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UNDERSTANDING THE FORCES DRIVING DISCLOSURE
Aggregate Spend and 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

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
  - AstraZeneca
  - Forest Laboratories
- Public disclosure of payments in readily accessible and searchable format
- OIG discretion to discontinue CIA disclosures when Sunshine Act becomes effective

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

AstraZeneca CIA

- Required Disclosures – on the AZ Website
  - Physician Payments – similar to Pfizer, Lilly and Cephalon
  - Charitable Contributions and Grants
  - Consultant Relationships
  - Clinical Trials
  - Representation that Authors of Reprints comply with ICMJE
  - Post-Marketing Commitments
- Forest Labs CIA (2010) contains same requirements

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

Comprehensive Health Reform

- The Patient Protection and Affordable Care Act (PPACA) passed March 23rd
- PPACA Section 6002
  - Requires reporting of payments to physicians and teaching hospitals, and ownership interests
  - Version of the Physician Payments Sunshine Act provisions that had been pending in Congress for several years
- PPACA Section 6004
  - Requires reporting of drug sample information

Key Takeaways

- Timing
  - Section 6002 -- first report on payments and ownership interests due March 31, 2013, based on transactions that occurred in 2012
  - Section 6004 - - first report on drug sample information is due in 2012 (not later than April 1, 2012)
- Regulations / Guidance
  - Not later than October 1, 2011, the Secretary of HHS must provide guidance on the definitions of terms and "establish procedures" for the submission and posting to the internet of physician payment information
  - **This guidance will be of critical importance in shaping reporting obligations**
- Preemption
  - PPACA has a limited preemption provision, and many State reporting obligations will continue

Reporting Obligations Under Section 6002

Reporting Requirements

- PPACA requires an "**applicable manufacturer**" of a "**covered drug, device, biological, or medical supply**" that provides "**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) to submit "Transparency Reports" about those payments to HHS
- Must submit first Transparency Report on March 31, 2013, and annually thereafter
- Reports will be submitted to HHS electronically

Key Definitions

- Applicable Manufacturer
  - “A manufacturer of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, possession, or commonwealth of the United States.”
- Covered Drug, Device, or Medical Supply
  - "Any drug, biological product, device, or medical supply for which payment is available under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [the Children’s Health Insurance Program] (or a waiver of such a plan).”

More Definitions

- Covered Recipient
  - "Physicians" and teaching hospitals
  - Does not include employees of an applicable manufacturer
- 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

Transparency Reports 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)

Transparency Reports Must Include (Cont'd)

- If payment is related to a particular drug, device or medical supply, report must identify the drug, device, or supply
- A description of the payment or transfer
- **Any other categories of information regarding the payment or other transfer of value HHS determines appropriate**

Transparency Reports - - Description of the Payment or Transfer

- Providing a description of the payment or transfer of value will require indicating whether the payment relates to:
  - Consulting fees
  - Compensation for services other than consulting
  - Honoraria
  - Gifts
  - Entertainment
  - Food
  - Travel (including the destination)
  - Education
  - Research

Transparency Reports - - Description of the Payment or Transfer (Cont'd)

- Descriptions continued:
  - Charitable Contribution
  - Royalty or License
  - Current or Prospective Ownership Interest
  - Direct compensation for service as speaker
  - Grant
  - Other (as defined by HHS)

Exclusions From Reporting

- 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 intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Trial loan (not more than 90 days) 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

Exclusions From Reporting (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
- If the applicable manufacturer self-insures for healthcare, payments for the provision of healthcare to employees under the plan

Physician Ownership Reporting

- Any applicable manufacturer or GPO must report the following information regarding any ownership or investment interest held by a physician (or an immediate family member) in the applicable manufacturer or GPO during the preceding year
  - The dollar amount invested by any physician
  - The “value and terms” of each such investment
  - For any payment or other transfer of value provided to a physician holding such an investment interest, all the information listed in the prior slides
  - **Any other information the Secretary determines appropriate**
- Exception: No reporting obligations for ownership or investment interest in a "publicly traded security" or mutual fund

Penalties

- Failure to Report in Accordance with Requirements
  - 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.

Government Reporting

- Information available on a public website by 2013
- Website will
  - Identify manufacturers and recipients
  - List values of transfers, nature of transfers, and **any other information the Secretary determines would be helpful to the average consumer**
- Reporting of transfers under an R&D agreement or clinical investigation regarding a new product is delayed until after the earlier of
  - FDA approval / clearance or
  - Four calendar years after the date of payment
- Manufacturers and recipients can review and submit corrections for at least 45 days prior to information being made public

Government Reporting (cont'd)

- Annual reports by HHS to Congress starting April 1, 2013, aggregated by manufacturer, 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

Limited Preemption

- "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 . . . 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 (except for the de minimis exclusion)]; (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

Limited Preemption (Cont'd)

- States can require disclosures of information if the information is:
  - Not "of the type" required to be disclosed under PPACA,
  - Excluded from PPACA's reporting requirements (with an exception for the de minimis exclusion), or
  - Regarding a payment by someone other than an applicable manufacturer and/or to someone other than a covered recipient

Limited Preemption (Cont'd)

- Exception: 6002 "shall not preempt any [State law] . . . that requires the disclosure or reporting of information" excluded from Section 6002 Transparency Reports, "except in the case of information described in" 6002's de minimis reporting exclusion
- State gift bans would not be preempted

Limited Preemption - - Vermont

- Not Preempted - - VT's requirements to report:
  - Allowable expenditures to entities that are not covered recipients, e.g., pharmacists, health benefit plan administrators, nursing homes, hospitals (that are not teaching hospitals), professional / educational / or patient organizations representing or serving providers or consumers
  - "Items that serve a genuine educational function provided to a health care provider for the benefit of patients"
  - Loans of medical devices for a short-term trial period, not to exceed 90 days, to permit evaluation of the device
- Preempted
  - At least information duplicative of information reported under 6002: value, nature, and purpose of payments and the name and address of the recipient for payments to physicians and teaching hospitals

Drug Sample Reporting Obligations Under Section 6004

Drug Sample Reporting

- Each manufacturer and authorized distributor of record must report
  - The identity and quantity of drug samples requested and distributed in a year, aggregated by name, address, professional designation and signature of practitioner and **any other category of information determined appropriate by the Secretary**
  - Reporting will be required for samples distributed by mail or common carrier, or otherwise
- Drug = prescription drug for which payment is made under Medicare, Medicaid, or CHIP.
- Manufacturers should already have access to this information by virtue of PDMA compliance (if HHS does not add non-PDMA required information to the Section 6004 reports)

Conclusion

- PPACA creates significant new reporting obligations
- Many open questions, but guidance issued not later than October 1, 2011 should clarify obligations
- Consider working with trade associations or individually to submit comments to HHS on this guidance
- States will continue to adopt payment reporting obligations and marketing restrictions

- Additional Resources:
  - www.aporter.com for our Healthcare Reform Chart, which includes links to key documents