Regulatory Developments Informing Compliance Programs & Lessons Learned from CIAs

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AGENDA

I. Office of Inspector General (OIG) Board of Directors Guidance

II. Yates Department of Justice (DOJ) Memorandum

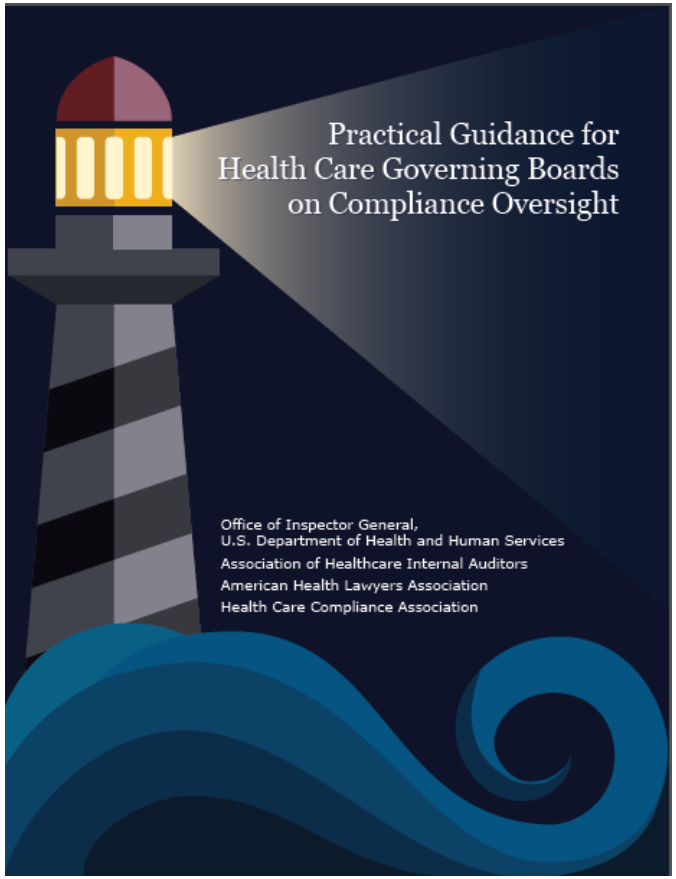
III. Lessons Learned from Recent Enforcement

IV. Key Corporate Integrity Agreement (CIA) Trends

V. Compliance Officer / General Counsel Dual Role Key Considerations

OIG Board of Directors Guidance

- Issued in April 2015 by the OIG in conjunction with the American Health Lawyers Association (AHLA), the Association of Healthcare Internal Auditors (AHIA) and the Health Care Compliance Association (HCCA)
- Supplements guidance related to Board of Director oversight previously issued by the OIG in 2003, 2004 and 2007



OIG Board of Directors Guidance

- "Previous guidance has consistently emphasized the need for Boards to be **fully engaged** in their oversight responsibility."
- "A critical element of effective oversight is the **process of asking the right questions of management** to determine the adequacy and effectiveness of the organization's compliance program, as well as the performance of those who develop and execute that program, and to **make compliance a responsibility for all levels of management**."
- ". . . this document seeks to provide **practical tips** for Boards as they work to effectuate their oversight role of their organizations' compliance with State and Federal laws that regulate the health care industry."

OIG Board of Directors Guidance

- Expectations for Board Oversight of Compliance Program Functions
  - Board must “act in good faith in the exercise of its oversight responsibility”
  - Benchmarks/baseline assessment tools = Federal Sentencing Guidelines, OIG’s voluntary compliance program guidance documents, OIG CIAs
- Roles and Relationships
  - Organizations should define in charters and other organizational documents the structure, reporting relationships, interactions, and interrelationship of the audit, compliance, legal, quality, risk management, and/or human resources functions as departmental roles and responsibilities are defined
  - Boards should be aware of, and evaluate, the adequacy, independence, and performance of different functions within an organization on a periodic basis

OIG Board of Directors Guidance

- Reporting to the Board
  - Board should set and enforce expectations for receiving particular types of compliance-related information from various members of management
  - Board should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently—from a variety of key players
- Identifying and Auditing Potential Risk Areas
  - Board should ensure that management and the Board have strong processes for identifying risk areas identified from internal or external information sources
  - Board must ensure that management not only reviews and audits risk areas, but also develops, implements, and monitors corrective action plans
  - Aware of emerging/recent industry trends

OIG Board of Directors Guidance

- Encouraging Accountability and Compliance
  - Methods to ensure industry-wide compliance, such as compliance assessments to withhold incentives or provide bonuses, participation in annual incentive programs contingent on satisfactorily meeting annual compliance goals, employee and executive compensation claw-back/recoupment provisions if compliance metrics not met.
  - Management certifications
  - Voluntary self-disclosure processes

Yates DOJ Memo

- In September 2015, Deputy Attorney General (AG) Sally Quillian Yates issued a memorandum to DOJ attorneys
  - Discusses the need to hold individuals accountable for corporate wrongdoing in both civil and criminal enforcement actions
  - “it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom.”
- Process changes apply to all future civil and criminal investigations, as well as any current investigations to the extent practicable
- Although public statements by the DOJ regarding the need for increased individual enforcement are not new, the Yates memo represents a key shift by putting into place a specific framework to actively pursue individual enforcement actions in parallel with investigations of corporate misconduct

Yates DOJ Memo

- 6 key steps for pursuing individual enforcement actions:
  1. **To be eligible for any cooperation credit, corporations must provide to the DOJ all relevant facts about the individuals involved in corporate misconduct**
     - Companies seeking credit for cooperation will not be eligible until they satisfy the "threshold requirement" of "identify[ing] all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority", and provide all facts related to that misconduct
  2. **Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation**
     - DOJ "maximize[s] the chances that the final resolution of an investigation uncovering the misconduct will include civil or criminal charges against" both the corporation and culpable individuals

Yates DOJ Memo

- 6 key steps for pursuing individual enforcement actions: (cont.)

3. **Criminal and civil attorneys handling corporate investigations should be in routine communication with one another**
    - Yates memo highlights the importance of regular communication between criminal and civil DOJ attorneys to ensure that parallel civil and criminal proceedings are pursued, when appropriate, against both corporations and individuals
4. **Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals**
    - Any such release of individual liability must be personally approved in writing by the relevant Assistant AG or United States Attorney

Yates DOJ Memo

- 6 key steps for pursuing individual enforcement actions: (cont.)
  5. **Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized**
     - Any such declination must be approved by the United States Attorney or Assistant AG whose office handled the investigation, or their designees
  6. **Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay**
     - Dual interest in returning funds to public fisc, deterring future misconduct
     - Individual suits should be considered regardless of an individual's ability to pay any settlement amounts because such actions "will result in significant long-term deterrence" and "minimize losses to the public fisc through fraud" over time

Lessons Learned from Recent Enforcement

- In February 2015, HHS and DOJ issued their Health Care Fraud and Abuse annual report for FY2015
- Key numbers:
  - ~$2.4 billion recovered for federal fisc and relators
  - 983 new criminal and 808 new civil health care fraud investigations opened by DOJ
  - 1,048 civil health care fraud matters pending at the end of the fiscal year

Monetary Results: Total Transfers/Deposits by Recipient FY 2015	
Department of the Treasury	
Deposits to the Medicare Trust Funds, as required by HIPAA	
Gifts and Bequests	$10,372
Amount Equal to Criminal Fines	56,549,115
Civil Monetary Penalties	45,772,271
Asset Forfeiture	14,791,644
Penalties and Multiple Damages	512,054,108
Subtotal	**629,177,509**
Centers for Medicare & Medicaid Services	
HHS-OIG Audit Disallowances — Recovered - Medicare	132,612,502
Restitution/Compensatory Damages	793,934,739
Subtotal*	**926,547,241**
Grand Total of Amounts Transferred to the Medicare Trust Funds	**$1,555,724,750**
Restitution/Compensatory Damages to Federal Agencies	
HHS/Other	$31,355,848
TRICARE	14,921,254
CMS	8,253,589
HHS-OIG Cost of Audits, Investigations and Compliance Monitoring	7,766,281
Other Agencies	18,200,774
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	135,866,585
HHS-OIG Audit Disallowances — Recovered - Medicaid	168,955,572
Subtotal	**385,319,903**
Relators' Payments**	**414,456,455**
TOTAL***	**$2,355,501,108**

*Restitution, compensatory damages, and recovered audit disallowances include returns to both the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.
**These are funds awarded to private persons who file suits on behalf of the Federal Government under the qui tam (whistleblower) provisions of the False Claims Act, 31 U.S.C. § 3730(b).
***State funds are also collected on behalf of state Medicaid programs; only the Federal share of Medicaid funds transferred to CMS are represented here.

Lessons Learned from Recent Enforcement

- Daiichi Sankyo (Jan. 2015)
  - Focus on speaker programs, including HCPs that took turns speaking on duplicative topics
  - "Lavish meals" that exceeded DSI's own internal limitation of $140/person
- Novartis (Nov. 2015) & AstraZeneca (Feb. 2015)
  - Focus on kickbacks paid to pharmacies and PBMs in the form of rebates, discounts and price concessions in exchange for switching patients from a competitor product or listing a company's product as the "sole and exclusive" product on a PBM formulary
- NuVasive (July 2015)
  - Focus on relationships with "independent" organizations that are used to provide remuneration in the form of promotional speaker fees, honoraria and expenses for HCPs' attendance at events

Key CIA Trends

- Global corporate reach (example: Sanofi CIA (effective 9/2/15))

> are engaged in or who supervise personnel who are engaged in Promotional and Product Services Related Functions, and all employees of Sanofi or of any foreign subsidiary of Sanofi who are based outside the United States and who are engaged in or who supervise personnel who are engaged in Promotional and Product Services Related Functions; and

Key CIA Trends

- Board of Directors
  - Independent, non-executive Board member
  - Annual Board resolution (example: Sanofi CIA (effective 9/2/15))

> "The Board of Directors has made a reasonable inquiry into the operations of Sanofi's North America Compliance Program during [add reference to time period], including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Sanofi has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

  - Training = General Training + 2 hours of Board training on Board responsibilities and corporate governance

Key CIA Trends

- Management Certifications
  - Broad scope: President/CEO, marketing, sales, medical, regulatory, all other business units that perform Promotional or Product Services Related Functions
  - Annual resolution (example: Sanofi CIA (effective 9/2/15))

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Sanofi Policies and Procedures, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Sanofi is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

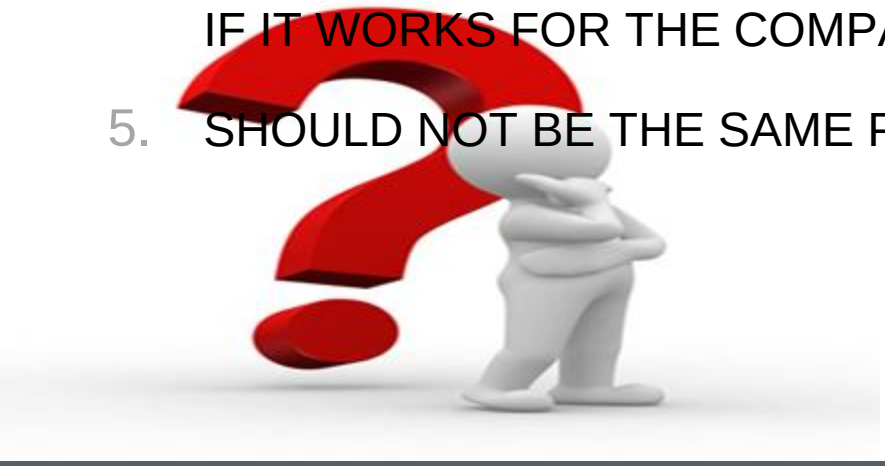
Key CIA Trends

- Corporate Assessment and Risk Evaluation Process
  - Compliance, Legal, business unit leaders
  - Process to identify and assess risks associated with government reimbursed products, including unapproved uses, misbranded products, adulterated devices, other healthcare compliance risks
    - Baseline activity risk
    - Audit history
    - Spend risk
    - Product risk
  - Centrally develop and implement audit plans to address identified risk areas

Thought Question

THE OIG BELIEVES THAT THE COMPLIANCE OFFICER AND GENERAL COUNSEL . . .

1. IDEALLY SHOULD BE THE SAME PERSON
2. CAN BE THE SAME THE PERSON IN A SMALLER ORGANIZATION, BUT SHOULD BE DIFFERENT PEOPLE IN A LARGER ORGANIZATION
3. CAN BE THE SAME PERSON IN A LARGER ORGANIZATION, BUT SHOULD BE DIFFERENT PEOPLE IN A SMALLER ORGANIZATION
4. CAN BE THE SAME PERSON IN A SMALLER OR LARGER ORGANIZATION IF IT WORKS FOR THE COMPANY
5. SHOULD NOT BE THE SAME PERSON IN ANY SIZE ORGANIZATION



Compliance Officer / General Counsel Dual Role Key Considerations

- OIG has expressly stated that the Compliance Officer and General Counsel roles should be separate
  - Example: Sanofi CIA

> any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of any Sanofi entity. Accordingly, the Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of Sanofi US and the General Counsel or Chief Financial Officer of Genzyme. The Compliance

  - OIG Board of Directors Guidance
    - "OIG believes an organization's Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner. While independent, an organization's counsel and compliance officer should collaborate to further the interests of the organization. OIG's position on separate compliance and legal functions reflects the independent roles and professional obligations of each function; . . . the compliance, legal, and internal audit functions should have access to appropriate and relevant corporate information and resources. As part of this effort, organizations will need to balance any existing attorney-client privilege with the goal of providing such access to key individuals who are charged with the responsibility for ensuring compliance . . ."

Compliance Officer / General Counsel Dual Role Key Considerations

Cooley LLP

Compliance Officer / General Counsel Dual Role Key Considerations

Cooley LLP

- ✓ Document the reason(s) for combining the roles and responsibilities of CO/GC
- ✓ Draft a formal, written job description for each role
- ✓ Careful consideration should be given to matters that may be subject to the attorney-client privilege and/or the work product doctrine
  - Cannot/should not assume that all work performed by a CO/GC is subject to applicable legal privileges
  - Careful analysis should be made and documented for each appropriate matter
- ✓ Consider the use of outside legal counsel for privileged and other sensitive matters where there is or may be a conflict between an individual serving both CO/GC

Compliance Officer / General Counsel Dual Role Key Considerations

Cooley LLP

- ✓ Consider the title under which documents, including e-mail and other communications, are signed
  - Should a document be signed under the title of CO, GC or both titles jointly?
- ✓ Maintain separate working files for CO vs. GC
  - Clear delineation between work that is done in a legal capacity to assist with maintaining the appropriate privilege(s)
- ✓ If a report is made to the CEO, Board of Directors, Compliance Committee and/or other senior management, the report should be made under CO role
  - Consistent with the OIG's expectation that the CO will have access to senior management and make periodic reports regarding corporate compliance matters
  - Ensure that Board and Compliance Committee know and understand that the report is being made under the CO role and not protected by any legal privileges without separate legal counsel

Compliance Officer / General Counsel Dual Role Key Considerations

Cooley LLP

- ✓ Consider a formal process for CO/GC to recuse him/herself from oversight responsibilities for a compliance audit or investigation that may relate to legal advice provided in his/her role as GC
  - Independent assessment

KEY RESOURCES

Cooley LLP

- Cooley Health Beat Blog
  - www.cooleyhealthbeat.com
- CMS Sunshine FAQs Tracker
  - http://cooleyhealthbeat.com/resources/
- Pharmaceutical/Medical Device Select Public Settlements Tracker
  - http://cooleyhealthbeat.com/resources/
- Select HIPAA Privacy & Security Enforcement Actions Tracker
  - http://cooleyhealthbeat.com/resources/
- Links to Key Health Regulatory Resources
  - http://cooleyhealthbeat.com/resources/

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