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Health Care Fraud: Enforcement Trends

Laura G. Hoey

Linda A. Wawzenski

Steven Dollear

September 30, 2014
Chicago

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Moderator: Laura G. Hoey

- Ropes & Gray Partner, Government Enforcement
- Former Assistant U.S. Attorney and Health Care Fraud Coordinator
- Represents clients in the health care, pharmaceutical, medical device, and dental industries who are facing government investigations and Congressional inquiries
- Directs internal investigations and advises clients on potential violations involving health care fraud, the False Claims Act, the Anti-Kickback Statute, the Food Drug and Cosmetic Act, the U.S. Foreign Corrupt Practices Act, and HIPAA privacy and security

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Panelist: Linda A. Wawzenski

- U.S. Attorney's Office for the Northern District of Illinois
  - Assistant U.S. Attorney
  - Deputy Chief of the Civil Division
  - Supervises all of the office's civil fraud work, including the coordination of parallel criminal cases
- Has handled a variety of significant health care fraud cases in connection with Anti-Kickback and Stark violations
- Has presented to various organizations on important health care fraud issues

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Panelist: Steven Dollear

- U.S. Attorney's Office for the Northern District of Illinois
  - Assistant U.S. Attorney
  - Health Care Fraud Coordinator
  - Deputy Chief in the Financial Crimes Section
- Has prosecuted notable cases of health care fraud, financial fraud, and theft of trade secrets
- Has presented on key issues and trends in government enforcement and litigation in the health care industry
- Currently serves as co-chair for the Midwest Subcommittee of the ABA's Criminal Justice Section White Collar Crime Committee

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Agenda

I. Enforcement Trends
   A. False Claims Act Trends
   B. Increased Focus on Charging Individuals
   C. Other Theories of Prosecution

II. Resolving Government Investigations
   A. Non-Monetary Remedies – DPA/NPA/Monitor
   B. Biggest Dos/Don'ts
   C. Role of Relator's Counsel

Enforcement Trends: False Claims

- DOJ activity during first half of 2014:
  - Over $2 billion in FCA settlements (not limited to health care matters)
  - Eight major settlements with health care companies
  - Increased focus on naming individuals as defendants in FCA cases

Recent Health Care Industry Settlements

- **Community Health Systems** (Multi-district Aug. 4, 2014) - $98 million to settle multiple *qui tam* lawsuits (overbilling)
  - Includes five-year CIA
- **Medtronic** (D. Cal. May 28, 2014) - $9.9 million to settle kickback allegations
- **Astellas Pharma US Inc.** (E.D. Pa. Apr. 16, 2014) - $7.3 million to settle allegations of off-label promotions and kickbacks
- **Teva/IVAX** (N.D. Ill. Mar. 11, 2014) - $27.6 million to settle kickback allegations relating to a single physician

Recent Health Care Industry Settlements (cont'd)

- **Endo Pharmaceuticals** (Multi-district Feb. 21, 2014) - $192.7 million to settle off-label promotion claims
  - Includes CIA & DPA
- **EndoGastric Solutions** (D. Mont. Feb. 19, 2014) - $5.25 million to settle allegations of false reimbursement advice and kickbacks
  - Includes CIA
- **CareFusion** (D. Kan. Jan. 9, 2014) - $40.1 million to settle allegations of kickbacks and off-label promotion
- **BioScrip** (S.D.N.Y. Jan. 8, 2014) - $15 million to settle allegations of kickbacks under a distribution agreement with Novartis

Health Care Fraud Strike Force

- Part of the Interagency Health Care Fraud Prevention and Enforcement Action Team (HEAT)
- Each team comprises DOJ, HHS, and FBI personnel
- Operates in nine cities
- Over 1,700 defendants charged nationwide with more than $5.5 billion in false Medicare billings
- 2013 saw record prosecution numbers since inception in 2007:
  - 137 cases filed
  - 345 individuals charged
  - 234 guilty pleas
  - 46 jury trial convictions
- Began operating in Chicago in February 2011

Increased Focus on Charging Individuals: Recent Notable Actions in N.D. Ill.

- **John Yousefzai & Armanouhi Arzomanian** (N.D. Ill. July 15, 2014) - Owners of home health care company indicted and arrested on allegations of Medicare fraud and kickbacks
- **Seth Gillman et al.** (N.D. Ill. May 27, 2014) - Owner and three former employees of hospice company indicted on allegations of Medicare and Medicaid fraud
- **Igor Sher & Eguert Nagaj** (N.D. Ill. March 3, 2014) - Chiropractor and physician indicted on allegations of a $2.98 million healthcare fraud scheme
- **Robert Kielar** (N.D. Ill. Feb. 24,2014) - Chicago pharmacist sentenced to seven years for collecting more than $1.7 million through false claims he submitted to insurance companies and stealing the identities of pharmacy customers

Other Theories of Prosecution

- Anti-Kickback Statute
- Food, Drug, and Cosmetic Act (FDCA):
  - Off-label promotion/Misbranding
  - Inspection violations
  - False statements regarding products
- Mail and Wire Fraud

Resolving Government Investigations

- Non-monetary remedies sought during first half of 2014 in health care sector:
  - Three new Corporate Integrity Agreements
  - One Deferred Prosecution Agreement
  - Increased focus on naming individuals in FCA cases
- Biggest Dos/Don'ts
- Role of Relator's counsel in *qui tam* lawsuits
  - Record filings in 2013
  - Relators recovered $345 million
  - Relators' counsel getting more sophisticated and creative

Questions?

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What Should CIAs Be Telling Me?

Using Recent Corporate Integrity Agreements to Inform and Assess Your Compliance Program's Effectiveness

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Timothy J. Throm

Matthew L. Stennes

September 30, 2014
Chicago

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Moderator: Deborah L. Gersh

- Ropes & Gray Partner, Co-Practice Group Leader, Health Care
- Represents healthcare providers, pharmaceutical and medical device companies, managed care plans, private equity investors and practice management companies on sophisticated regulatory and enforcement matters and transactions, including negotiation of and compliance with CIAs
- Advises clients on an array of data privacy, protection and security matters under HIPAA and state privacy, security and data breach notification laws

Panelist: Timothy J. Throm

- Legal Counsel, Performance Solutions, Stryker Corporation
- Responsible for legal affairs and compliance for Stryker's newly created professional services division focused on orthopedic service line development, data analytics and payment reform consulting
- Serves as the corporate-wide subject matter expert on global data privacy compliance for Stryker

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Panelist: Matthew L. Stennes

- Senior Counsel, Global Investigations, Medtronic
- Manages government and high-risk internal investigations
- Previously a trial attorney at the U.S. Department of Justice in the Public Integrity Section, Criminal Division

Agenda

- Background on CIAs
- Relevance of CIAs to Companies Not Under a CIA
- Common Themes from Recent CIAs
  - Structure and Oversight of a Compliance Program
  - Individual Responsibility and Accountability
  - Written Policies and Procedures
  - Monitoring and Auditing
  - Independent Oversight / Third-Party Audits
- Application of CIA Themes to Your Compliance Program
- Nuts and Bolts: How to Use CIAs to Assess Your Compliance Program

Background on CIAs

What are CIAs?

- A contract between a health care company and the HHS-Office of Inspector General (OIG) (or analogous state enforcement authority)
- Requires the company to adhere to certain compliance requirements for the term of the CIA (usually five years)
- A common feature of health care fraud settlements
  - The OIG declines to exercise its exclusion authorities in exchange for the company's agreeing to ongoing compliance and reporting requirements
  - A material breach of the CIA may result in stipulated penalties and exclusion from federal health care programs

Background on CIAs

- CIAs are designed to achieve greater corporate adherence to health care compliance principles and to prevent recurrence of past misconduct
- CIAs are industry-specific
  - Pharmaceutical and device manufacturers
  - Hospitals and health systems
  - Managed care organizations
  - Physicians and physician group practices
- Specific obligations may also differ based on the nature of the conduct giving rise to the settlement (*i.e.*, the "Covered Conduct")

Relevance of CIAs

CIAs offer important lessons for all health care companies about the OIG's expectations for the features of an effective compliance program

- Reflective of the OIG's thinking on best practices for compliance programs by expanding on the "seven elements"
  - Helps companies not under a CIA move toward having a compliance program that reflects the OIG's expectations
  - Helps "benchmark" against what other companies within the industry are doing and answers questions about how other companies approach the seven elements (*e.g.*, What does "monitoring" mean? How does it differ from "auditing"?)
  - Informs the annual risk assessment process
  - Readies an organization should an investigation arise, which may mitigate penalties and help prepare for ongoing mandatory compliance obligations

Common Themes from Recent CIAs

How does your compliance program measure up?

- Structure and Oversight of a Compliance Program
- Individual Responsibility
- Written Policies and Procedures
- Monitoring and Auditing
- Independent Oversight / Third-Party Audits

Common Themes

Structure and Oversight of a Compliance Program

Responsibility for the day-to-day operation of the compliance program should be assigned to Chief Compliance Officer (CCO)

- Centralizing compliance authority in a CCO
  - *Does the CCO's authority have to reside in a single position or person?*
  - *What is the appropriate organizational reporting relationship for a CCO?*
  - *How is the identity of the CCO affected by diversified operations, multiple lines of business or multi-national operations?*

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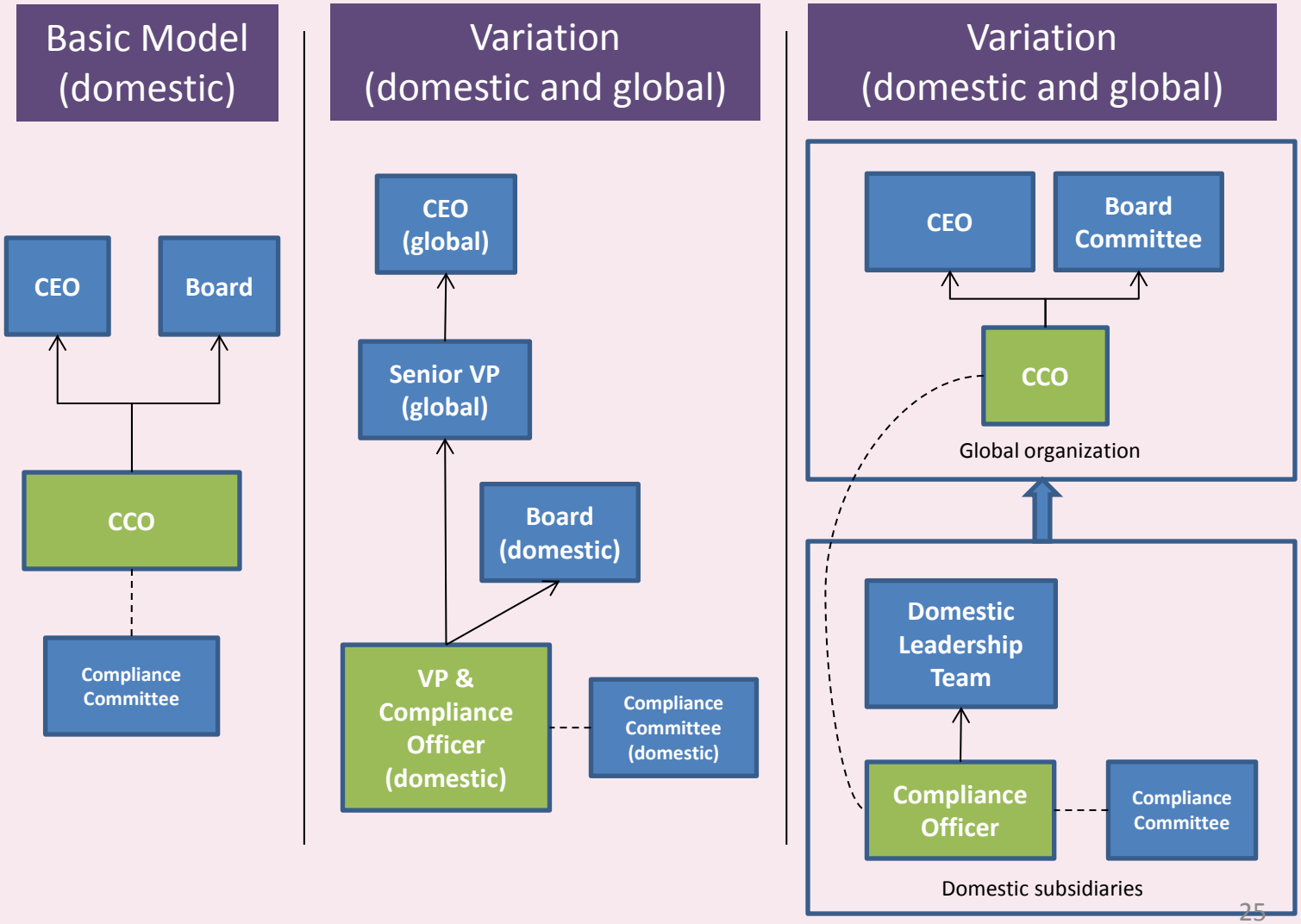
Common Themes

Structure and Oversight of a Compliance Program



Common Themes

Structure and Oversight of a Compliance Program

- Board completion of a separate compliance program assessment
  - Performed independently or through the engagement of an independent advisor
  - Informs annual certification requirement
- Board oversight for the compliance program
  - Delegation of oversight to a Board committee
  - Annual Board resolutions certifying compliance
  - Quarterly reports to the Board (or Board committee) concerning compliance issues

Common Themes

Structure and Oversight of a Compliance Program

- Creation of a Compliance Committee composed of senior company leadership
  - *How many members?*
  - *Who should sit on the Compliance Committee?*
  - *What outputs should the company expect of the Compliance Committee?*
    - *Coordination of efforts among senior compliance employees*
    - *Managerial buy-in of the compliance program*

Common Themes

Individual Responsibility and Accountability

CIAs strive to hold individuals accountable for potential corporate misconduct

- One preferred mechanism is annual certifications of compliance
  - Individual certifications (CCO/CEO required in CIAs spanning all industries)
  - Management certifications
    - Acknowledgment of compliance training by the manager and subordinates
    - Acknowledgment of monitoring and oversight of compliance by department
    - Acknowledgment that department operates in compliance with applicable regulatory requirements
    - Exceptions statement
- Over time, CIAs have varied in the number of certifications that are required

Common Themes

Individual Responsibility – Management Certifications

Requirement	Implication
Acknowledgment of compliance training	Managers are responsible for ensuring subordinates are trained; highlights importance of training
Acknowledgment of monitoring and oversight	Managers participate in the compliance program and are directly responsible for compliance
Department operates in compliance with federal and state laws	Strategic objectives are aligned with legal requirements and support the compliance program
Exceptions statement	Informs compliance organization of any overlooked issues

<u>Emerging Trend</u>

False managerial certifications can result in a clawback or recoupment of executive compensation

September 17, 2014 Remarks by DOJ Attorney Marshall Miller

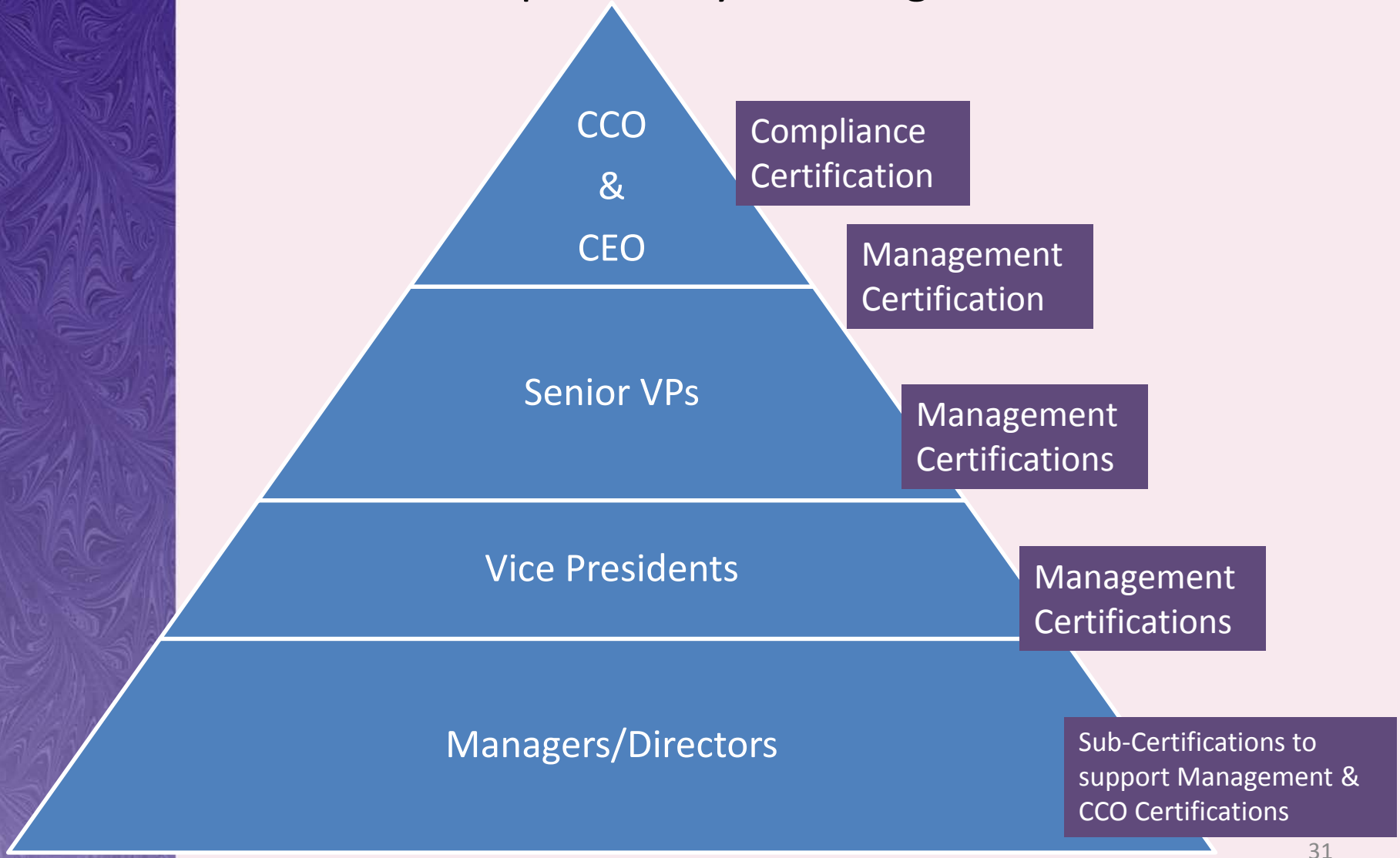
- Criminal Division of the DOJ using tools like wiretaps, body wires, physical surveillance in connection with investigations of companies
- Notes importance of cooperation with criminal investigations likelihood of a lesser penalty

> "If you want full cooperation credit, make your extensive efforts to secure evidence of individual culpability the first thing you talk about when you walk in the door to make your presentation."
>
> "Make securing evidence of individual culpability the focus of your investigative efforts so that you have a strong record on which to rely."[1]

[1] Remarks found at: http://www.justice.gov/criminal/pr/speeches/2014/crm-speech-1409171.html

Common Themes

Individual Responsibility – Management Certifications



Common Themes

Policies and Procedures

Companies under CIAs are required to maintain a Code of Conduct and certain written policies and procedures to govern operational areas

- CIAs provide insight on the OIG's thinking of which business areas a company's policies and procedures should address
- CIAs usually expand on what existed previously
- The policies and procedures required by a CIA are not limited to the conduct giving rise to a CIA

Common Themes

Policies and Procedures: Pharmaceutical/Device

- Recent pharmaceutical and device manufacturer CIAs require policies regarding
  - Materials used by sales reps and requests for information about off-label uses
  - Sponsorships, grants and charitable contributions
  - Incentive compensation for sales reps

Common Themes

Policies and Procedures: Pharmaceutical/Device

- Possible emerging trends:
  - Social media and direct-to-consumer advertising policies
  - Recoupment of employees' annual performance pay if compliance issues are detected

Common Themes

Policies and Procedures: Hospitals

Hospital CIAs are generally narrower regarding policy requirements

- The list of required policies ties more closely to the conduct that led to the CIA
- Examples include:
  - Billing and reimbursement
  - Clinical and quality issues
  - Stark Law and Anti-Kickback Statute

Common Themes

Monitoring and Auditing

- Monitoring and auditing has traditionally been the most difficult compliance program element to conceptualize and implement
  - *How is monitoring different from auditing?*
  - *Should monitoring be live, paper-based or both?*
  - *What is the frequency of certain monitoring activities?*
  - *How should monitoring findings inform the larger compliance program?*
- Most pharmaceutical manufacturer CIAs require monitoring of specific business activities in the field and at headquarters
  - **Field monitoring requirements**: Ride-alongs with sales reps, attendance at speaker programs, record reviews of sales reps' interactions with health care professionals
  - **Headquarters-based monitoring requirements**: Review of consulting arrangements, publication activities and certain types of research studies

Common Themes

Monitoring and Auditing

- Hospital CIAs are less prescriptive regarding monitoring and auditing requirements
  - Monitoring requirements, when included, do not address specifics such as frequency and sampling
  - Some hospital CIAs contain specific requirements for monitoring arrangements with health care professionals for Anti-Kickback Statute or Stark Law compliance
  - CIAs focused on conduct related to quality of care may require a hospital to engage quality experts for monitoring purposes

Common Themes

Monitoring and Auditing

- Monitoring should be in real time and designed to provide the Board and senior management with a current view of key compliance metrics
- Monitoring activities should reflect risk-based areas as determined by senior management
- CIAs also include other information helpful in structuring monitoring activities
  - *Who should conduct monitoring?*
  - *What information should monitoring reports contain?*
  - *How often should monitoring be performed?*

Common Themes

Independent Oversight / Third-Party Audits

Regardless of industry, CIAs typically require the company to engage an independent review organization (IRO)

- Ensures regular independent reviews of compliance program implementation
- The IRO's function is instructive to companies not under a CIA:
  - The IRO provides an independent assessment of a company's compliance program and related systems
  - The focus of the IRO is to ensure that identified risks are addressed and mitigated

Common Themes

Independent Oversight / Third-Party Audits

- Recent pharmaceutical and device manufacturer CIAs have fairly standard IRO requirements, with variations based on the conduct that led to the CIA
  - **Compliance Systems:** Standard requirement; the internal controls that are designed to ensure compliance
  - **Identified Risk Areas:** Variable; relates to the conduct at issue, such as off-label promotion or price reporting
- Some recent hospital CIAs include unallowable cost reviews, validation reviews and claims reviews
  - One hospital's IRO must review a discovery sample for inpatient medical necessity, and, depending on those results, a full sample
  - Another hospital must engage both a billing IRO *and* a Quality Review Organization

Application of CIA Themes

By internalizing requirements outlined in recent CIAs, companies can strengthen their compliance programs

- Individual Accountability
  - *Management* – Consideration of ways to achieve managerial buy-in, especially if state law requires an organizational certification (*e.g.*, New York)
  - *Board* – Board and senior management should consider whether compliance reports to the Board provide sufficient information to discharge fiduciary duties related to compliance program oversight
- Strong and Well-Developed Policies and Procedures
  - Achieve best practices by comparing current policies and procedures to those mandated by CIAs in your industry
  - The detail provided in CIAs can be used to bolster current practices

Application of CIA Themes

- Monitoring and Auditing
  - Review the types of monitoring and auditing required by recent industry CIAs to determine whether adjustments are needed in your program
- Independent Reviews / Third-Party Audits
  - Beyond internal auditing, consider whether a periodic assessment by an independent auditor or compliance expert is worthwhile
  - Such reviews may help the Board discharge its fiduciary duties
- Other instructive areas
  - Training (recipients, certifications, content, duration)
  - Code of Conduct
  - Exclusion check process and frequency
  - Disclosure program components

Application of CIA Themes

Be mindful of trends in CIAs

- CIAs reflect how the OIG's thinking on compliance programs has evolved
- Be careful not to over apply – the latest may not be the greatest
  - Some CIA elements reflect *only* the conduct giving rise to the CIA
  - Some CIA elements reflect esoteric company processes
  - Some CIA elements may not appropriately balance benefits and costs (*e.g.*, email monitoring, executive recoupment)
  - Some CIA elements may reflect an emerging trend that is not likely to "stick"
- But, be very careful not to under apply

Questions?

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