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Criminal, Civil, and Administrative Enforcement Developments and Compliance Professionals

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General Expectations of Boards

- Understand member role and responsibilities
- Awareness of the complexity of health care laws and regulations governing provision of care and reimbursement of services
- Provide advisory oversight and direction

What is the Basis for Boards' Need to Know?

- Why does the government focus on Board involvement?
- What federal "*written document*" specifically details Board oversight?
- How are Boards educated about regulatory issues?
- What specific regulations should the Board be aware of, if any?

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What are the Obligations of the Board of Directors?

Two Primary Obligations

1. **Decision-making function**
   Applying duty of care principles to a specific decision or board action

2. **Oversight function**
   Applying duty of care principles with respect to the general activity in overseeing the day-to-day business activities of the organization, including compliance oversight.

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What is "Duty of Care"?

Fiduciary duty of care involves the determination of whether the board of directors has acted:

- In good faith
- With the level of care that an ordinary prudent person would exercise under the circumstance
- In a manner that they reasonably believe is in the "best interest" of the organization

Embedded in duty of care is the concept of "reasonable inquiry" and avoidance of conflict of interest and self dealing.

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Compliance Program Focus Areas for the Board of Directors

Structural

- Understanding the scope of CP

Operational

- Understanding of the operations and funding of the CP

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Board Oversight Structure

Determine whether compliance program oversight will be assigned to the full board or to a sub-committee, e.g., compliance, quality or audit committee.

Role of the sub-committee

- Ensure that appropriate policies and procedures are in place to preserve and safeguard the organization's assets
- Ensure proper ethical and legal standards are present and maintained in meeting with all applicable laws, rules and regulations
- Monitor compliance with applicable laws, rules and regulations

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Board's Responsibilities

- Understand the organization's internal reporting system;
- Determine if the structure of the organization's CP is appropriate to the size and complexity of the operations
- Determine whether there is the level of compliance resources available to the compliance function to adequately address the identified compliance risks
- Ensure the compliance officer (CO) has the authority to act?
- Ensure compliance reports are received from the CO?

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Compliance Program Oversight by the Board of Directors

- Are there periodic compliance risk assessments with subsequent prioritization of identified risks and an action plan to mitigate those risks?
- Is there a compliance audit and monitoring plan?
- Are there appropriate policies, procedures or other internal controls to address potential risks?
- Is there open communication or is there fear of retaliation?

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Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices

- Congressional and Executive Branch officials concerned that organizations are considering fines and penalties and Deferred Prosecution and Corporate Integrity Agreements as the cost of doing business and not deterring fraudulent and abusive conduct.
- Consequently recent enforcement actions target organization executives for criminal, civil and administrative liability based on organizational misconduct
  - Assumption is that organizational misconduct cannot occur without individual involvement
  - What individuals are responsible for organizational misconduct?
  - Responsible Corporate Officer Doctrine

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Responsible Corporate Officer Doctrine

- *U.S. v. Dotterweich and U.S. v. Park* (1975) originally established Responsible Corporate Officer Doctrine
- Corporate misconduct and violations of law can result in conviction of organization executives without individual involvement in wrongdoing or even knowledge that wrongdoing was taking place.
  - Recent application in cases involving violations of law which protects the health and safety of Medicare and Medicaid Program beneficiaries (i.e. Purdue Frederick, Inc. – promotion of "off-label" use of Oxycontin).

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Responsible Corporate Officer Doctrine
(Cont'd.)

  - Individual criminal (i.e. plea to misdemeanor conviction), civil (i.e. individual multi million dollar fines) and administrative (Federal health program exclusion) liability for CEO, GC and CMO.
- Individual criminal, civil and administrative liability against Purdue executives not based on personal involvement or even knowledge of organization wrongdoing.
- Based on Responsible Corporate Officer doctrine where each executive had "responsibility and authority to prevent or to promptly correct the organizational misconduct."

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Responsible Corporate Officer Doctrine and Program Exclusion

- Responsible Corporate Officer Doctrine – Strict liability application-without need for establishing personal involvement in wrongful conduct-criminal and administrative liability-misdemeanor and exclusion
- Pharma and Medical Device Industry for violations of Food, Drug & Cosmetics Act (Purdue Frederick and Synthes, Inc.)
- Exposure for health care organization and Board Member and upper level management.
  - Responsibility for and authority to prevent or correct non-compliant activity.

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Responsible Corporate Officer Doctrine and Program Exclusion

- Federal Health Care Program Exclusion also based on Responsible Corporate Office Doctrine
  - No knowledge of or participation in core activity
  - Twelve year exclusion of CEO, GC, CMO upheld. See *Friedman v. Sebelius,* 2010 U.S. Dist. Lexis 131465 (D.D.C. December 13, 2010)
- Board Members – knew or should have known; Manager-strict liability

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Responsible Corporate Officer Doctrine and Program Exclusion **(Cont'd.)**

- Sufficient nexus and common sense connection to misconduct
- Individual exclusion liability based solely on position in organization hierarchy
- See Criteria for Implementing Permissive Exclusion Authority under Section 1128(b)(7) of the Social Security Act; available at: **http://oig.hhs.gov/fraud/exclusions/asp**. April 18, 2016

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Broad Application and Additional Actions Against Individuals

- Criminal, civil and administrative liability based on Responsible Officer Doctrine can be applied for organizational violations of the Anti-Kickback and Self-Referral laws and/or the submission of false and fraudulent claims
- Corporate Integrity Agreements have already required individual responsibility and accountability for Board members, management officials, business unit managers and Chief Compliance Officers (i.e. Pfizer and Astra Zeneca).

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Broad Application and Additional Actions Against Individuals (Cont'd.)

- Individual liability under criminal statutes, the False Claims Act and Civil Money Penalty and Exclusion authorities
  - *U.S. v. Sulzbach* (i.e. General Counsel and Compliance Officer)
  - *OIG v. Montijo* (i.e. physician arrangements with medical device companies)
  - *OIG v. Baskt* (i.e. Stark law violations by CEO of Hospital)
  - *U.S. v. Lauren Stevens* (i.e. criminal prosecution of General Counsel at Glaxo Smith-Kline)
  - *Denkel v. OIG* (i.e. exclusion of owner of diagnostic imaging company)
- Recent DOJ Yates Memorandum – Individual Accountability for Corporate Wrongdoing

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Individual Accountability for Corporate Wrongdoing (Yates Memo)

- Not a new policy for the Department of Justice or the Office of Inspector General of Health and Human Services – but increased focus on individual conduct and new requirements in practice
- Deterrence of organizational misconduct and promoting compliance and ethical culture
- Cooperation credit for organizations; disclosure of facts related to individual conduct in criminal and civil cases.

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Individual Accountability for Corporate Wrongdoing (Yates Memo) (Cont'd.)

- Criminal liability ordinarily focuses on individuals, but now civil liability will shift focus from exclusively on recovery of money to also focus on individuals liability regardless of ability to pay
- Criminal and civil organization resolutions and settlements will not include releases for individuals except in rare circumstances and declinations to prosecute individuals must be explicitly justified to DOJ supervisors.
- Consequences for organizational compliance – cooperation and self-disclosure and related internal investigations – individual accountability.

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Enforcement

- DOJ
- OIG-HHS
- Attorneys General
- SEC
- FTC
- Other Federal and State Agencies
- Multi Agency Task Forces – HEAT Program

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How Investigations are Initiated

- Competitor complaints
- Consumer complaints
- Current or former employee – "whistleblower" complaints
- Insurance company complaints

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Investigative Techniques

- Informal interviews and requests for documents
- Insider informants and whistleblowers
- Search warrants
- Subpoenas
- Electronic surveillance

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When The Government Knocks to Obtain Documents ……

- Subpoena or search warrant or request by government agent
- Employees notify executives immediately
- Executives refer agent to company's counsel

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Remember

- Search warrant
- Agents can seize original documents
- Corporations do not have 5th amendment privilege
- If agent demands copy of personal records – (5th Amendment) respectfully decline and refer to counsel
- Important to label documents

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If Search Warrant

- Request copy of warrant and affidavit (may not be available)
- Accept warrant and immediately fax to counsel and/or organization contact (i.e. general counsel or compliance officer)
- If you are not there…have employee fax to you and your counsel
- Send all employees (except essential response team or coordinator) away from work location where search is taking place

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And….

- DO NOT INTERFERE WITH AGENTS AND AVOID CONFRONTATION
- Review warrant carefully
  - Technically, agents can only seize what is listed on warrant
  - Bring to agent's attention if search areas are not listed in warrant
- List may include personal (5th Amendment) and corporate records and privileged documents

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AND…. Remember

- No requirement to speak to agents or respond to questions
- Respectively decline & refer agent to counsel
- Search warrant is for documents and E data, not testimonial evidence

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If Search Warrant (cont'd.)

- Attempt to identify attorney/client privileged documents
- Identify and determine agency of each investigator and the agent in charge and request contact information; government attorney assigned to case
- Agents will request signature on a vague inventory of items seized – avoid execution of document
- Keep your own inventory of areas searched, documents and items seized and questions asked by the agents

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Post Search

- Counsel typically requests debriefing from investigators and/or government attorneys
- Consider public relations
- Debrief employees and response coordinator/team – prepare statement with counsel
- Attempt to obtain copies of documents seized through counsel
- Notice and instruction to employees
  - Notice of investigation
  - Litigation hold and suspension of document destruction
  - Instruction regarding interaction with government agents

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Subpoena

- Served by Mail or Personally by Agent
- Does not Require Immediate Response
- Typically Has Future Return Date
- For Documents and/or Testimony
- Turn Over to Counsel for Appropriate Response

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Subpoena

- Prepare to assist counsel with response
- Different types of subpoenas (Civil Investigative Demand, HIPAA Subpoena, OIG Subpoena)
- Complete and timely response is important
- May negotiate scope and timing of response (i.e. Rolling production)
- Custodian of records for response to subpoena

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What To Do When The Government Knocks to Interview You or Your Employees

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Employee Rights

- May decline to speak with Agents
- May voluntarily speak to agents, but no obligation to do so
- 5th Amendment Right to Refuse
- Ask Agent to contact Company Counsel
- Joint Defense Agreement – Share information between parties – still privileged
- Company can advance $ for cost of employee counsel (if necessary)

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Employee Rights (Cont'd.)

- Right to be represented by counsel at interview
- Organization's Counsel can assist, but typically does not directly represent Employees
- Organization's Counsel represents organization
- Employee can retain their own counsel
- Organization should not forbid Employee to speak to government agents
  - Obstruction of justice
  - Ask employees to advise if visited by government agents
  - Organization memorandum regarding investigation is advisable

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Follow-Up Response to Initial Government Contact Conducting an Internal Investigation

- Responding to reports of non-compliant activity and proliferation of Federal and State government initiated investigations have led organizations to consider a response to and a strategy for such events and "internal investigations" are a central feature of an organization's ability to effectively deal with these situations.

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Conducting an Internal Investigation (cont'd.)

- The initiation of an internal or parallel investigation is critical with reference to allegations raised against the organization or in connection with an internal compliance matter
- It is important for an organization's resolution of an external enforcement investigative matter
- It is also important for an organization's compliance strategy and compliance program and resolution of internal matters
- No substitute for the facts regarding a resolution of external and internal matters.

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The Current Hostile Environment

- Criminal and civil enforcement risks
- Administrative and regulatory enforcement risks- Sanctions, Audits and Overpayments
- Whistleblowers
- Federal and state enforcement
- Media and public scrutiny
- Compliance program challenges and risks

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Overview Of Health Care Fraud Enforcement

- Criminal Statutes Specifically Relating to Health Care Fraud (established by HIPAA)
  - Health Care Fraud [18 U.S.C. § 1347]
  - Theft or Embezzlement in Connection with Health Care [18 U.S.C. § 669]
  - False Statements Relating to Health Care Matters [18 U.S.C. § 1035]
  - Obstruction of Criminal Investigation of Health Care Offense [18 U.S.C. § 1518]

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Affordable Care Act Reforms

- Dramatically increased funding for health care fraud enforcement – HEAT Program, FBI and OIG, State Medicaid Fraud Control Units, private contractors for Medicare and Medicaid program integrity
- Foreign Corrupt Practices Act Enforcement
- Food, Drug and Cosmetic Act Enforcement.

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Affordable Care Act Reforms
(Cont'd.)

- Health Care Fraud Offense – 18 U.S.C. § 24(a) – includes violations of Anti-Kickback Statute, Food, Drug and Cosmetic Act and provisions of Employment, Retirement Income Security Act.
- Knowing and willful standard does not require proof of actual knowledge of health care fraud statute or specific intent to violate the statute (i.e. similar to Anti-Kickback Statute) – Ignorance of law is not a defense.

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I. The Anti-kickback Statute

- 42 USC § 1320a-7b(b)(2)

  It is unlawful to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person - -

  a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

  b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program

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The Anti-kickback Statute

- What it all means? – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program
- 42 states and D.C. have enacted their own anti-kickback statutes

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Elements

- Remuneration
- Offered, paid, solicited, or received
- Knowingly and willfully
- To induce or in exchange for Federal program referrals

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Remuneration

- Anything of value
- "In-cash or in-kind"
- Paid directly or indirectly
- Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations

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Offered, Paid, Solicited, Or Received

- Different perspectives – payors and payees
- "It takes two to tango"
- Old focus: payors subject to prosecution
- New focus: payors and payees (usually doctors)

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To Induce Federal Program Referrals

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test and culpability can be established without a showing of specific intent to violate the statutory prohibitions

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Fines And Penalties

- The Government may elect to proceed:

  Criminally:

  - Felony, imprisonment up to 5 years and a fine up to $25,000 or both
  - Mandatory exclusion from participating in Federal health care programs
  - Brought by the DOJ

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Fines And Penalties (Cont'd.)

- Civilly:
  - A violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the Civil False Claims Act
  - Penalties are same as under False Claims Act (more later)
  - Expanding use of the FCA

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Fines And Penalties (Cont'd.)

- Administratively:
  - Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved
  - Discretionary exclusion from participating in Federal health care programs
  - Brought by the OIG

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Exceptions And Safe Harbors

- Many harmless business arrangements may be subject to the statute
- Approximately 24 exceptions ("Safe Harbors") have been created by the OIG
- Compliance is voluntary
- Must meet all conditions to qualify for Safe Harbor protection
- Is substantial compliance enough?

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Affordable Care Act

- *Linkage to False Claims Act* – Many courts have held under an express or implied certification theory that a violation of AKS is actionable under the False Claims Act
  - Allows for significant penalties
  - Allows for whistleblowers to bring actions
- *ACA Section 6402(f)* adds language on this issue –

  "in addition to the penalties provided for in this section. . ., a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [False Claims Act]." § 1128B(9)(g) (Emphasis added)

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ANTI-KICKBACK CASE LAW AND SETTLEMENTS UPDATE

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United States ex rel. Kosenske v. Carlisle HMC, Inc., 554 F.3d 88 (3rd Cir. 2009)

- Anesthesiologist brought *qui tam* action under FCA, alleging hospital and owners submitted outpatient hospital claims to Medicare and other Federal healthcare programs that falsely certified AKS and Stark Compliance
- 3rd Circuit reversed summary judgment in defendants' favor and found that exclusive service arrangement for pain management services between Relator's former practice (Blue Mountain Anesthesia Associates) and defendants (1) triggered Stark and AKS; and (2) did not meet the personal service exception to either statute.
- In 1992, Hospital and BMAA entered Anesthesiology Services Agreement:

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United States ex rel. Kosenske v. Carlisle HMC, Inc., 554 F.3d 88 (3rd Cir. 2009) (Cont'd.)

- Hospital would provide space, equipment and supplies at no charge and allow only BMAA physicians to provide anesthesia or pain management services at Hospital;
- BMAA would provide anesthesia coverage for hospital patients 24/7 and use personnel, space, equipment and supplies provided by Hospital solely for practice of anesthesiology and pain management for Hospital's patients; and
- BMAA physicians would not practice anesthesia or pain management at any other location other than the Hospital or other facilities/locations operated by Hospital et al

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United States ex rel. Kosenske v. Carlisle HMC, Inc., 554 F.3d 88 (3rd Cir. 2009) (cont'd.)

- In 1998, Hospital opened a pain management clinic and BMAA began providing pain management services to its patients. Hospital did not charge BMAA rent for the space or equipment, or a fee for support personnel provided by Hospital. Parties did not execute a new agreement.
- **Lessons**
  - **Have (and update as necessary) a written agreement.** The only written agreement between parties was executed in 1992 and did not address pain management services later provided at a facility opened after the Agreement was signed. Nor did it address the free hospital space, staff or facilities provided to BMAA

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United States ex rel. Kosenske v. Carlisle HMC, Inc., 554 F.3d 88 (3rd Cir. 2009) (Cont'd.)

- **Beware non-monetary remuneration**. The exclusive right to provide services and in-kind remuneration can also trigger AKS.

- The District Court heard the case on remand and denied the parties' renewed cross-motions for summary judgment, finding numerous disputed issues of fact. (*United States ex rel. Kosenske v. Carlisle HMA Inc.*, 2010 U.S. Dist. LEXIS 31619 (W.D. Pa. 2010).
- The parties settled the case.

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United States v. Borrasi 639 F.3d 774 (7th Cir. 2011)

- Seventh Circuit Court of Appeals upheld Dr. Roland Borrasi's conviction for violations of the Anti-Kickback Statute and joined other circuits in adopting the "one purpose" test.
- "One purpose" test: a payment or offer of remuneration violates AKS so long as *part* of the purpose of a payment to a physician or other referral source by a provider or supplier is an inducement for past or future referrals.
- Administrators of an inpatient psychiatric hospital (Rock Creek Center, L.P.) paid Dr. Borrasi and colleagues bribes to refer Medicare patients. Between 1999 and 2002, Dr. Borrasi, et al received $647,204 in potential bribes. In 2001 alone, they referred 484 Medicare patients to Rock Creek

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United States v. Borrasi
(Cont'd.)

- Dr. Borrasi, et al were placed on the Rock Creek payroll, received false titles and job descriptions, and submitted false time sheets. They were not expected to perform any of the duties listed in their job descriptions and attended very few meetings at Rock Creek.
- Dr. Borrasi and certain Rock Creek administrators were charged with conspiracy to defraud the U.S. Government and Medicare-related bribery. Dr. Borrasi was found guilty and sentenced to 72 months in prison, two years of supervised release and $497,204 in restitution.

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United States v. Borrasi
(Cont'd.)

- He appealed his conviction, arguing that AKS exempts "any amount paid by an employer to an employee (who has bona fide employment relationship with such employer) for employment in the provision of covered items or services."
- He urged the Court to adopt a "primary motivation" doctrine: if, upon examining the defendants' intent, the trier of fact found the *primary motivation* behind the remuneration was to compensate for bona fide services provided, the defendants would not be guilty.
- The Court declined, adopted the "one purpose" test and held that "[b]ecause at least part of the payments to Borrasi were "intended to induce" him to refer patients to Rock Creek, the statute was violated, even if the payments were also intended to compensate for professional services."

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United States v. Borrasi
(Cont'd.)

- What does Borrasi mean for interpreting the employment exception and Safe Harbor?
- Will Borrasi limit the protections of the employment exception and Safe Harbor?
- But see *U.S. ex rel. Baklid-Kuntz v. Halifax Hospital Medical Center (November 26, 2013, M.D Fla.) – Rejects "One Purpose Test" for employee exception*
  - ***"One Purpose Test" eviscerates employer/employee exception to Anti-Kickback Statute even if payments are to a "legitimate" (i.e. bona fide) employee***

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Guidance On The Anti-Kickback Statute

- Advisory Opinions from the OIG
  - A party may request advice on the law, concerning (1) remuneration within the meaning of the law, (2) whether they are meeting one of the law's exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - General guidance and notice on compliance matter, but not precedential law

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Guidance On The Anti-Kickback Statute

(Cont'd.)

- Fraud Alerts and Special Advisory Bulletins
- Preamble to the Safe Harbor Regulations
- Compliance Program Guidance's
- **www.oig.hhs.gov**

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Foreign Corrupt Practices Act

- Offers of payment of a bribe to a foreign government official to obtain a business advantage
- Pharmaceutical and medical device manufacturers
- Others who do business in foreign countries (i.e. hospitals).

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The Stark Law

- Section 1877 of the Social Security Act, 42 U.S.C. 1395nn
- The law is complicated and consists of the original statute (Stark I in 1989) and the amended provisions (Stark II in 1996)
- Stark regulations have gone into effect in phases (I, II and III) in 2002 and 2004, 2008 and 2009.

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The Stark Law

- A prohibition on physician self-referrals
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception

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Difference Between Anti-kickback Statute And The Stark Law

- Physician referrals only
- No "knowingly and willfully standard" – strict liability
- Involves Designated Health Services ("DHS")
- Anti-kickback Statute is an intent-based law and applies to all payment and referral relationships.

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Types Of Designated Health Care Service ("DHS")

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology and Imaging Services (MRI, CAT, scan, ultrasound)
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

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What Is A Financial Relationship?

- Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will quality as a financial arrangement under the Stark law
- Examples:
  - Stock ownership
  - Partnership interest
  - Rental contract
  - Personal service contract
  - Salary
- Compensation agreements can be direct or indirect
  - Exceptions for certain indirect compensation arrangements

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Exceptions

- Compliance is mandatory
- Types of exceptions:
  - In-office ancillary services
  - Personal physician services by member of group practice
  - Pre-paid health plan
  - Certain publicly traded securities
  - Rural provider (investment interests)
  - Rental of office space and equipment
  - Bona fide employment
  - Personal services arrangement
  - Physician recruitment

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Closer Look At Stark Exceptions

- *In Office Ancillary Services* (an exception that applies to both ownership and compensation)
- The *Physician Services Exception* (an exception that applies to both ownership/investment interests and compensation)
- The *Rural Provider* exception (an exception that applies to only ownership/investment interests)
- The *Rental of Office Space and Equipment* exception (a compensation only exception)
- The *Personal Services Arrangements* exception (a compensation only exception).

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Other Stark Exceptions (Cont'd.)

- The exception for *Electronic Health Records* (a compensation only exception).
- The exception for *Electronic Prescribing* (a compensation only exception)
- The exception for *Technology Provided as part of a Community-wide Information System* (a compensation only exception)
- There are also a number of other Stark Law exceptions. Each of the Stark Law exceptions has specific and technical requirements that must be met.

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Anti-Kickback Statute & Stark

AKS	**Stark**
Criminal/Civil	Civil Only
Any Federal Healthcare Program	Medicare only
Requires proof of Improper intent	Strick Liability
Applies to any referral source	Must be a physician and an entity in the mix
Safe Harbors	Exceptions
OIG Advisory Opinions	CMS Advisory Opinions

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Part I: The False Claims Act

- 31 USC § 3729 – The False Claims Act ("FCA") sets forth seven bases for liability. The most common ones are:
  1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
  2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid
  3. Conspiring to commit a violation of the False Claims Act
  4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government
- Obligation defined as an established duty, whether or not fixed, arising…from retention of any overpayment

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Elements Of An FCA Offense

- The Defendant must:
  - Submit a claim (or cause a claim to be submitted)
  - To the Government
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal Treasury
  - Damages (maybe).

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Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - had "actual knowledge of the information"; or
  - acted in "deliberate ignorance" of the truth or falsity of the information; or
  - acted in "reckless disregard" of the truth or falsity of the information.

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Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claims Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- The relationship between Relator and Government
  - Collaborators in the recovery of money.

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FCA Statistics

- If the government intervenes and obtains recovery, the Relator can receive between 15% and 25% of the proceeds
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 22-25%
- Billions in health care FCA recoveries since 1986, with annual average recoveries of $1.9 billion
- Recoveries have increased (higher penalties and more publicity)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action.

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Health Care Reform (i.e. Affordable Care Act) and False Claims Act Amendments

- Liability for overpayments and failure to return a known overpayment within 60 days from identification-return of known overpayment an affirmative and express obligation
- Claims for payment from government contractors, grantees or other recipients if money is spent on government's behalf or to advance a government program or interest
- Materiality requirement for False Claims Act liability

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Application Of Fraud And Abuse Laws To Private Exchange Insurers

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse
- Federal payments to private insurance exchanges subject to False Claims Act

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Role of the OIG in FCA Cases

- May assist in the investigation
  - Settles as client agency on behalf of HHS
  - Permissive exclusion authority – Assesses effectiveness of organization compliance program and risk of continued participation in Federal Health Programs
  - May waive exclusion authority in exchange for Corporate Integrity Agreement
    - ✓Organizational and Individual Accountability
    - ✓Monitoring and annual reports
    - ✓Successor liability

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FALSE CLAIMS ACT ENFORCEMENT ACTIONS

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False Claim Settlements, 21st Century Oncology, Middle District of Florida

- *United States ex rel. Barnes v. 21st Century Oncology, LLC* (M.D. Fla. 2015)
- *United States, ex rel. Ting v. 21st Century Oncology, Inc.* (M.D. Fla. 2016)

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United States, ex rel. Barnes v. 21st Century Oncology, LLC (M.D. Fla. 2015)

- Allegations
  - 21st Century knowingly billed Medicare and Medicaid for expensive and medically unnecessary *fluorescence in situ hybridization*, or "FISH" tests.
  - 21st Century incentivized physicians to order unnecessary FISH tests by providing bonuses to the physician who ordered the most tests.
  - The relator, a former employee of 21st Century, was terminated from employment prior to filing this complaint.

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United States, ex rel. Barnes v. 21st Century Oncology, LLC (M.D. Fla. 2015)

- Resolution
  - In 2015, 21st Century entered into a settlement agreement with the United States, agreeing to pay **$19.75 million**.
    - ✓ The settlement resolved the allegations that 21st Century submitted claims to Medicare and Tricare for "FISH" tests that were not medically necessary.
    - ✓ The settlement did not resolve allegations that 21st Century encouraged physicians to order unnecessary "FISH" tests by offering bonuses that were based in part on the number of tests referred to 21st Century's laboratory.
  - To avoid exclusion from Federal Healthcare programs, 21st Century also entered into a Corporate Integrity Agreement with the OIG-HHS, imposing five years of continuing compliance obligations.

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United States, ex rel. Ting v. 21st Century Oncology, Inc. (M.D. Fla. 2016)

- Allegations
  - 21st Century encouraged physicians to treat more patients with intensity modulated radiation therapy (IMRT), reimbursed at a higher rate than conventional radiation, when it was medically unnecessary and physicians had not seen or evaluated the patient.
  - 21st Century encouraged physicians to automatically prescribe and improperly bill for a medical procedure called the Gamma function, even when the physician did not think the procedure was medically necessary.
  - 21st Century paid physicians for improper referrals to its radiation treatment centers in violation of the Stark Law.

86

United States, ex rel. Ting v. 21st Century Oncology, Inc. (M.D. Fla. 2016)

- Resolution
  - In 2016, 21st Century settlement with the United States for **$34.7 million** to resolve this case.
  - The settlement covered the following conduct:
    - ✓ Submission of Gamma function claims at locations where physicians and physicists had not been properly trained;
    - ✓ Submission of claims where no physician reviewed the Gamma results until seven or more days after the last radiation treatment therapy; and
    - ✓ Submission of claims where no Gamma result was available due to technical failure that produced no reference or quality assurance image, and as such, offered no value or meaning to any healthcare practitioners.

87

Other Basis for False Claims Act Liability for Oncology Services

- Lack of required supervision for radiation therapy services
- Improper payments for referrals under the Anti-Kickback Statute and/or the Stark Law
  - Chemotherapy revenue
- Lack of medical necessity of the treatment services
  - Chemotherapy administration

88

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.)

- Halifax Hospital is in Daytona Beach, Florida
- In 2014, paid $86 million to settle alleged Stark Law and Anti-Kickback violations, brought by a *qui tam* Relator.
  - The Relator was a Halifax compliance officer turned whistleblower.
  - Hospital/Physician Compensation Arrangements
- The government alleged that the prohibited referrals resulted in the submission of 74,838 claims and overpayment of $105,366,00.

89

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont'd)

- Executed contracts with six medical oncologists that included an incentive bonus that improperly included the value of prescription drugs and tests that the oncologists ordered and Halifax billed to Medicare.
  - Bonus Pool = 15% of Halifax Hospital's "operating margin" from outpatient medical oncology services (*i.e.*, pool includes revenue from "designated health services" referred by oncologists)
  - Does not comply with Employment Exception (1) FMV and (2) Volume/Value referral prohibition
  - Share of pool paid to individual oncologists is based on each individual physician's personal productivity, not referrals
  - However, pool includes "profits" from services referred, but not personally performed by oncologists.

90

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont'd)

- Paid three neurosurgeons more than fair market value for their work.
  - Bonus = 100% of collections after covering base salary, no expense sharing
  - Total Compensation = As much as double neurosurgeons at 90th percentile of FMV.

91

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015)

- In 2005, Dr. Michael Drakeford, an orthopedic surgeon, sued Tuomey under the False Claims Act (FCA). The United States intervened in 2007.
- In 2010, the case went to trial in the U.S. District Court for the District of South Carolina.
  - The jury found that Tuomey violated the Stark Law but not the FCA.
  - The district court set aside the jury's verdict and ordered a new trial, but entered a $45 million judgment against Tuomey.

92

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont'd.)

- In 2012, Tuomey appealed to the Fourth Circuit which vacated the monetary judgment and ordered a new trial.
- In 2013, the case was retried in district court and the jury found that Tuomey violated the Stark Law and FCA and awarded $237,454,195 to the U.S.
- Tuomey appealed for a second time and the Fourth Circuit affirmed the judgment against Tuomey on July 2, 2015.

93

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont'd)

- Tuomey Healthcare System is a nonprofit hospital in Sumter, South Carolina.
- Sumter is a federally-designated medically underserved area.
- Tuomey was concerned about doctors who previously performed outpatient surgery at the hospital now performing the surgeries at other off-site facilities.
- Tuomey sought to negotiate part-time employment contracts with physicians to perform outpatient surgeries at the hospital.
- Physician compensation exceeded FMV, not commercially reasonable and based on volume and value of referrals

94

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont'd)

- The terms of the physicians' contracts:
  - Physicians were to perform all outpatient surgeries at Tuomey for a 10 year term.
  - Upon termination, the contracts had a non-compete provision for 2 years within 30 miles of Tuomey.
- Physicians' compensation varied with the number of referrals made to Tuomey, implicating the Stark Law.
- Tuomey was found to have submitted 21,730 false claims.

95

U.S. ex rel. Reilly v. North Broward Hospital District, et al. (S.D. Fla.)

- North Broward Hospital District ("NBHD") is located in Broward County, Florida.
- In 2010, Dr. Michael Reilly, a Fort Lauderdale orthopedic surgeon employed by NBHD, sued NBHD under the False Claims Act.
- Paid $69.5 million to settle allegations of violations of the FCA.
  - Hospital/Physician compensation arrangements.

96

U.S. ex rel. Reilly v. North Broward Hospital District, et al. (S.D. Fla.) (Cont'd)

- Allegations:
  - Physicians and physician groups were excessively overcompensated for services.
  - NBHD maintained secret compensation records called "Contribution Margin Reports" for cardiologists, oncologists and orthopedic surgeons, who collected salaries of $1 million and higher.
  - The records compensated physicians based on the value and volume of referrals for hospital services, such as radiology and physical therapy.
  - Penalized the physicians for taking on low-paying charity cases.

97

United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al. (W.D.N.C)

- Adventist Health System ("AHS") is a Florida-based system, which includes 44 hospital campuses in 10 states.
- In 2012, two lawsuits filed under the qui tam provisions of the False Claims Act respectively by whistleblowers:
  - Michael Payne, Melissa Church, and Gloria Pryor, who worked at Adventist's hospital in Hendersonville, North Carolina
  - Sherry Dorsey who worked at Adventist's corporate office.
  - AHS self-reported non-compliant hospital/physician arrangements
- In 2015, Adventist Health System agreed to pay the U.S. $115 million to settle the allegations.
  - Hospital/Physician Compensation Arrangements
  - Miscoding claims

98

United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al. (W.D.N.C)
(Cont'd)

- Allegations:
  - Adventist-owned hospitals paid doctors' bonuses based on the number of test and procedures they ordered.
  - As part of its corporate policy, Adventist told its hospitals to purchase physician practices and group practices or employ nearby physicians so it could control all patient referrals in those areas.
  - Up-coded Medicare claims for patients in nursing and assisted-living facilities.
  - Unbundled services and submitted them as separate claims to get larger reimbursements from the government.
  - Submitted claims for services that weren't documented in patients' medical records.

99

United States ex rel. Barker v. Columbus Regional Healthcare (M.D. Ga., September 4, 2015)

- Allegations
  - Improper Upcoding of Evaluation and Management Services
  - Compensation in excess of Fair Market Value taking into account the volume and value of referrals to hospital
  - Physician Employee Compensation not commercially reasonable, but for referrals to hospital for chemotherapy
  - Physician Compensation artificially inflated by productivity of other practitioners (i.e. physician extenders) and systemic upcoding of E&M visits
- Settlement with hospital for $35 million, but also with excessively compensated physician for $425 thousand
- Hospital Corporate Integrity Agreement requiring Board and Management obligations, compliance program and governance commitments, IRO arrangements review and Board and Management compliance training

100

United States ex rel. Beaujon v. Hebrew Homes Health Network, Inc., et al. (S.D. Fla.)

- Hebrew Homes provided skilled nursing facilities at seven rehabilitation and skilled nursing facilities in Miami-Dade County, Florida.
- In 2015, paid $17 million to settle alleged FCA and Anti-Kickback violations, brought by a *qui tam* Relator.
  - Largest settlement involving violations of the Anti-Kickback Statute by a skilled nursing facility.

101

United States ex rel. Beaujon v. Hebrew Homes Health Network, Inc., et al. (S.D. Fla.) (Cont'd)

- Allegations:
  - From 2006 through 2013, Hebrew Homes hired numerous physicians ostensibly as medical directors pursuant to contracts that specified numerous job duties and hourly requirements.
  - The medical directors performed almost none of the job duties listed in their contracts, but were paid the salaries provided in their contracts.
  - Paid for their patient referrals to the Hebrew Home facilities.

102

United States ex rel. Bisk et al v. Westchester Medical Center., et al. (S.D.N.Y.)

- In 2015, paid $18.8 million to settle alleged Stark Law and Anti-Kickback violations, brought by a *qui tam* Relator.
  - Relator was former Westchester Medical Center Compliance Officer Dan Bisk.
- WMC made improper payments to a local cardiology practice (CCW) in exchange for hundreds of referrals, and obtained Medicare reimbursements for costs it did not incur.
  - Advanced monies to CCW to open a practice for the express purpose of generating referrals to the hospital.
  - WMC allowed its fellows to work at the practice free of charge.
  - Illegal remuneration under Stark and/or the Anti-Kickback Statute

103

United States ex rel. Parikh, et al v. Citizens Medical Center, et al. (S.D. Tex.)

- In 2015, paid $21.75 million to settle alleged Stark Law and Anti-Kickback violations.
- Allegations:
  - Hospital provided compensation to several cardiologists that exceeded the fair market value of their services.
    - ✓ Salaries of three cardiologists' increased from $630,000 to $1,400,000 during their first year of employment despite experiencing loses within the cardiology practice as a whole.
  - Paid bonuses to emergency room physicians that improperly took into account the value of their cardiology referrals.

104

Robinson Health System (OH)

- In March 2015, Robinson Health System, a single hospital system, agreed to pay $10 million to settle claims for violating the Stark Law and Anti-Kickback Statute.
  - Self disclosure
- Allegations:
  - Engaged in management agreements with two physician groups
  - Physicians failed to provide sufficient bona fide management services to have justified the payments they received.

105

U.S. Ex Rel. Singh V. Bradford Regional Medical Center (W.D. Pa.)

- Alleged violation of Stark Law/physician-hospital arrangement
- Hospital agreed to sublease a Nuclear Imaging Camera from a physician group
- FCA and kickback violation to induce physicians to continue referrals to Hospital for imaging services

106

St. Joseph's Medical Center Settlement For $22 Million

- FCA and AKS and Stark violations
- Professional Service Agreements with cardiology group in return for referrals to Hospital-cardiac surgical procedures
- Payments above fair market value for physician services not commercially reasonable
- One purpose for Professional Service Agreements was to induce referrals
- Sham Professional Services Agreements led to unnecessary cardiac stent procedures and resulting Corporate Integrity Agreement with Quality of Care Monitor

107

IRS Code Similarities

- Section 501(c)(3) of the Internal Revenue Code grants exemptions to entities that are organized and operated exclusively for charitable purposes.
  - To qualify for exemption from Federal income tax under section 501(c)(3) of the Code, a nonprofit organization (i.e. hospital) must be organized and operated exclusively in furtherance of some purpose considered charitable in the generally accepted legal sense of that term, and the organization may not be operated, directly or indirectly, for the benefit of private interests.
- Charitable organizations cannot allow any individual to receive an undue benefit from working for or contracting with the organization.
  - No part of the net earnings of a 501(c)(3) organization may inure to the benefit of any private shareholder or individuals (i.e. physicians).
  - An employee of a 501(c)(3) organization may not receive excessive compensation from the organization (i.e. executives).

108

IRS Code Similarities (Cont'd.)

- The IRS can impose significant penalties and fines where an undue benefit occurs. In addition, the organization's tax-exempt status may be revoked.
- Compliance tracks Federal Anti-Kickback Statute and related health care fraud and abuse laws
  - Payment for identifiable, bona fide services actually performed
  - Paid at fair market value
  - In furtherance of charitable purpose and consistent with community benefit.

109

Administrative Sanctions

- Introduction
  - The term “sanctions” represents the full range of administrative remedies and actions available to the Federal and State governments to deal with questionable, improper or abusive actions of health care providers under Federal Health Programs.
  - Does not include private contractor actions, such as pre-payment and post-payment audit of claims and demands for overpayments and/or revocation of enrollment status

110

Suspension, Offset And Recoupment Of Payments To Providers

- Suspension of payment is the withholding of payment by an intermediary or carrier from the provider of an already approved Medicare payment amount before a final determination is made as to the amount of any overpayment. See 42 U.S.C. § 1395y; 42 U.S.C. § 1396(b)(i)(2); 42 C.F.R. § 405.370(a).
- Offset is the recovery by the Medicare program of a non-Medicare debt (i.e. Medicaid) by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. 42 C.F.R. § 405.370(a).
- Recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. 42 C.F.R. § 405.370(a).

111

Exclusion
42 U.S.C. § 1320A-7

- When an exclusion is imposed, no payment is made to anyone for any item or service furnished, ordered, or prescribed by an excluded party under Medicare, Medicaid, or any other Federal Health Program. In addition, no payment is made to any business or facility – e.g., a hospital that submits bills for payment of items or services provided or ordered by an excluded party. See generally authority for exclusion at 42 C.F.R. Part 1001 et seq.

112

Exclusion (Cont'd.)

- Unless and until an individual or entity is re-instated, no payment will be made by Medicare, Medicaid, or any other Federal Health Program for any item or service furnished by an excluded individual or entity, or at the medical direction of, or on the prescription of, a physician or other authorized individual who is excluded.

113

Exclusion (Cont'd.)

- It is important to note that a provider may not submit claims to Medicare automatically upon the expiration of the period of exclusion. Excluded health care providers must petition for reinstatement, and be reinstated by the Department of Health and Human Services; Office of Inspector General ("OIG"), before they can lawfully submit claims to Federal Health Programs. An excluded individual or entity submitting, or causing the submission of, claims for items or services furnished during an exclusion period is subject to at least a civil monetary penalty, potential criminal liability, or both.

114

Exclusion (Cont'd.)

- The Secretary of Health and Human Services (the "Secretary") must exclude individuals and entities from Medicare, Medicaid, and other Federal Health Programs when they are convicted of certain offenses.
- First, if an individual or entity has been convicted of a criminal offense relating to the delivery of an item or service under Medicare or under any state health care program, (i.e. Medicaid) exclusion is mandatory.

115

Exclusion (Cont'd.)

- Second, if an individual or entity has been convicted under federal or state law of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service, exclusion is mandatory. This is true even when such patients are not program beneficiaries.
- Third, exclusion is required for individual or entities that have been convicted, under federal or state law, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

116

Exclusion (Cont'd.)

- Finally, if an individual or entity has been convicted, under Federal or state law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, exclusion must be imposed.

117

Exclusion (Cont'd.)

- A mandatory exclusion based on an initial program-related crime must be imposed for at least five (5) years. Those convicted of three health care-related crimes must be permanently excluded from any Federal health care program. Individuals convicted of two health care-related crimes are subject to a mandatory minimum 10-year exclusion.
- There are numerous provisions authorizing exclusion actions on a discretionary basis by the OIG (i.e. "Permissive Exclusion").

118

Civil Money Penalty Law

- Civil Monetary Penalties Law
  - Since 1981, HHS has had the authority to levy administrative penalties and assessments against providers as punishment for filing false or improper claims or as a collateral consequence of prior bad acts. 42 U.S.C. § § 1320a-7 and 1320a-7a. Since then, the statute has been amended regularly to apply to other Federal programs and agencies and to apply to a broader range of acts and omissions.
- Treble damages and penalties

119

Civil Money Penalty Law

- The submission of false and fraudulent claims
- Illegal remuneration under the Stark and Anti-Kickback Statutes
- Numerous other bases for imposition of civil money penalties.

120

Corporate Integrity Agreements ("CIA'S")

- The OIG imposes compliance obligations on health care organizations as part of settlements of Federal enforcement actions arising under a variety of health care fraud statutes
- The option for a health care provider to agree to corporate integrity obligations is in return for the OIG's agreement to not seek program exclusion.

121

Corporate Integrity Agreements ("CIA'S")
(Cont'd.)

- A part of global criminal and/or civil settlements
- May represent OIG's opinion on the effectiveness of the organization's compliance program
- CIA's adhere to the essential elements of an effective compliance program in the United States Sentencing Guidelines for Organizations
  - Board and Management Accountability
  - Business Unit Accountability

122

Quality Of Care, Medical Necessity And Reasonableness Of Services

- Hospital/physician services
  - Cardiac Implant and Cardiac catheterization procedures
  - Hospital/medical staff responsibility
- Quality of care in nursing homes
  - Services not provided
  - "Deficient" services vs. "worthless" services
- Physician services
- Deficient services versus "worthless" services – medically unnecessary and unreasonable.

123

Settlement Trends – Medical Necessity

- Fairfax Nursing Center paid $700K (unnecessary speech therapy)
- Ensin Group (NF chain) paid $48M (unnecessary speech and physical therapy and failure to discharge SNF patients who no longer required SNF level care)
- Grace Healthcare paid $2.7M (unnecessary therapy)
- Williston Rescue paid $800K (unnecessary ambulance transports)
- Lynch Ambulance paid $3M (unnecessary ambulance transports)
- EMH Regional and N. Ohio Heart Center paid ($4.4M (unnecessary angioplasty and stent cases)
- Jackson Cardiology paid $4M (unnecessary cardiac procedures)
- Dr. Korban (cardiologist) paid $1.15M (unnecessary cardiac procedures)

124

Settlement Trends - Other

- FCA settlements based upon physician financial relationships – Self-Disclosure
  - Cooper Hospital paid $12.6M (Stark allegations)
  - Intermountain Health Care paid $25.5 (Stark allegations)
  - St. Vincent Healthcare paid $3.95M (Stark issues with 86 employed physicians)
  - White Memorial paid $14M (below FMV rent and above FMV compensation for teaching services)
  - St. James Healthcare paid $3.85M (real estate JV issues)
- Inpatient vs. Outpatient Cases continue
  - St. Joseph (Maryland) paid $4.9M
  - Shands HealthCare paid $26M
  - Beth Israel Deaconess paid $5.3M
  - Halifax Medical Center $1 Million
  - Community Health Systems $98.15 Million

125

Other Noteworthy Cases

- Potential application of the Stark Law to Medicaid claims through the FCA
  - *U.S. ex rel. Schubert v All Children's Health* and *U.S. ex rel. Osheroff v. Tenet Healthcare* (alleging FCA violations for Medicaid claims), *but compare U.S. ex rel. Heesch v. Diagnostic Physicians Group* (DOJ complaint alleges Stark violations, but no Medicaid)
  - Florida False Claims Act
- Violations of enrollment and CLIA rules not basis for FCA claims
  - *U.S. ex rel. Hobbs v. MedQuest Associates* (CHOW deficiencies not basis for FCA claims)
  - *U.S. ex rel. Hansen v. Deming Hospital* (CLIA noncompliance not basis for FCA claim).
- See also recent Supreme Court Decision in *U.S. ex rel. Escobar v. Universal Health Services* (June 16, 2016) (failure to comply with supervision requirements for behavioral health services ("Materiality")).

126

Noteworthy Cases (Cont'd.)

- Failure to return a "Known Overpayment".
  - *U.S. ex rel. Kane v. Health First, Inc. and Continuum Health Partners, Inc. et al.*
  - Identification occurs when organization is "put on notice" of "known overpayment" and 60 day clock begins to run
  - Factual circumstances of case begged for Court's decision.
  - Do not ignore report of non-compliance and exercise due diligence to determine "known overpayment".
  - Compliance with requirements of February 18, 2016 regulation on return of known overpayments.
    - ✓ Reasonable diligence in identifying "known overpayment" (i.e. 6 months)
    - ✓ 6 year "look back" requirement from date payment received.
    - ✓ Repayment within 60 days of identification of overpayment.
    - ✓ Report and return to most appropriate government agency.

127

Settlement Trends – HIPAA and HITECH

- Increase in cases and settlement amounts
  - Hospice of No. Idaho paid $50k (lost laptop; OCR claims 1st settlement based upon security rule affecting less than 500 individuals)
  - Idaho State Univ. paid $400K (data breach involving 17,500 records)
  - Affinity Health Plan paid $1.2M (photocopier hard drive with 344K individuals' records)
  - Dermatology group paid $150K (lost thumb drive with 2200 individuals' data, OCR claims 1st settlement based upon CE's failure to have P&Ps)
  - Shasta Regional Med Center paid $275K (privacy breach; PHI shared with reporters)

128

Private Payor Fraud

- What is private payor insurance fraud?
  - Fraud against those who pay for private health insurance coverage

129

Federal Statues Prohibiting Private Payor Insurance Fraud

- Mail Fraud
- Wire Fraud
- Fraud against health care benefit plans
- Conspiracy to commit fraud through false claims and false statements
- Fraud under the RICO statute
- Increasing actions by private payers in civil litigation.

130

Types Of Criminal And Civil Health Care Fraud Cases

- Hospital/physician relationships (Stark and Anti-Kickback Statutes)
  - Medical Directorships
  - Physician Recruitment
  - Employment Arrangements
- Joint Ventures
- Pharma and Medical Device Marketing and Kickback Arrangements
- Research Grant and Clinical Trial Fraud
- Actions Based on Violations of Food Drug & Cosmetics Act
  - Misbranding and adulteration of drugs and promotion of off-label use

131

Type of Criminal and Civil Health Care Fraud Cases (Cont'd.)

- Quality of Care/Medical Necessity and Reasonableness of Services
- Effective Compliance Programs
- Anti-Kickback and Stark Compliance
- Improper Site of Service (inpatient/outpatient)

132

Type of Criminal and Civil Health Care Fraud Cases (Cont'd.)

- Improper Reimbursement Criteria (physician supervision requirements)
- Improper Billing and Coding (use of modifiers on claims)
- Cardiac Catheterization and Stent Procedures
- Discounts and Swapping Arrangements
- False Claims Act Liability-Overpayments
  - Failure to return known overpayments within 60 days of identification

133

Type of Criminal and Civil Cases

- Claims for services not provided or not provided as claimed
- Claims "unbundled" and submitted as a single service, which is reimbursed as part of another service
- Claims for non-covered services (implantable Cardiac Defibrillators)
- Claims for duplicate services
- Claims involving false or inflated cost reports

134

What Does the Government Expect From Business Organizations?

- Partnership with Federal and State governments in detecting and preventing misconduct and promoting an ethical corporate culture
- Organizations which fail to ferret out wrongful conduct and non-compliant activity will likely suffer the consequences of not doing so
- Cooperation in investigating and organization's own wrongdoing-self-disclosure and individual liability

135

"Cooperation" or "Unconditional Surrender"

- Cooperation taken into consideration in charging and sentencing decisions by Department of Justice
  - Organization's ability to make witnesses available
  - Disclosure of organization's internal investigation to identify facts and scope of conduct and responsible individuals
  - Disclosure in a timely and complete manner before facts become stale and to better enable recovery of losses by government

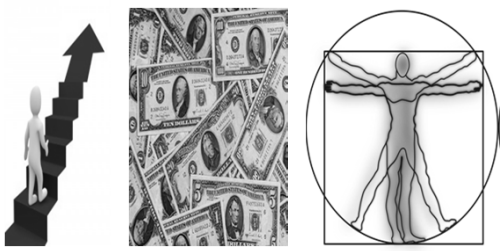
136

"Cooperation" or "Unconditional Surrender" (cont'd.)

- Cooperation evaluated on case-by-case basis
- Deferred Prosecution Agreement – survival of business organization – Corporate Integrity Agreement with Department of Health and Human Services
- Circumstances exert acute pressure on business organizations to cooperate and compromise employee rights and protections and the Courts and United States Sentencing Commission have taken notice of impact on constitutional protections

137

CONFLICTS-OF-INTEREST



138

Conflict of Interest

- A conflict of interest is a situation in which someone in a position of trust, such as a **lawyer, insurance adjuster, a politician, executive or director of a corporation or a medical research scientist or physician,** has competing professional or personal interests.

139

Common Form of Conflicts of Interest

- Self-dealing
- Outside employment and other professional relationships
- Family interests
- Gifts from friends
- Stock
- Bribes
- Self-policing
- Position specific

140

Board of Directors, Organizational Management, Employees and Contractors

- A conflict of interest arises when anyone has two or more duties which conflict.

141

Annual Conflicts of Interest Questionnaire

CERTIFICATION

142

- During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) hold any position or financial interest in a business enterprise that does business with or competes with your employer? If yes, please list company name, address and financial interest or position.

Answer:

_____

(If "yes," please explain.)

143

- During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) provide any directive, managerial, consultative, or any other services to a business enterprise that does business with or competes with your employer?

Answer:

_____

(If "yes," please explain.)

144

- With the exception of salary or other compensation regularly received by you as an officer or employee, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) profit financially in any way during the past twelve months as the result of any decisions made or action taken by you in the capacity of officer or employee?

Answer:

_____

(If "yes," please explain.)

145

- During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, children, and/or other household members) receive any gift or favor from any contractor, subcontractor, supplier or any representative thereof, who has a contract with your employer, has performed such contract within the past twelve (12) months, or who anticipates bidding on such a contract in the future?

Answer:

_____

(If "yes," please explain.)

146

- Do you consider that during the past twelve (12) months there was any conflict in any way between your duties as an officer or employee and your personal interests?

Answer:

_____

(If "yes," please explain.)

147

- During the past 12 months, did you have dual employment?

Answer:

_____

(If "yes," please explain.)

148

RESEARCH COMPLIANCE

149

Research Compliance Motivators

- Research volume and complexity are increasing
- The number of research constituents is increasing
- Broader, multiple and nontraditional collaborations
- Shift from "traditional" funding to alternate funding sources and sponsors
- Numerous areas exist for potential non-compliance
- Increasing focus on requirements/enforcement
- The risks associated with non-compliance are high
- Changes in healthcare regulation/system
- Increasing external access to information.

150

Research Compliance Environment

FISCAL

- Award monitoring
- Cost sharing
- Cost transfers
- Direct changing practices
- Effort reporting
- Pre-authorized spending authority
- Program income
- Service and recharge centers
- Sub awardee management
- Other Support

RESEARCH CONDUCT

- Animal subject protections
- Human subject protections
- Conflicts of interest
- Biosafety & Select agents
- Environmental health and safety
- Laboratory safety
- Invention licensing, disclosure & reporting
- Scientific misconduct & research integrity
- Data and information security

151

Common Contributors to Research Compliance Problems

- Inadequate resources
- Lack of understanding of roles and responsibilities
- Inadequate training and education
- Outdated or nonexistent policies and procedures
- Inadequate management systems (e.g., effort reporting, financial management)
- Perception that in internal control systems are not necessary
- Poor communications between components.

152

Case for a Research Compliance Program

- Good business practice
- Expected as part of a comprehensive compliance program
- Enhances public trust
- Meets expectations of internal and external constituents
- Establishes institutional expectations and accountability
- Provides real time insight into current issues which facilitates identification and prevention of significant compliance issues
- Reduces negative impact of having non-compliance identified by external regulators or agencies
- Reduces/prevents civil/criminal enforcement by regulatory agencies
- Provides structure for continuous quality improvement
- Promote 'engagement' between research administration office and research community
- Helps ensure research integrity and high quality data.

153

Characteristics of an Effective System for Research Oversight

- Proactive
- Objective
- Consistent
- Authoritative
- Autonomous
- Transparent
- Accountable

154

The Challenge

Develop a research compliance program that:

- Establishes a culture of compliance
- Promotes ethical conduct
- Ensures statutory and regulatory requirements are met
- Makes operational sense
- Is achieved with the least burden possible.

155

Organizational Self Disclosure Process and Practice

1. Investigation and Evaluation
2. Consider the Benefits and Risks
3. Consider Which Entity to Disclose to
4. Submit a Timely, Complete and Transparent Disclosure
5. Anticipate Government Validation
6. Resolution – Strategies and Options

156

Is it "Voluntary?"

- Misprision of a Felony – 18 U.S.C. § 4 provides that "whosoever…having knowledge…of a felony…conceals and does not as soon as possible make known the same…shall be fined…imprisoned…or both
  - Requires active concealment
- Medicare Statute – 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or "fail to disclose" facts affecting right to receive payment

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Is it "Voluntary?"

- False Claims Act – Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) – 31 U.S.C. § 3729(a)(1)(G)
  - Illegal to "knowingly conceal…or knowingly and improperly avoid…or decrease…an obligation to pay or transmit money or property to the Government…
- Presentment of claim not essential for False Claims Act Liability under Affordable Care Act
- Affordable Care Act establishes "obligation" to report "identified" overpayment within sixty (60) days

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Disclosure Considerations

- Decision to disclose should be made in conjunction with counsel, but is a business decision – weighing potential risks and benefits
  - Where available, self disclosure may offer protections too significant to pass up and is it really voluntary
  - Useful for substantial violations of law and whistleblower risk
  - Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
  - Continuing focus on compliance programs, good faith cooperation and prompt disclosure

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Investigate and Evaluate

- Preserve and collect all potentially relevant documents
  - Both hard and electronic copy-Key Word Search
- Interview key witnesses
- Disclosure will be validated by government
- Disconnected parties should conduct internal investigation

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Weigh Pros and Cons With Counsel

- "Potential advantages of self-disclosure:
  - Goodwill with government
  - Limiting possibility of external investigation
  - Expediting process of resolution
  - Reducing criminal and civil liability
  - Neutralizing whistleblower threat and lawsuits
  - Lessening overall damages and penalties

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Weighing Pros and Cons (cont'd.)

- Potential disadvantages of self disclosure:
  - Financial loss – government motivated by recovery whether discovered or disclosed
  - Increased government scrutiny – validation process
  - No immunity from liability or prior commitments
  - Possible penalties for conduct that may have remained undiscovered.

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Choosing A Government Entity

- Self-disclosure can be made to:
  - Office of Inspector General of the Department of Health and Human Services (**OIG-HHS**) – Self Disclosure Protocol (SDP)
  - Centers for Medicare and Medicaid Services (**CMS**) – Self Referral Disclosure Protocol (SRDP)
  - Department of Justice, U.S. Attorney's Office (**DOJ**)
  - State Attorney General's Office

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General Guidelines

- Disclose billing errors and mistakes to entity processing claims and payment
- Disclose matters indicating civil liability under Civil False Claims Act to DOJ and/or OIG-HHS
- Disclose matters indicating criminal liability to DOJ and/or OIG-HHS
- Where, when and how to voluntarily disclose involves careful considerations

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OIG Self-Disclosure Protocol (SDP)

- Full cooperation and complete disclosure
- Submission violates laws, not a "mistake"
- Minimum settlement amount of $50,000
- Submit within 60 days from discovery
  - False Claims Act - 30 days limits damages
- Ongoing fraud scheme = more immediacy
- Physician self-referral matter with colorable anti-kickback statute violation
- Follow Self-Disclosure Protocol, done in 3 months

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CMS' Stark Self-Referral Disclosure Protocol (SRDP)

- Report and return overpayment 60 days from identification or from when cost report due
- Follow CMS' Protocol - SRDP
- Open access to all financial records, including work product
- Intended to resolve physician self-referral matters ("Stark" law) without extraordinary financial liability
- When no anti-kickback matter exists, use CMS' Protocol
- When anti-kickback matter exists, must choose either CMS or OIG for disclosure, not both

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CMS - SRDP
Settlement Factors

- CMS may consider the following:
  1) the nature and extent of the improper or illegal practice;
  2) the timeliness of the self-disclosure;
  3) the cooperation in providing additional information related to the disclosure;
  4) the litigation risk associated with the matter disclosed; and
  5) the financial position of the disclosing party

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Self-Disclosure to DOJ

- DOJ is a law enforcement agency
- Unlike OIG and CMS, No formal protocol
- Criminal jurisdiction and civil authority under the False Claims Act
- Ability to release organization from liability

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Agency Coordination

- OIG confers with DOJ before acceptance
- OIG confers with DOJ before resolution
- OIG resolution not binding on DOJ
- Disclosing party can request DOJ or OIG presence in settlement discussions to resolve parallel liability
- CMS or Fiscal Agents can refer matters to OIG and DOJ

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Many Possible Settlement Factors

- Effectiveness of pre-existing compliance program
- Nature of the conduct and financial impact
- Ability to repay
- First-time offender, isolated and distinct incident
- Low-level bad actors
- Efforts to correct problem
- Successor liability under former management
- Period of conduct
- How matter was discovered
- Level of cooperation, candor, flexibility
- Relationships
- Etc.

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Final Advice

- There is no “one size fits all” approach to voluntary self-disclosure
- These decisions should be made with the assistance of competent and experienced counsel

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How is the Compliance Program Addressing Significant Risks

- One of the primary goals of the compliance program is to attempt to get it right the first time, but in any case minimize the known risks.
- New business ventures are evaluated for potential risk.
- Responding to reports of non-compliant activity
- Timely response is made to newly developed rules and regulations
- Overall Risk Assessment Monitoring Plan.

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Board Questions to Evaluate a Compliance Program

- Is there anyone interfering with your ability to implement any of the elements of an effective compliance program?
- Is there anyone interfering with your ability to prevent, find, or fix this organization's legal, policy, or ethical issues?
- Do you have any responsibilities outside of compliance and ethics that could cause you to have a conflict?
- Do you report to anyone who has any responsibilities that could cause conflicts of interest for the compliance program?
- Is anyone with a conflict of interest guiding or directing the compliance and ethics program?

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Board Questions to Evaluate Compliance Program (cont'd.)

- Are there any issues that have been reported to you that have not or are not being addressed satisfactorily?
- Has any issue been outstanding beyond a reasonable amount of time?
- Have we ever had an outside evaluation of our compliance and ethics program?
- Are we staying abreast of current trends in enforcement and effective compliance program management?
- Are we anticipating any potential new legal risks in the near future?
- Are there any substantive compliance issues currently under investigation?

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Board Questions to Evaluate a Compliance Program (cont'd.)

- What issues are the enforcement community currently reviewing/investigating in our industry and where do we stand on those issues?
- How do you evaluate our organization's ethical culture?
- Is there anything that leadership can do to help further develop, maintain, or support the compliance and ethics programs?
- Is there any further compliance and ethics education that you think leadership should attend?
- Do we need more compliance and ethics expertise on our governing body?

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Board Questions to Evaluate a Compliance Program (cont'd.)

- Do you have a good working relationship and independent access to internal and external legal counsel, consultants, and auditors?
- Are you getting cooperation on compliance training and what type of feedback are you getting from the training?
- What are you most concerned about?
- Do you feel that everyone in this organization feels comfortable reporting potential issues and do they have a reasonable opportunity/mechanism to share their concerns about a policy, legal, or ethical infraction with you?

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Next Steps

- The governing body and leadership can engage in an effective dialogue with the compliance professional with some version of the suggested Board questions
- Once your organization develops this best practice, the leadership question list can further evolve into a more effective tool for maintaining an effective relationship with leadership in the future

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THE END