civil fraud allegations.
- Industry Voluntary Disclosure Practices. Global trend in disclosure.
- Hospital, Health Systems and Medical Societies Voluntary Disclosure Efforts. 2010 AAOS Disclosure Program.
- FCPA Enforcement.

Council of Medical Specialty Societies

- 32 medical societies/650,000 members (family doctors, pediatricians, neurologists, obstetricians, cardiologists, oncologists)
- Society to publish financial support from industry
- Publish financial ties between industry and leaders or board members
- Prohibits financial ties if:
  - journal editor
  - society officer (usually 4-5 year term)
- Decline industry support for developing medical practice guidelines
- Ban branded giveaways at conferences (pens, etc.)

Global Self-Regulation Initiatives

- EucoMed Transparency Principles. 2009.
- EMEA Transparency Policy. 2009 Draft.
- EFPIA Transparency Encouragement. 2009.
- ABPI Code of Practice. 2006.

- Note: Australian Competition and Consumer Comm'n. 2007. Example of Government Agency Regulation with Transparency References.

Global Transparency Challenges

- Transparency and Conflict of Interest Management is not limited to health industry. Major corporate responsibility initiative.
- Environment, Labor, Financial, Corporate Governance-areas of transparency. 2003 S&P European Transparency and Disclosure.
- Corporate challenges to integrate and systemize transparency as corporate value and mandated legal requirement. Role of technology and audit will change to implement and monitor multiple expectations and requirements.

Global Transparency Challenges

- Differences in legal requirements and protections for commercial confidential information and data privacy and overall public availability of disclosures.
- Global codes of ethics identify transparency as a core value but there do not exist consistent delineated principles for disclosure.
- Government enforcement drives transparency, not self-regulation or corporate responsibility initiatives. Lines of ethics v. law is blurred?
- Corporate infrastructure and resources impact scope of disclosures.
- Are disclosures in mandated format meaningful disclosures?

State Comparison

State	State Code of Conduct	Compliance Requirement	Disclosure Requirement	Disclosure Public?	Medical Devices
California		√			√ (without disclosure)
Maine			√		
Massachusetts	√	√	√	√	√ (with disclosure)
Minnesota			√	√	
Nevada		√			√ (without disclosure)
Vermont			√		
W. Virginia			√		
District of Columbia			√		

Health Industry State Law Transparency Requirements

State	Requirement
California	**Comprehensive Compliance Program.** Every pharmaceutical company is required to adopt a Comprehensive Compliance Plan, that: (1) Is consistent with HHS/OIG Compliance Program Guidance for Pharmaceutical Manufacturers; (2) Includes policies for compliance with PhRMA's Code on Interactions with Health Care Professionals; and (3) Includes limits on gifts and incentives to medical or health professionals, including a specific annual dollar limit on gifts, promotional materials, or other items provided to medical/health professionals.

Health Industry State Law Transparency Requirements

State	Requirement
California	**Annual Declaration.** A pharmaceutical company must disclose to the public annually a written declaration that the company is in compliance with both its Comprehensive Compliance Program and California law. The Comprehensive Compliance Program and annual written declaration must be made available to the public on the company's website and through a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written declaration may be obtained. Cal. Health & Safety *Code § 119400, 119402.*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	***Reporting of Marketing Activities and Expenses.*** *A manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District must report to the Department of Health by July of each year a report with information on the value, nature, purpose, and recipient of certain advertising or promotional expenses, including with regard to all persons and entities licensed to provide health care in the District (including the company's own employees), the following:*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	*(1) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials; (2) All expenses associated with food, entertainment, gifts valued at more than $25, and anything provided to a health care professional for less than market value; (3) All expenses associated with trips and travel; and (4) All expenses associated with product samples, except for samples that will be distributed free of charge to patients.*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	*The following are exempt from this requirement: (1) Expenses of $25 or less; (2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; (3) 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.*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	*Manufacturers or labelers of prescription drugs must also submit to the District an annual fee of $2,500.* *D.C. Code § 48-833.01 - 09.* ***Licensure of Pharmaceutical Detailers.*** *Any person engaged in the practice of pharmaceutical detailing in the District must obtain and maintain a license with the Board of Pharmacy. A pharmaceutical detailer shall not: (1) Engage in any deceptive or misleading marketing of a pharmaceutical product;*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	*(2) Use a title or designation that might lead a licensed health professional to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation unless the pharmaceutical detailer currently holds such a license.; or (3) Attend patient examination without the consent of the patient.*

Health Industry State Law Transparency Requirements

State	Requirement
District of Columbia	*The Board of Pharmacy shall waive the educational requirements for licensure if a pharmaceutical detailer can demonstrate that he/she has been performing the functions of a pharmaceutical detailer on a full-time, or substantially full-time, basis for at least 12 months immediately preceding March 26, 2008.* *D.C. Code § 3-1201.02; D.C. Code § 3-1207.*

Health Industry State Law Transparency Requirements

State	Requirement
Maine	**Reporting of Marketing Activities and Expenses.** Manufacturers and labelers of prescription drugs dispensed in Maine that employ, direct, or utilize marketing representatives in Maine must disclose to the Department of Health and Human Services in Maine by July 1 of each year marketing costs for prescription drugs in Maine, including the value, nature, purpose and recipient of certain advertising or promotional expenses, including with regard to all persons and entities licensed to provide health care in Maine, all expenses associated with:

Health Industry State Law Transparency Requirements

State	Requirement
Maine	(1) Educational or informational programs, materials and seminars and remuneration for promoting or participating in educational or informational sessions; (2) Food, entertainment, gifts valued at more than $25 and anything provided to a health care professional for less than market value; (3) Trips and travel; and (4) Product samples, except for samples that will be distributed free of charge to patients.

Health Industry State Law Transparency Requirements

State	Requirement
Maine	The following are exempt from this requirement: (1) Expenses of $25 or less; (2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment; and

Health Industry State Law Transparency Requirements

State	Requirement
Maine	(3) 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. Manufacturers or labelers of prescription drugs must also submit an annual fee of $1,000. *Me. Stat. Ann. tit. 22, § 2698-A.3 – A.4.*

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	**Reporting of Marketing Activities and Expenses.** Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts must disclose to the Department of Public Health July 1 of each year starting July 1, 2010 information on the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other prescriber of drugs/devices in Massachusetts.

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	Pharmaceutical or medical device manufacturing companies must also submit an annual fee of $2,000, starting July 1, 2009. *Mass. Gen. Laws ch. 111N, § 6.* **Marketing Code of Conduct.** The Department of Public Health will establish a Marketing Code of Conduct for drug/device manufacturing companies that is no less restrictive that the most recent versions of PhRMA's and AdvaMed's Codes on Interactions with Health Care Professionals. The code will prohibit:

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(1) provision of or payment for meals for health care practitioners (“practitioners”) that: (a) are part of an entertainment or recreational event; (b) are offered without an informational presentation made by pharmaceutical marketing agent (“agent”) or without [agent] being present; (c) are offered, consumed, or provided outside of the practitioner's office or hospital setting; (d) are provided to a practitioner's spouse or other guest.

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(2) provision or payment of entertainment or recreational items of any value, including . . . tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any practitioner who is not a salaried employee of the company; (3) sponsorship or payment for continuing medical education . . . that does not meet the Accreditation Council for [CME] Standards For Commercial Support, or that provides payment directly to a practitioner;

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(4) financial support for the costs of travel, lodging or other personal expenses of non-faculty practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor, except in cases as determined by the department; (5) funding to compensate for the time spent by practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(6) provision of or payment for meals directly at any CME event, third-party scientific or educational conferences, or professional meetings; (7) payments in cash or cash equivalents to practitioners either directly or indirectly, except as compensation for bona fide services; (8) any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a practitioner in exchange for prescribing prescription drugs or using medical devices or for a commitment to continue prescribing prescription drugs or using medical devices.

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	The code will allow: (1) provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information; (2) purchase of advertising in peer reviewed academic, scientific or clinical journals; (3) prescription drugs provided to a practitioner solely and exclusively for use by the practitioner's patients;

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(4) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project or a clinical trial (5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(4) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project or a clinical trial (5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts is required to: (a) Adopt and comply with the most recent marketing code of conduct as adopted by the department; (b) Adopt a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct;

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	(c) Conduct annual audits to monitor compliance with the marketing code of conduct; (d) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct and take corrective action in response to noncompliance and the reporting of instances of noncompliance to the appropriate state authorities; and (e) Identify a compliance officer responsible for operating and monitoring the marketing code of conduct. *Mass. Gen. Laws ch. 111N, § § 2 and 4.*

Health Industry State Law Transparency Requirements

State	Requirement
Massachusetts	***Declaration for Marketing Code of Conduct.*** *Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts shall disclose to the Department of Public Health annually by July 1 a declaration stating the following: (1) Description of its training program; (2) Description of its investigation policies; (3) Name, title, address, telephone number and electronic mail address of its compliance officer; and (4) Certification that it has conducted its annual audit and is in compliance with the marketing code of conduct.* *Mass. Gen. Laws ch. 111N, § 5.*

Health Industry State Law Transparency Requirements

State	Requirement
Minnesota	***Ban on Gifts.*** *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.* *Exemptions to this ban include the following: (1) Professional samples of a drug provided to a prescriber for free distribution to patients; (2) Items with a total combined retail value 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;*

Health Industry State Law Transparency Requirements

State	Requirement
Minnesota	*(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; and (7) Salaries or other benefits paid to employees.* *Minn. Stat. Ann. Sec. 151.461.*

Health Industry State Law Transparency Requirements

State	Requirement
Minnesota	***Reporting of Payments to Practitioners.*** *Wholesale drug distributors must report to the Board of Pharmacy annually by May 1 reports identifying all of the following types of payments, honoraria, reimbursement or other compensation from the preceding calendar year: (1) 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;*

Health Industry State Law Transparency Requirements

State	Requirement
Minnesota	*(2) Reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting; (3) Compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project. The report must include the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and the identity of the practitioner. Reports filed under this provision are public data.* *Minn. Stat. Ann. Sec. 151.44 and 151.47.*

Health Industry State Law Transparency Requirements

State	Requirement
Nevada	***Marketing Code of Conduct.*** *A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in Nevada shall: (1) Adopt a written marketing code of conduct which establishes the practices and standards that govern the marketing and sale of its products; (2) Adopt a training program to provide regular training to appropriate employees, including, without limitation, all sales and marketing staff, on the marketing code of conduct;*

Health Industry State Law Transparency Requirements

State	Requirement
Nevada	*(3) Conduct annual audits to monitor compliance with the marketing code of conduct; (4) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct; and (5) Identify a compliance officer responsible for developing, operating and monitoring the marketing code of conduct.*

Health Industry State Law Transparency Requirements

State	Requirement
Nevada	***Disclosure of Code of Conduct.*** *A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in Nevada must disclose to the Board of Pharmacy annually by June 1 the following: (1) A copy of its marketing code of conduct; (2) A description of its training program; (3) A description of its investigation policies; (4) The name, title, address, telephone number and electronic mail address of its compliance officer.; and (5) Certification that it has conducted its annual audit and is in compliance with its marketing code of conduct.* *Nev. Rev. Stat. § § 639.570.1(a)-(e); Nev. Rev. Stat. § § 639.570.2(a)-(e).*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	***Ban on Gifts to Practitioners.*** *It is unlawful for any drug, device or biologic manufacturer or wholesaler distributor of medical devices, or any agent thereof, to offer or give any gift to a healthcare provider. A "gift" is defined as (A) anything of value provided to a health care provider for free; or (B) any payment, food, entertainment, travel, subscription, advance, services, or anything else of value provided to a health care provider, unless it is an allowable expenditure or the health care provider reimburses the cost at fair market value. Vt. Stat. Ann. tit. 18, § 4631a.*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	The general categories of allowable expenditures, all subject to detailed restrictions and requirements, include the following: (1) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar; (2) Honoraria and payment of expenses of a health care professional who serves on the faculty at such a conference or seminar; (3) Payment for a bona fide clinical trial; (4) Payment for a research project of scientific interest or value;

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	(5) Payment or reimbursement of reasonable expenses necessary for technical training of health care professionals on the use of a medical device; (6) Royalties and licensing fees paid to health care providers for purchased patent rights or other intellectual property; and (7) Other reasonable fees, payments subsidies or other economic benefits provided by a manufacturer at fair market value

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	The Vermont statute also identifies allowable gifts, subject to detailed restrictions and requirements. These allowable gifts include the following: (1) Samples given to a health care provider for free distribution to patients; (2) The loan of a medical device for a short-term trial period, not to exceed 90 days; (3) The provision of reasonable quantities of medical device demonstration or evaluation units;

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	(4) The provision, distribution and dissemination of peer-reviewed scientific/medical/clinical journals or articles or other items that serve a genuine educational function; (5) Scholarships or other support for medical students, residents and fellows to attend a significant educational, medical, scientific, or policy-making conference or seminar; (6) Rebates and discounts; and (7) Labels approved by FDA for prescribed products. *Vt. Stat. Ann. tit. 18, § 4631a.*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	***Reporting of Allowable Expenditures and Gifts.*** *Every manufacturer of prescribed products are required to disclose to the Office of the Attorney General the name and address of the individual responsible for the company's compliance with these requirements and allowable expenditures and gifts as defined above. Disclosures must be on a form provided by the Office of the Attorney General and must include the following:*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	*(1) the value, nature, and purpose of each allowable expenditure and gift; (2) the name of the recipient; (3) the recipient's address; (4) the recipient's institutional affiliation; (5) prescribed product or products being marketed, if any; and (6) the recipient's state board number.*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	*The following expenditures/gifts are not required to be reported: (1) Royalties and licensing fees; (2) Rebates and discounts for prescribed products; (3) Certain payments for clinical trials, until the earlier of (i) the date the product is approved or cleared by FDA or (ii) two calendar years after the payment was made; and (4) Samples of a prescription drug provided to a health care professional for free distribution.*

Health Industry State Law Transparency Requirements

State	Requirement
Vermont	*For 2009, only drug manufacturers are required to report on the following dates: on or before July 1, for identifying the responsible person at the company, and on or before November 1 for disclosure of marketing activities (under old statutory requirements).* *For 2010 and thereafter, both drug and device manufacturers are required to report on the following dates: annually on or before July 1, for identifying the person at the company responsible for ensuring compliance with the reporting requirements, and annually on or before October 1 for disclosure of allowable expenditures and gifts.* *Vt. Stat. Ann. tit. 18, § 4632(a)(1)-(3).*

Health Industry State Law Transparency Requirements

State	Requirement
West Virginia	**Reporting of Advertising Costs.** All manufacturers and labelers of prescription drugs dispensed in West Virginia that employ, direct or utilize marketing representatives must disclose to the West Virginia Pharmaceutical Cost Management Council annually on April 1 advertising costs for prescription drugs, based on aggregate national data, including all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of West Virginia.

Health Industry State Law Transparency Requirements

State	Requirement
West Virginia	The following exemptions apply to this requirement: (1) All free samples of prescription drugs intended to be distributed to patients; (2) All payments of reasonable compensation and reimbursement of expenses in connection with a *bona fide* clinical trial; (3) All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient . . . is selected by the association. *W. VA. Code R. § 16-29H-8.*

Discussion Panelists

Ann DesRuisseaux, JD, LL.M. Law Office of Ann E. DesRuisseaux 3104 Cornell Avenue Dallas, Texas 75205 (214) 264-1826 ann@globalcompliancestrategies.com	Kathleen McDermott, Esq. Morgan, Lewis & Bockius LLP 1111 Pennsylvania Ave, NW Washington, DC 20004 202.739.5458 kmcdermott@morganlewis.com
Donald H. Romano, Esq. Arent Fox LLP 1050 Connecticut Avenue, NW Washington, DC 20036 202.715.8407 romano.donald@arentfox.com	

Morgan Lewis