National Pharma Audioconference – Examining the Latest Developments in Drug and Device CIAs: How Corporate Integrity Developments Continue to Reshape Compliance

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Compliance Environment Overview

2009 was a record year for recoveries for fraud and abuse violations in the healthcare industry.

Moreover, key legislative initiatives including changes to the False Claim Act (FCA) serve to expand liability and signal added resources, authority and focus on the part of regulatory and government enforcement entities.

Compliance Environment Overview

For 2010 and beyond, new trends have emerged through Congressional and state legislation and in recent government settlements

- Transparency increase
- Mandated Board and senior management responsibility for compliance programs success
- Comprehensive clinical and medical monitoring
- Management certification

OIG Final Guidance (2003)

In April 2003, OIG issued a "Compliance Program Guidance for Pharmaceutical Manufacturers."

- Reflected intention of federal government to examine industry practice
- Addressed both patently illegal practices as well as "gray areas" of physician-industry interaction including consultancies, gifts and grants
- Grants and other payments made to healthcare providers not covered by a recognized safe harbor carried "significant potential for abuse" under the anti-kickback and related fraud and abuse statutes

OIG Final Guidance

- Research and educational services must reflect bona fide activities of scientific and medical substance, not thinly-veiled marketing activities
- Safe harbor concepts (e.g., written agreements outlining services to be rendered, payments reflecting "fair market value") to be utilized

OIG Final Guidance

- Regarding grants and to reduce, if not eliminate, the risk that such payments are inducing or rewarding prescribing activity
  - urged separation of grant-making function from marketing and sales
  - suggested that CME programs sponsored and organized by independent and recognized medical associations raise “little risk of fraud and abuse, provided that the grant or support is not restricted or conditional with respect to content or faculty”

A Perspective on the PhRMA Code

- Originally created in 2002 as a voluntary marketing code by the Pharmaceutical Research and Manufacturers of America, revised as of January 2009
- Code was effectively designated a minimum standard for industry relationships with healthcare professionals ("HCPs") under the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 2003 (http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
- Compliance with the Code is now mandatory under the laws of two states (and is the basis for Massachusetts and DC's codes)

PhRMA and AdvaMed Codes Implemented to Adopt OIG Guidelines by Addressing Issues Including:

- issue of off-label promotion ("Promotional materials should be … consistent with all other … FDA requirements governing such communications." PhRMA Code, § 1)
- issue of speaker bureaus (payment representing FMV, companies must develop policies to set appropriate number of speakers, limiting speaker engagements, and cap annual speaker payments)
- issue of self and external verification process and certification of policies to foster compliance (PhRMA Code, § 15)

State Initiatives Including: Maine, District of Columbia, Massachusetts and Vermont

- Maine presents an example of a jurisdiction that has implemented a detailed reporting statute which includes specific reference to speaker bureaus.
  - The reporting period runs from July 1 for the period January 1-December 31 of the prior year
  - Parties required to report include "a manufacturer…of prescription drugs or biological products, or an affiliate of the manufacturer…", among others
  - Covered health care providers or related recipients include a "person or entity licensed to provide health care in the state of Maine…"
  - Relating specifically to speaker bureaus, the statute requires reporting of payments for participants in speaker bureaus and speaking at or attending meetings or conferences. ME. Rev. Stat. Ann, tit. 22, § 2698-A; 10-144, ME. Code R. § 2.04.2

Maine

- The report requires submission of detailed information relating to the participant, including date of payment/gift, name of recipient, type of recipient, credentials of recipient, if applicable, nature of payment, primary purpose of payment and amount of monetary payment
- To the extent that any gift represents less than market value, the reporting entity must establish internal support for establishing what constitutes “fair market value”
- Except for aggregate data that does not reveal trade secret information, data submitted is confidential and not considered a public record

District of Columbia ("Safe Rx")

- Focus is on registration of sales representatives in the District
- Reporting requirements include:
  - 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.

Massachusetts

- The marketing code of conduct prohibits "payments in cash or cash equivalents to healthcare professionals either directly or indirectly except as compensation for bona fide service."
- All payments must be reported to the state DHP by July 1 of each year, including the "value, nature purpose and the particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50 provided directly or indirectly to any physician authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the Commonwealth."

Vermont

- Assuming the item of value provided is permitted under state law, the reporter must disclose information as to the value and nature of the item as well as identification of the recipient *regardless of value*
- Disclosure applies to both allowable expenditures and exempted gift items (e.g., dissemination of peer-reviewed journal reprints, provision of FDA-approved labeling)

Impact of Comprehensive Health Reform on Fraud and Abuse

- Patient Protection and Affordable Care Act (PPACA) signed into law 3.23.10
- Health Care and Education Reconciliation Act of 2010 ("Reconciliation Bill") (affecting PPACA)
- Expansion of False Claims Act/Fraud Enforcement and Recovery Act of 2009
  - PPACA states that a claim submitted which violated the Anti-Kickback Statute ("AKS") is "false" under the FCA
  - PPACA provides that violation of AKS does not require specific knowledge or intent

Impact of Comprehensive Health Reform on Fraud and Abuse

- PPACA provides additional government authority
  - Expanded HHS Subpoena Power (may be delegated to HHS-OIG)
  - Additional Investigational Funding
  - Expanded Permissive Exclusion
- Sunshine Provisions of PPACA include:
  - Requires electronic reporting of payments to HCPs and teaching hospitals and physician ownership and investment interests
  - Exemption to reporting requirement include:
    - Transfers of $10 or less unless aggregate annual amount exceeds $100

Impact of Comprehensive Health Reform on Fraud and Abuse

- Samples for patients (reporting required)
- Patient educational materials
- Effective 09.30.13

– Preemption

- Preempts state laws requiring reporting but
  - does not state requirements to report information not covered or exempted by PPACA, or
  - applicable to reporting entities and recipients not covered by the Act

- Transparency under PPACA
  - Sample reporting requirement

Anticipated Impact of FCA and Anti-Kickback Legislation on Future Enforcement Activities

- Significant increase in government enforcement funding (investigational and regulatory)
- Amendment to FCA's "Public Disclosure Bar" and "Original Source Exception" to increase whistleblower activity
- Notifying government regarding "overpayments" to which recipient not entitled
- Expansion of authority to issue Civil Investigative Demands (CIDs) and share with realtors

- Invites scrutiny of FMV paid for performance-based discounts
- Industry to factor in the following when negotiating performance-based discounts:
  - impact of costs to federal health care reimbursement
  - potential for increased utilization of company products
  - possible skewing of clinical decision-making
  - effect on patient safety

Off-Label as a Continuing Focus of Federal and State Investigations and FDA Activity

- FDA Guidance on Off-Label Reprints and HHS-OIG prosecutions
- "Ghostwriting" as an increasing basis of liability
  - covered in PhRMA Code
  - covered in academic institutions policies and medical journal procedures (ICMJE)
  - addressed in CIAs
  - Congressional activity
    - Senate investigation determines role of pharmaceutical and medical device companies "unclear or hidden"; institutional policies insufficient
    - Senator Grassley (R-IA) requests responses from medical journals and academic institutions

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