

Health Care Compliance Association  
21<sup>st</sup> Annual Compliance Institute  
March 28, 2017

**“COMPLIANCE, THE C-SUITE, AND THE BOARD OF DIRECTORS: WHAT TO REPORT AND HOW?”**

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**OIG Issuances**

- Annual Work Plan
- Compliance Program Guidances (CPGs)
- Fraud Alerts, Special Advisory Bulletins
- Corporate Integrity Agreements (CIAs)
- “Compliance 101” Educational Materials and Podcasts

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### Prior Board Guidance

- *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007)
- *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors* (2004)
- *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (2003)

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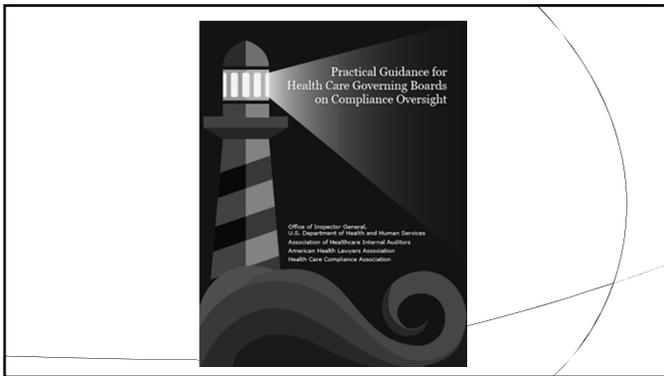
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### OIG: *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (April 2015)

- Board must act in good faith in the exercise of its oversight responsibility, including making inquiries to ensure:
  - A corporate information & reporting system exists and
  - The reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course

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### OIG Guidance to Boards

- Ensure that management is aware of the Guidelines, compliance program guidance, and relevant CIAs
- Ensure that Board members are periodically educated on the organization's highest risks
- Develop a formal plan to stay abreast of changing regulatory landscape and operating environment

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### OIG Guidance to Boards

- Add to Board, or periodically consult with, experienced regulatory, compliance, or legal professional
- Receive compliance & risk related information in a format sufficient to satisfy the interests or concerns of members and to fit their capacity to review that information

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### OIG Guidance to Boards

- Consider conducting regular "executive sessions" (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication
- Risk areas include referral relationships and arrangements, billing problems (e.g., upcoding, submitting claims for services not rendered and/or medically unnecessary services), privacy breaches, and quality-related events

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### OIG Guidance to Boards

- When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within organizations
- Monitor new areas of risk: increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement

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### OIG Guidance to Boards

- Boards of entities that have financial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws
- Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments (60 day repayment rule)

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### Sample Board Certification

"The Board of Directors has made a reasonable inquiry into the operations of Center's Compliance Program 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, Center has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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### Sample Management Certification

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [department] with all applicable Federal health care program requirements, obligations of the CIA, and Center's policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [department] is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

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### Government's Interest in Individuals' - Impact on C-Suite and Boards of Directors

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### Government's Ongoing Interest in Individual Culpability is Not New

**Criminal Trials of Former Health-Care Executives Set to Begin**

**Former top WellCare execs sentenced to prison in fraud case**  
By Rachel Lunden | May 19, 2014



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**Government's Ongoing Interest in Individual Culpability is Not New**

- InterMune
- Wellcare
- Bostwick Laboratories
- GlaxoSmithKline
- Tenet Healthcare
- Purdue Pharma

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**InterMune**

- In 2006, InterMune resolved civil and criminal liability
  - \$37M penalty
  - Deferred Prosecution Agreement
  - 5 Year Corporate Integrity Agreement
- In 2009, InterMune's then CEO, Scott Harkonen, was convicted of felony wire fraud
- In 2011, OIG notified Harkonen of mandatory exclusion for 5 years

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**Wellcare**

- In 2009, WellCare entered into a Deferred Prosecution Agreement
  - Also paid \$40 million in restitution and forfeited an additional \$40 million
- In 2012, WellCare paid an additional \$137.5M to settle allegations under the False Claims Act
- U.S. Attorney's office also pursued criminal charges against several former Wellcare employees, including former CEO Todd Farha and former CFO Paul Behrens

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### Bostwick Laboratories

- In 2013 and 2014, Bostwick settled two matters for an aggregate \$6.5M to resolve allegations of violating the Federal False Claims Act by offering kickbacks to physicians in exchange for referrals

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### The Yates Memo

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### Pre-Cursors to the “Yates Memo”

- 1999 Holder Memo – “Bringing Criminal Charges Against Corporations”
  - Framework for prosecutors
  - Emphasized taking action against individuals
- Thompson Memo
- McNulty Memorandum
- Filip Memo

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# The Yates Memo



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## Policy 1

*To be eligible for **any** cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct*

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## Policy 2

*Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation*

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DOJ's Civil and Criminal Divisions - Working Together

- Assistant Attorney General for the Criminal Division, Leslie Caldwell, September 17, 2014:

"[e]xperienced prosecutors of the Fraud Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open up a parallel criminal investigation. Those prosecutors then coordinate swiftly with the Civil Division and U.S. Attorneys Office as to the best ways to proceed in parallel investigations ".

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Policy 3

*Criminal and civil attorneys handling corporate investigations should be in routine communication with one another*

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Policy 4

*Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for individuals*

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Policy 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 individual in such cases must be memorialized*

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Policy 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*

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**Acting Associate AG Baer –  
Remarks of June 9, 2016**

- ⦿ Individual accountability applies with equal force and logic to the department's civil enforcement
- ⦿ Holding individuals accountable for corporate wrongdoing – even through civil enforcement actions – provides a powerful deterrent against future misconduct
- ⦿ Department attorneys to make sure they are examining the potential liability of individual actors at the outset of an investigation into corporate wrongdoing
- ⦿ Reaching a resolution with the company does not end the inquiry into whether and which individuals should also be pursued
- ⦿ Do not assume individuals will be released from FCA liability in corporate settlement

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**Acting Associate AG Baer –  
Remarks of June 9, 2016**

- Implications that civil accountability for corporate executives hold for companies seeking cooperation credit:
  - Disclosure expected of all facts relating to individuals involved, regardless of hierarchy
  - There is nothing in the individual accountability policy that requires companies to waive attorney-client privilege
  - Cooperation does not require a company to characterize anyone as "culpable"
  - Timing is of the essence. A company should come in as early as possible
  - Prompt voluntary disclosure by a company is viewed favorably
  - A thorough defense investigation may result in better negotiated resolutions

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**The Yates Memo In Action**

- 10/29/15 - DOJ announces Warner Chilcott's agreement to pay \$125 million to resolve criminal and civil liability arising from alleged illegal marketing of certain drugs.
- Same day, DOJ announces the indictment of W. Carl Reichel, a former Warner Chilcott president, with conspiring to pay kickbacks to physicians to induce them to prescribe the company's drugs.
- DOJ Press Release: "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."
- June 17, 2016 – after two days of deliberations – the jury acquitted Reichel.

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**The Yates Memo In Action**

- 12/1/15  
**Osceola Laboratory and Founders agrees to pay \$8.5 million to resolve false billing case**
- 12/18/15  
**Splint supplier and its president to pay over \$10 million to resolve False Claims Act allegations**

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### The Yates Memo In Action

9/19/16

**North American Health Care Inc. to pay \$28.5 million to settle claims for medically unnecessary rehabilitation therapy services**

Chairman of the Board and Senior Vice President of Reimbursement Analysis to pay an additional \$1.5 million

1/26/17

**Former Executive of Tenet Healthcare Corporation Charged for Alleged Role in \$400 Million Scheme to Defraud**

Among other things, alleges false and fraudulent statements to HHS-OIG in connection with Tenet's 2006 the CIA, including falsely certifying compliance with the terms of participation in the Medicare and Medicaid Programs, and the terms of the CIA

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### Ralph J. Cox III (September 2016)

- Former CEO of Tuomey Healthcare System
- \$1 million settlement and four-year exclusion
- Exclusion extends to management or administrative services paid for by federal health care programs

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### DOJ's Criminal Fraud Division and Compliance

#### "Evaluation of Corporate Compliance Programs"

- Acquisition Due Diligence
- Root Cause Analysis
- *Board and Senior Management Involvement: The DOJ wants to see that the company's top management and board are committed to compliance and involved in (a) adequately funding and monitoring the compliance program, (b) remediation of identified noncompliance, (c) direct reporting from the compliance officer, and (d) access to outside auditors and experts.*
- Dedication to Compliance
- Robust Auditing

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### Communicating with the Board

- ⦿ Not everything is a burning platform
  - Don't sweat the small stuff
- ⦿ Know when to provide the 30,000 foot view vs. highlight the REAL risks
- ⦿ When do you run to Board of Managers about a compliance issue and bypass your C-suite?
- ⦿ When do you spend the money and make the call to outside counsel?

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### I think I have a problem, now what do I do?

- ⦿ Confirm the "problem"
- ⦿ Is it a regulatory issue or business decision
  - Who needs to know?
  - Which stakeholders should be involved?
  - Should my organization's legal team be involved?
  - Do you need to consult with outside counsel?
- ⦿ How do you document your investigation and your recommendations?
- ⦿ Weigh the exposure risks to the organization

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### Forming an action plan

- ⦿ Can you direct how the investigation should be conducted?
  - Who to bring into the investigation?
  - How deep to look into the problem?
  - Can you limit what time frame to investigate?
  - Who should be making these decisions?
  - Do you bring your Board into the decision making process?

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### How do I weigh the risks to my organization?

- ⦿ Each step along the way there are business decisions to be made
- ⦿ Weighing the business risk:
  - What's the cost?
    - patient safety
    - regulatory risks
    - reputation (yours and your employer's)
  - Whose job is it to weigh the risk?
  - What's your duty as CO if you don't agree?

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### Briefing The Board

- ⦿ When communicating – **GET/KEEP their attention**
- ⦿ Focus on the "high risk" compliance issues that will impact the business (don't sweat the small stuff)
- ⦿ Identify how compliance issues may impact the organization AND them personally
- ⦿ Provide real numbers/demonstrate real impact
- ⦿ Highlight industry trends and enforcement actions that may impact the business

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### Briefing Leadership

- ⦿ Show examples of other organization / Board Of Mangers who are similarly situated
- ⦿ Be selective on what documentation / handouts you provide
- ⦿ Don't forget attorney-client privilege
- ⦿ Be mindful of their time
- ⦿ Show your progress and success stories, and positive impact on the business
- ⦿ Don't surprise your C-suite

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### Understand your role in the organization

- ⦿ Know your scope of authority in your organization
- ⦿ Remember that compliance is interdisciplinary and should be enterprise-wide
- ⦿ Understand your organization's appetite for risk vs. potential exposure to liability
- ⦿ Consider what is a legal decision and what is acceptable business risk
- ⦿ The less your hair is on fire, the more effective you will be

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### Practical Tips

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#### PRACTICAL TIP 1

##### ***If You Haven't Heard ... Make Sure Your Organization Has an Effective Corporate Compliance Program***

- ⦿ An Effective Compliance Program's Goal is to ferret out improper conduct
- ⦿ Investigators are asking for information about organizations' Corporate Compliance Programs
- ⦿ Proactively Have Third Parties Verify the Program's "Effectiveness"
  - OIG CIA's are now requiring external reviews

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PRACTICAL TIP 2

***Maintain and Protect the Privileges, But Keep in Mind that Internal Investigations May Be Shared with the Government***

- ⦿ Attorney Client Privileged Communications
- ⦿ Attorney Work Product Doctrine
- ⦿ DOJ does not require waiver of privileges BUT may be encouraged and ultimately the corporate officers and directors may choose to waive privilege

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PRACTICAL TIP 3

***Review Coverage and Indemnification Provisions***

- ⦿ Review D&O Insurance Policy to determine extent of coverage (and any limitations that may apply)
- ⦿ Review corporate policies and employment agreement and obligations to indemnify and exclusions that may apply

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PRACTICAL TIP 4

**Toolkit for Health Care Boards**

- ⦿ Evaluate the Compliance Program
  - Ask questions that assess the compliance program
  - Protect the compliance officer's independence by separating the role from legal counsel and other senior management
  - Learn how quality, patient safety and compliance information flows to the board
  - Ensure that the organization can validate the accuracy of its quality data
  - Talk to employees
  - Perform self-assessments

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**PRACTICAL TIP 4 - CONTINUED**  
**Examples of Structural Questions**

- How is the compliance program structured and who are the key employees responsible for its implementation and operation?
- How is the Board structured to oversee compliance issues?
- How does the organization's compliance reporting system work?
- How frequently does the Board receive reports about compliance?
- Does the compliance program address the significant risks of the organization?

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**PRACTICAL TIP 4 - CONTINUED**  
**Examples of Operational Questions**

- How has the Code of Conduct been incorporated into corporate policies across the organization?
- Has management taken affirmative steps to publicize the importance of the Code to all its employees?
- Does the Compliance Officer have sufficient authority to implement the compliance program?
- How is the Board kept apprised of significant regulatory and industry developments?
- Does the organization have policies that address the appropriate protection of whistleblowers?
- Are the board and senior management working to foster a culture of compliance?

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**QUESTIONS?**



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