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Understanding the Forces Driving Disclosure

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Forces Behind the Trend Toward Disclosure

- State Laws/Legislatures/NLARx
- Academic Institutions
- Voluntary Changes in Company Policy
- Corporate Integrity Agreements/Consent Orders
- Congress: Sunshine Bill/Health Care Reform

The Rationales For Disclosure

- Increasing Health Care Costs
- Perceived Conflicts of Interest
- Persuade Physicians to “Rethink” Relationships
- Allow Payers, Academics, Reporters and Others to Shed Light on Physician-Industry Relationships

Arguments Against Disclosure

- Many Relationships Between Manufacturers and Physicians Are Appropriate and Healthy
- Burden of Compliance
- Cost to the Government

THE STATES

State Laws
Marketing Cost Disclosures

- California
- District of Columbia
- Maine
- *Massachusetts
- Minnesota
- *Vermont
- West Virginia

Massachusetts

- **August 2008:** Massachusetts enacts "An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare" which contains a new chapter entitled "Pharmaceutical and Medical Device Manufacturer Conduct."
  - **Goal:** To address potential undue influence in interactions between pharmaceutical or medical device manufacturing companies and health care practitioners.
  - **Challenge:** Increase the level of transparency while protecting manufacturers' legitimate confidentiality interests, trade secrets and other intellectual property rights.
- **December 2008:** Proposed regulations issued, Massachusetts Public Health Council (PHC) holds two public hearings and receives written comments during the comment period closing January 19, 2009.
- **March 2009:** PHC adopts the final set of implementing rules after the Department of Public Health (DPH) reviews input from industry stakeholders.

MA Law

- **To whom does this law apply?**
  - "Covered providers" include a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals.
- **What does the law require?**
  - The State Department of Public Health (DPH) must:
    - Promulgate a Marketing Code of Conduct
    - Enforce the Code of Conduct & manufacturer disclosure/reporting requirements
  - Pharmaceutical & medical device companies must:
    - Adopt the Code of Conduct
    - Administer a compliance program related to the Code of Conduct
    - Comply with payment disclosure/reporting requirements

MA Law (Cont'd)

The Massachusetts Department of Public Health (DPH) is required to promulgate and update a code of conduct for pharmaceutical and medical device companies every two years. Companies employing persons in the sales/marketing of a drug or device in the Commonwealth are required to adopt the Code of Conduct and create a training program regarding the Code of Conduct for those employees.

- **What conduct is permitted?**
  - Compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or a clinical trial
  - 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.
  - Provision or receipt of peer reviewed academic, scientific or clinical information
  - Purchasing advertising in peer reviewed academic, scientific or clinical journals
  - Provision of drug samples solely for patient use

MA Law – Gift Ban

- **What conduct is prohibited?**
  - Payments for or Provision of Meals:
    - related to entertainment or recreation
    - offered without the marketing agent and an informational presentation
    - offered/consumed outside of the practitioner's office/hospital setting
  - Provision of Entertainment/Recreation other than to salaried employees of the pharmaceutical or device company
  - Sponsorship of CME that does not meet ACCME Standards for Commercial Support or that offers direct payment to a practitioner
  - Direct or Indirect financial Support for travel, lodging, personal expenses of non-faculty CME attendees
  - Direct payments to practitioners except for bona fide service agreements
  - Providing grants, scholarships, subsidies, support, consulting contracts, or educational/practice items to any practitioner in exchange for prescription or use of a drug or medical device

MA Law – Compliance

Compliance Deadline: By July 1, 2009, each manufacturer must have adopted a compliant Code of Conduct and submitted a training program on the Code to the DPH.

- **What are the compliance requirements? Manufacturers must:**
  - Engage in annual compliance audits
  - Undertake investigations into and report any breaches of the Code
  - Submit annual certifications to the DPH regarding the above actions.
  - Not use prescriber data for promotional purposes if HCP has so requested

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MA Law – Disclosure

- Reporting Deadline: By July 1, 2010, each manufacturer must commence filing annual payment reports to DPH.
- **Who must report?**
  - Pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the Commonwealth of Massachusetts.
- **Who is a covered recipient?**
  - Health care practitioners as defined above.

MA Law – Disclosure (Cont'd)

- **What payments must be reported?**
  - Any fee, payment, subsidy or other economic benefit with a value of at least $50, directly or through a company's agents, to any covered recipient in connection with the company's sales and marketing activities.
- **What payments are exempt?**
  - Reasonable compensation for bona fide services (including related expenses) pursuant to a written agreement
  - Reimbursement for expenses related to technical training of health care practitioners on the use of a medical device (per written purchasing agreement)
  - Dissemination or receipt of peer reviewed academic, scientific or clinical information

MA Law – Disclosure (Cont'd)

  - Purchasing advertising in peer reviewed academic, scientific or clinical journals; provision of samples (including medical device demonstration units)
  - Rebates and discounts; reimbursement information; patient assistant program support (financial or free product)
  - Charitable donations
- **What information must be in the report?**
  - The annual report to the DPH must include the value, nature, purpose, and particular recipient of any fee, payment, subsidy or economic benefit with any value of at least $50 provided to a covered health care provider by agents of a pharmaceutical or device company.

MA Law – Disclosure (Cont'd)

- **How do you calculate the reporting trigger?**
  - The regulations do not require aggregate reporting, meaning that for purposes of computing the $50 reporting trigger, fees, payments, subsidies and other economic benefits that relate to separate events or transactions are to be calculated on a transactional, not aggregate, basis for the covered recipient.
- **What will DPH do with the reported information?**
  - The new law requires DPH to establish a public database to enable listing payments to health care practitioners by manufacturers that employ persons to sell or market prescription drugs and to set fees in conjunction with the disclosure requirements of the chapter.

Note: Manufacturers are prohibited from structuring payments to avoid reporting requirements.

MA Law – Enforcement

- **What are the penalties for violation of the new law?**
  - Knowing and willful violations of the regulations may be assessed a $5000 penalty per violation.
- **Who is charged with enforcement responsibilities?**
  - The attorney general, the district attorney with jurisdiction over a violation, or the DPH are provided with authority for enforcement of the law and regulations, and are allowed to issue fines and notice via mail for violations. Recipients are afforded the opportunity to dispute the fine, including judicial review related to issued fines. The enforcement authorities are allowed to pursue a civil action for recovery of lodged and unpaid fines.
- For further information, including responses to FAQs, see www.mass.gov

Vermont Law

- Vermont is the latest to adopt new disclosure laws. The new law, effective July 1, 2009, bans all "gifts" of any value, including food and requires disclosure of all "allowable expenses."
  - For guidance, see www.atg.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php
- Gifts:
  - Anything of value provided to a health care provider for free; or . . . [a]ny payment, food, entertainment, travel, subscription, advance, service or anything else of value provided to a health care provider, unless . . .[deemed an allowable expenditure]"

VT Law (Cont'd)

- Allowable Expenditures:
  - Payments by a manufacturer to the sponsor of a "significant educational, medical, scientific, or policy making conference or seminar (no direct payments to the health care provider, limited to bona fide purposes, program content must be objective, free from industry control, and non-promotional).
  - Honoraria and payment of faculty (must have specific contract with the health care professional establishing specific services that are restricted to medical issues and not marketing activities).
  - Payment of gross compensation, direct salary, and investigator expenses for bona fide clinical trials and research projects.

VT Law (Cont'd)

- Payment of necessary expenses related to the technical training of individual health care professionals on the use of medical devices is permitted if the expenses to be paid are described in a written agreement.
- Royalties and licensing fees & other reasonable fees provided at fair market value.

VT Law – Gift Ban

- "It is unlawful for any manufacturer of a prescribed product, or any wholesale distributor of medical devices, or any agent thereof, to offer or give a gift to any health care provider."
- Exceptions:
  - Samples provided to a health care provider for free distribution to patients
  - Loan of a medical device for a short trial period (not exceeding 90 days) to permit evaluation by a health care provider or patient
  - Provision of reasonable quantities of medical device demonstration or evaluation units
  - Provision of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function, if provided to a health care professional for the benefit of patients

VT Law – Gift Ban (cont'd)

- Exceptions (cont'd)
  - Scholarships or other support of medical students to attend a scientific or educational exchange
  - Rebates and discounts for prescribed products provided in the normal course of business
  - Labels approved by FDA.
- Penalties: AG action in Washington County Superior Court for injunctive relief, costs, attorney's fees and penalties of up to $10,000 per violation

VT Law – New Disclosure

- On October 1 of each year, manufacturers must disclose the value, nature, purpose and recipient information of:
  - Any allowable expenditure or gift provided to a health care provider (broadly defined) or an academic institution or a professional, educational or patient organization representing or serving health care providers or consumers, except:
    - Royalties and licensing fees
    - Rebates and discounts for prescribed products provided in the normal course of business
    - Payments for clinical trials, which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by FDA or two years after payment was made
    - Samples of a prescription drug provided to a health care professional for free distribution to patients

VT Law – New Disclosure (cont'd)

- Disclosure should include, for each reported expenditure: (a) the recipient's name; (b) recipient's address; (c) recipient's institutional affiliation; (d) the prescribed product being marketed, if any; and (e) recipient's state board number
- Attorney General annual report due April 1
- Penalty of up to $10,000 per violation for a failure to disclose as required.
- Study of advisability of disclosing drug samples – report on findings due December 15, 2009
- No trade secret protection for reported information
- Annually on July 1 of each year, manufacturers must disclose name and address of person responsible for Vermont law compliance.

OIG/STATE ENFORCEMENT ACTIONS AND CIAs

HHS OIG

- Proponent for Disclosure (2/27/08 Testimony on Physician-Industry Relationships)
  - Continue to support DOJ in pursuing health care fraud prosecutions relating to inappropriate marketing practices
  - Conduct outreach to physicians and industry to improve awareness of compliance risks
  - Supports efforts by Congress and academia to promote transparency in relationships

Corporate Integrity Agreements

- OIG mandating disclosure of HCP payments through CIAs. For example,
  - Zimmer
  - Cephalon
  - Lilly
  - Pfizer
- Public disclosure of payments in readily accessible and searchable format
- OIG discretion to discontinue CIA disclosures in the event Sunshine Act becomes law

Pfizer CIA (2009)

- Most recent and robust disclosure requirements
  - Post all direct “or indirect” payments to U.S. Physicians or “related entities” in accessible and searchable format on Pfizer web site for each year of CIA.
  - Annual postings required in March of each year – including cumulative information about Payments made in prior years
  - Produce work papers upon request
- “For purposes of this Section, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest. The term "physician" as used herein does not include bona-fide employees of Pfizer or its subsidiaries.”

Pfizer CIA (Cont'd)

- Payments = "all payments or transfers of value (whether in cash or in kind) made to physicians including all payments (including, for example, honoraria payments, other payments, and reimbursement for lodging, travel and other expenses) made in connection with physicians serving as speakers, participating in speaker training, or serving as Consultants or Authors; payments or compensation for services rendered; grants; fees; payments relating to research; payments relating to education; and payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred. The term also includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Pfizer would otherwise report a Payment if made directly to the physician. The term "Payments" includes any Payments made, directly or indirectly, by Pfizer to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement."

Pfizer CIA (Cont'd)

- "Payments" does not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.
- Only for purposes of the reporting of Payments on March 31, 2010, the term "Payments" does not include: i) individual Payments of less than $25 per instance, or ii) aggregate Payments in a year to a physician or Related Entity of less than $500.
- Beginning with the March 31, 2011 report and all reports thereafter, individual Payments' under $25 per instance and aggregate Payments of less than $500 shall be included in the Payment amounts listed in the applicable report.
- CIA contemplates potential modification if Sunshine Act passes .

Pfizer CIA (cont'd)

- Other Disclosures:
  - Charitable Contributions and Medical Education Grants
  - Consultants and Authors Must Disclosure Relationships with Pfizer
  - All Company-Sponsored Clinical Trials Must Be Registered in www.clinicaltrials.gov
  - Post Information on Company Website about Post-Marketing Commitments

State AGs

- Settlements include various disclosure requirements
  - Lilly (required disclosure to each signatory AG of any HCP promotional speakers or consultants paid more than $100)
  - GSK (NY AG required clinical trial disclosure)
  - Pfizer (OR AG required disclosure of relationship in conduct and funding of clinical research and in CME sessions)
  - Merck (OR AG required disclosure of relationships with CME providers and recent NJ Sup Ct settlement includes disclosure of clinical trial data on a public registry)

CONGRESS

Physician Payment Transparency Bills

- Sunshine Bill
  - Introduced 2008
  - Re-Introduced 2009 and is now part of House and Senate-passed health reform bills
- Background
  - Prior investigations by Sen. Grassley of payments to academic physicians at Harvard, Stanford, etc.
  - MedPac Report/Institute of Medicine Report
  - State Laws
  - Enforcement Official Support

Health Reform – Background

- Senate Bill: Patient Protection and Affordable Care Act, HR. 3590, Section 6002.
  - Passed Senate on December 24, 2009
- House Bill: The Affordable Health Care for America Act, HR, 3962, Section 1451.
  - Passed House of Representatives on November 7, 2009
- Prospects for Passage of Comprehensive Health Reform Unclear, but Commitment to Transparency Initiatives Appears To Have Bi-Partisan Support
- Senate Bill More Likely To Move than House Version
- House Bill Effective Two Years Earlier (2010 vs. 2012) and Broader Definition of Covered Recipients and Narrower Exclusions

Senate Bill: Transparency Requirements

- "Transparency Reports"
  - Beginning on March 31, 2013, and the 90th day of each calendar year beginning thereafter
  - Reporting of manufacturer payments or other transfers of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient)
  - Electronic reporting as designated by Secretary

Senate Bill (key terms)

- Covered Drug, Device or Medical Supply
  - Any drug, biological products, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan) of the Social Security Act
- Covered Recipient
  - Physicians and teaching hospitals
  - Does not include employees of the manufacturer who meet the definition of physician
  - Must also submit electronically information about ownership or investment interests of physician (or immediate family member of the physician) in the manufacturer (or a GPO) during the reporting year
- Payment or Other Transfer of Value
  - A transfer of anything of value, unless excluded.
  - Transfers of value do not include a transfer that is made indirectly to a covered recipient through a third party where the manufacturer is unaware of the identity of the covered recipient

Senate Bill Requirements

- Reports starting on March 31, 2013 (for payments in Calendar Year 2012) – must include:
  - Name of covered recipient
  - Business address of covered recipient and, if a physician, the specialty and NPI number
  - The amount of the payment or other transfer of value
  - The dates of the payment or other transfer of value
  - A description of the form of the payment or transfer, indicated as: (a) cash or cash equivalent; (b) in-kind items or services; (c) stock, stock option, or ownership interest, dividend, profit, or other return on investment; or (d) other (as defined by HHS)
  - If payment is related to a particular drug, device or medical supply, report must identify the drug

Senate Bill Requirements (Cont'd)

- A description of the payment or transfer, indicated as:
  - Consulting fees
  - Compensation for services other than consulting
  - Honoraria
  - Gifts
  - Entertainment
  - Food
  - Travel (including the destination)
  - Education
  - Research

Senate Bill Requirements (Cont'd)

- A description of the payment or transfer, indicated as:
  - Charitable Contribution
  - Royalty or License
  - Current or Prospective Ownership Interest
  - Direct Compensation for Service as Speaker
  - Grant
  - Other (as defined by HHS)

Senate Bill Exclusions

- Any transfers of value less than $10, unless the aggregate transfer of value to the covered recipient exceeds $100 during the calendar year (not taking into account items below)
- Product samples not intended to be sold and provided solely for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Trial (less than 90 days) loan of a covered device to permit evaluation by the covered recipient
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device

Senate Bill Exclusions (Cont'd)

- Transfer to a physician where physician is a patient and not acting in the professional capacity of a covered recipient
- Discounts (including rebates)
- In-kind items 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
- For covered recipients who are licensed non-medical professionals, transfers solely for non-medical professional services
- Payments solely for the services of the covered recipient with respect to expert or other services in connection with litigation matters

Senate Bill Penalties

- Failure to Report in Accordance with Regulation
  - Civil penalty of not less than $1,000, but not more than $10,000, for each payment/transfer of value not reported as required
  - Total penalty shall not exceed $150,000 for each annual submission
- Knowing Failure to Report
  - Not less than $10,000, but not more than $100,000 for each payment/transfer of value not reported as required
  - Total shall not exceed $1,000,000 for each annual submission
  - "Knowingly" defined as under 31 USC §3729(b) (False Claims Act)
    - means that a person, with respect to information-- (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information
      - no proof of specific intent to defraud is required.

Senate Bill Penalties (Cont'd)

- Funds collected used to implement Sunshine Act
- Information available on a public website by 2013
- Annual reports to Congress starting April 1, 2013, including description of enforcement actions taken to implement transparency requirements
- Annual reports to states, starting by September 30, 2013, and on June 30 of each subsequent year
  - Summarizing information submitted during the preceding year with respect to covered recipients in that state

Senate Bill: Limited Pre-emption

- "Relation to State Laws.—
  - (A) In General.– [Effective on January 1, 2012,] subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer…to disclose or report, in any format, the type of information … regarding such payment or other transfer of value.
  - "(B) No Preemption of Additional Requirements.—
    - Subparagraph (A) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information (i) not of the type required to be disclosed or reported under this section; (ii) [excluded from the definition of payments or other transfers of value]; (iii) by any person or entity other than an applicable manufacturer or a covered recipient; or (iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes

Senate Bill – Limited Pre-emption (Cont'd)

- Information produced in connection with transparency requirements discoverable in litigation
- HHS must consult with OIG in implementing pre-emption section

Conclusion

- Disclosure requirements have broad support
- Open question about timing of health reform and prospects for passage
- Open question about impact of Sunshine Bill, if enacted, on state laws and obligations under CIAs and Settlement Agreements
- States will continue to pursue further marketing restrictions