

Understanding the Forces Driving Disclosure

Preconference Session

First Annual Summit on Sales & Marketing Disclosure for
Drug, Device and Biotech Companies



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Proponents of Disclosure

- State Laws/Legislatures/NLARx
- Academic Institutions
- MedPac/Sunshine Bill
- Corporate Integrity Agreements/Consent Orders
- Congress

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

State Laws

Marketing Cost Disclosures

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

Summary of State Laws/Trend

- Massachusetts Law (2008)
 - Proposed Rules Pending
 - Applies to both pharmaceutical and medical device manufacturers
 - Trade Secret Protection?
 - Broad Definition of Sales and Marketing Leads to a Number of Open Questions
 - Application to MSLs?
 - Include Rebates/Discounts?
 - Include Royalties/Licensing Fees?
 - Include Retail Value of Samples?
 - Include Clinical Trial Expenses?

MedPac

- Report to Congress in June 2008 and Recommendations in November 2008
 - Support disclosure and public posting of financial relationships with physicians, pharmacists, health plans, PBMs, hospitals, medical schools, CME sponsors, patient organizations and professional organizations
 - Support reporting of information about drug samples
 - Support requiring hospitals and other entities that bill Medicare to disclose ownership interests of physicians and requiring CMS to report on those interests to Congress

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,
 - Cephalon
 - Lilly
- Public disclosure of payments in readily accessible and searchable format
- OIG discretion to discontinue CIA disclosures in the event Sunshine Act becomes law

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 relationship in CME)

Congress

- Sunshine Bill
 - Introduced 2008
 - Re-Introduced 2009
- Background
 - Prior investigations by Sen. Grassley of payments to academic physicians at Harvard, Stanford, etc.
 - MedPac Report
 - State Laws
 - Enforcement Official Support

Sunshine Bill

- Reintroduced Senate Bill – S. 301 (Grassley (R-IA)/Kohl (D-WI))

“To amend title XI of the Social Security Act to provide transparency in the relationship between physicians and manufacturers of drugs, devices or medical supplies for which payment is made under Medicare, Medicaid or SCHIP.”

Sunshine Bill Requirements

- “Transparency Reports”
 - Beginning on March 31, 2011, 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

Sunshine 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
 - Physician, physician medical practice and physician group practice
 - Disclosure under covered recipient name if payment/transfer of value made to a third-party on behalf of a covered recipient or physician (as applicable)
- Payment or Other Transfer of Value
 - Any compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in an applicable manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a public traded security and mutual fund)

Sunshine Bill (exclusions)

- Aggregate payment or transfer of value does not exceed \$100 during the calendar year (not taking into account items below)
- Product samples not intended to be sold and 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
- 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.

Sunshine 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)
 - 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.
- Funds Collected Used to Implement Sunshine Act
- Annual Reports to States
 - Summarizing information submitted during the preceding year with respect to covered recipients in that state

Sunshine Bill (Pre-emption)

- “Relation to State Laws.—

(A) In General.— Effective on January 1, 2010, subject to subparagraph (B), the provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer...to disclose or report information (as defined in subsection (a)) regarding a payment or other transfer of value provided by an applicable manufacturer to a covered recipient (as so described).”

“(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 not required to be disclosed or reported under this section.”

Sunshine Bill (Next Steps)

- Key issues
 - Timing, levels and specificity of reporting
 - Breadth of preemption/Inter-relationship with state laws

Conclusion

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

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