



Health Care Compliance Association
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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

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What is the Basis for Boards' Need to Know?

- Why does the government focus in on Board involvement?
- What federal "*written agreement*" 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

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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 ordinarily 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 of the CP

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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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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 – payers and payees
- “It takes two to tango”
- Old focus: payers subject to prosecution
- New focus: payers 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)
- ❖ Controversial, yet common basis for FCA liability (more later)

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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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❑ *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

❑ The following language in the Statute presents as follows:

“in addition to the penalties provided for in this section. . . , a claim that includes items or services resulting from a violation of this section (i.e. Anti-Kickback Statute) constitutes a false or fraudulent claim for purposes of the [False Claims Act].” § 1128B9g) (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), setting the stage for a multi million dollar settlement.

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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 was “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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*U.S. ex. rel. Slowick v. Olympus Corp. of the Americas
and U.S. v. Olympus Corp. of the Americas*
(D.N.J. Mar. 1, 2016)

- Former chief compliance officer of Olympus Corp. of the Americas (OCA) brought *qui tam* action under FCA, alleging from 2006 to 2011 OCA provided kickbacks to doctors and hospitals to induce purchases of OCA's equipment paid for by Federal healthcare programs .
- OCA, the U.S. Largest distributor of endoscopes, was also criminally charged with conspiracy to violate the AKS.
- Olympus settled for \$632.2 million for violating the AKS and FCA and entered into a three-year Deferred Prosecution Agreement (DPA) and a five-year Corporate Integrity Agreement (CIA)
- Goal of the DPA and CIA: eliminate misconduct, fraudulent billing, and improper financial relationships between health care providers

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*U.S. ex. rel. Slowick v. Olympus Corp. of the Americas
and U.S. v. Olympus Corp. of the Americas*
(D.N.J. Mar. 1, 2016) (Cont'd)

Anti-Kickback Statute Violations

- The Anti-Kickback Statute (AKS) prohibits payments to induce purchases paid for by Federal health care programs.
- OCA faced criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals
- OCA provided kickbacks such as disguised payments, foreign travel, lavish meals, millions of dollars in grants, and free endoscopes to doctors and hospitals to induce purchases of their equipment
- OCA's kickbacks caused false claims to be submitted to Medicare, Medicaid and TRICARE, in violation of the AKS and the FCA
- OCA also settled a criminal case brought under the Foreign Corrupt Practices Act (FCPA) for bribing foreign government officials to secure business in Central and South America.

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*U.S. ex. rel. Slowick v. Olympus Corp. of the Americas
and U.S. v. Olympus Corp. of the Americas
(D.N.J. Mar. 1, 2016) (Cont'd)*

Deferred Prosecution Agreement (DPA)

- Requires OCA to enhance its compliance training and maintain an effective compliance program
- Maintain a confidential hotline and website for OCA employees and customers to report wrongdoing
- OCA's Chief Executive Officer and Board of Directors must certify annually that its program is effective; and
- Must adopt an executive financial recoupment program that requires executives to forfeit three years of performance pay if they engage in misconduct or fail to enforce compliance
- Appointment of an independent monitor to oversee and evaluate organization's compliance with DPA
- If OCA complies with the reform and compliance requirements of the DPA, then they will avoid conviction for violation of the AKS.

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*U.S. ex. rel. Williams, ex al. v. Tenet Healthcare Corp. et al. and U.S.
v. Tenet Healthcare Corp. et al
(M.D. Ga.) (2014)*

- Williams, a Georgia resident and a healthcare industry accountant, filed a qui tam lawsuit against Tenet Healthcare Corp., a large hospital chain and its two subsidiaries in Georgia and South Carolina, alleging that Tenet paid kickbacks and bribed prenatal clinics to unlawfully refer Medicaid patients to its hospitals
- Subsequent criminal charges and civil claims were brought against Tenet and its subsidiary hospitals
- From 2000 to 2013, prenatal care clinics were paid to advise pregnant women that they must deliver their child at a Tenet hospital to receive Medicaid coverage for costs associated with their childbirth and care of their newborn, resulting in over 20,000 Medicaid patient referrals

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U.S. ex. rel. Williams, et al. v. Tenet Healthcare Corp. et al. and U.S. v. Tenet Healthcare Corp. et al
(M.D. Ga.) (2014)

- ❑ Tenet and its two subsidiaries, Atlanta Medical Center, Inc., and North Fulton Medical Center, Inc., submitted Medicaid claims for these deliveries, a violation of the FCA. The subsidiary hospitals pled guilty to conspiracy to pay kickbacks and bribes and the parent company, Tenet Health System Medical, Inc., entered into a Non-Prosecution Agreement (NPA) and ultimately paid \$513 million to settle these cases
- ❑ The prenatal clinic ensured that its patients delivered at Tenet hospitals by only employing physicians in their clinic who were permitted to deliver at Tenet hospitals and in return for payments disguised as compensation for unnecessary, duplicative and phantom management, marketing and other operational services
- ❑ As a result, the prenatal clinic received over \$12 million from Tenet hospitals over a 10-year period. In turn, Tenet and its two subsidiary hospitals received over \$125 million in Medicaid funds and \$20 million in Federal DSH funds for services provided to the prenatal clinics patients.
- ❑ Tenet and its subsidiaries were under a prior Corporate Integrity Agreement (CIA) for earlier non-compliant activity, which further colored the egregious nature of the kickback scheme in this case
- ❑ The problem: The referral of these pregnant women should not be induced by illegal kickback payments and Medicaid patients should be able to make an informed choice about where to seek medical care without undue interference of healthcare corporations seeking to make a profit

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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, but some are still pending.

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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”)

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Types Of Designated Health Care Service (“DHS”)

- | | |
|--|---|
| <input type="checkbox"/> Clinical laboratory | <input type="checkbox"/> Parenteral and enteral nutrients, equipment and supplies |
| <input type="checkbox"/> Physical therapy | <input type="checkbox"/> Prosthetics, orthotics and prosthetic devices and supplies |
| <input type="checkbox"/> Occupational therapy | <input type="checkbox"/> Home health services |
| <input type="checkbox"/> Radiology and Imaging Services (MRI, CAT, scan, ultrasound) | <input type="checkbox"/> Outpatient prescription drugs |
| <input type="checkbox"/> Durable medical equipment and supplies | <input type="checkbox"/> 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 qualify 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)
 - ❖ Hospital ownership (must be in the “whole” and not “specialty” hospital)
 - ❖ 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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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 of 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

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FCA Statistics

- If the Government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds
- Since 1986, of all of the *qui tam* actions filed, the average yearly intervention rate has been about 20-25%
- Approximately \$4.7 billion in health care FCA recoveries in FY 2016
- Recoveries have increased (higher penalties and greater publicity); \$6.8 billion since 2009 and over \$35 billion (in excess of \$23 billion in health care) overall since 1986
- Highest number of False Claims Act filings during 2014 (in excess of 700 new cases)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including investigation, initiation, testimony for, or assistance in the action (Anti-Retaliation Provision and Cause of Action)

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Recent 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 and Other Commercial Health Insurance
Plans

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse
- Federal payments to private insurance exchanges subject to False Claims Act
- Medicare Advantage Plans – Part C & D

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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
 - ❖ May waive exclusion authority in exchange for Corporate Integrity Agreement
 - Monitoring and annual reports
 - Successor liability

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**ADDITIONAL
FALSE CLAIMS ACT
ENFORCEMENT ACTIONS**

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*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.

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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.

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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.

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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.
- ❑ 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.

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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

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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.

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*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.

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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.

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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

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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.

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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

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U.S. ex rel. Ford et al. v. Abbott Northwestern et al
(S.D. Fla.) (2008)

- 51 hospitals in 15 states settled with the Department of Justice (DOJ) for more than \$23 million in connection with a *qui tam* lawsuit brought under the FCA
- From 2003 to 2010, these hospitals implanted cardiac defibrillators (ICD's) in Medicare patients in violation of Medicare coverage requirements
- An ICD costs approximately \$25,000 and is governed by a National Coverage Determination (NCD) published by CMS
- NCD requires a medical waiting period for a patient's heart to heal before the implantation of an ICD is considered covered and medically necessary and reasonable
 - 40 day waiting period for a heart attack
 - 90 day waiting period for a bypass/angioplasty

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U.S. ex rel. Ford et al. v. Abbott Northwestern et al
(S.D. Fla.) (2008) (Cont'd)

- The settlement in the case was based on those cases where a hospital implanted ICD's during the respective waiting periods, which were considered non-covered services and procedures and not reimbursable
- Impact
 - These settlements represent the final batch of cases related to DOJ's nationwide investigation into hundreds of hospitals engaged in improper Medicare billing for ICD's. As a result, more than 500 additional hospitals settled totaling more than \$280 million

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U.S. ex rel. Taylor v. Life Care Centers of America, Inc. and
 U.S. ex rel. Martin v. Life Care Centers of America, Inc.
 (E.D. Tenn.) (2012)

- Two former Life Care employees filed civil *qui tam* lawsuits under the FCA alleging violations of FCA for submitting false claims for rehabilitation therapy that were not reasonable, necessary, or skilled to Federal healthcare programs
- Life Care Centers of America, Inc. settled both lawsuits for \$145 million
- From 2006 to 2013, Life Care submitted fraudulent claims for rehabilitation therapy to systematically increase Medicare and TRICARE billings in violation of the FCA

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U.S. ex rel. Taylor v. Life Care Centers of America, Inc. and
 U.S. ex rel. Martin v. Life Care Centers of America, Inc.
 (E.D. Tenn.) (2012)

- Life Care allegedly had corporate-wide policies and practices designed to place as many recipients in the highest reimbursement level even if this level of therapy was unreasonable or unnecessary based on the patients individual needs
- Life Care entered into a five-year Corporate Integrity Agreement (CIA) that requires an annual independent review to assess the medical necessity of therapy services that Life Care bills to Medicare
- Goal of the CIA: to prevent fraudulent billing and claims for services for medically unnecessary services
- The issue of the use of statistical sampling to establish liability as well as damages was raised in this case

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U.S. ex rel. Swoben and Poehling v. United Health Insurance Company
(9th Circuit Court of Appeals, August 2016)

- Qui Tam* case alleging Medicare Advantage (MA) organizations violated FCA by employing biased review procedures to identify only diagnosis codes for additional reimbursement by Federal health programs, but not to identify erroneously reported diagnosis
- The Circuit Court decision stated that purposeful avoidance of erroneously submitted diagnosis codes, which would have been identified with reasonable diligence, precludes a certification to the government of the accuracy of data submitted for Federal health program payment
- The Court of Appeals reinstated the previously dismissed complaint and the decision potentially impacts government funded risk adjustment health programs (i.e. managed care capitated payment programs) where retrospective audits and reviews are common practices
- DOJ intervened in Swoben and Poehling: Swoben has been voluntarily dismissed, but Poehling is still pending

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Hospice Care and Compliance

Hospice care is covered under Medicare subject to certain conditions that include:

- The patient's attending physician and the medical director of the hospice program must both certify in writing that the individual is terminally ill. 42 U.S.C. § 1395f(a)(7)(A)(i);
- "Terminally ill" means that a patient has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course. 42 U.S.C. § 1395xx(dd)(3)(A);
- A patient must elect hospice care and agree to forego Medicare coverage for curative treatment;
- An individualized written plan ("plan of care" or "POC") must be established and periodically reviewed by the attending physician and medical director and all hospice care must be provided in accordance with that plan. 42 U.S.C. § 1395f(a)(7)(B) & (C); and
- All hospice services "must be reasonable and necessary" for the palliation and management of the terminal illness as well as related conditions. 42 C.F.R. § 418.200.

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Health Care Fraud Cases and Hospice Care Providers

- Falsely certifying that a patient is terminally ill.
- Admitting and retaining patients in hospice care knowing that they did not qualify for hospice care.
- Deceiving patients into enrolling in hospice care.
- Up-coding to inflate Medicare reimbursement and rewarding staff members who participated in the up-coding with promotions and/or increased salaries.
- Falsifying documents and patient records indicating patients were eligible for or had elected hospice benefits.
- Knowingly billing Medicare for services not in compliance with patients' plan of care and failing to provide services consistent with the plan of care.
- Instructing staff to enroll patients for hospice care without proper physician authorization or clinical information.
- Providing inadequate or incomplete services.

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Anti-Kickback Cases and Hospice Care Providers

- Obtaining referrals of patients for hospice services by promises and payment of incentives and kickbacks to employees, primary care providers, nursing homes, and assisted living facilities.
- Providing incentives such as gifts or free services to referral sources (e.g., physicians, nursing homes, hospitals, patients, etc.).
- Paying kickbacks to employees in the form of bonuses, prizes, better performance evaluations, free meals and other valuable items given to staff that generated the most referrals.
- Incentivizing patients to elect to stay in hospice care by providing them gifts.
- Physicians referring patients to hospices that they have a financial interest in (e.g., physician owns a percentage of the hospice and benefits from increasing enrollment).

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Health Care Fraud and Home Health Providers

- Performing medically unnecessary procedures to increase Medicare or Medicaid reimbursement.
- Billing for home health services not actually rendered.
- Billing unskilled services as skilled services.
- Falsifying documents to make it appear that patients are homebound and qualify for home health services when they do not, or that those services were provided when they were not.
- Forging physician signatures when such signatures are required to receive reimbursement.
- Double billing for the same visit under multiple categories.
- Up-coding routine treatments by billing them as more complicated, elevated levels.
- Billing for services not provided by certified home health workers.

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Health Care Fraud and Home Health Providers (Cont'd)

- Purchasing Medicare or Medicaid beneficiary information and creating fake patient files.
- Paying kickbacks/bribes (cash, drugs, free services, etc.) to recruit beneficiaries (from group homes, senior housing developments, homeless shelters, etc.) for home health services, regardless of whether the beneficiaries needed home health care.
- Paying physicians to sign medical documents falsely certifying that beneficiaries required home health care when patients are not under their care or do not qualify for home health services.
- Paying physicians or others to hold sham positions, when payments were actually inducements to refer patients to the HHA.
- Receiving other types of payments in exchange for referring patients to HHAs.

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Civil Money Penalties and Affirmative Exclusions for Hospice and Home Health Providers

The Office of Inspector General of the Department of Health and Human Services (“OIG”) also has the authority to levy administrative penalties and assessments against providers as punishment for filing false and improper claims. Sanctionable conduct includes the submission of false and fraudulent claims and illegal remuneration in violation of the AKS.

Additionally, the submission of false or fraudulent claims or a violation of the AKS can lead to a provider’s exclusion from federal health care programs. The OIG has authority to exclude HHAs and hospice care providers from Medicare that engage in this unlawful activity. Recently, the OIG has pursued HHAs and hospice providers that employ individuals which it knows or should know are excluded from participation in federal health care programs.

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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).

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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.

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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

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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).

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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.

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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.

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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.

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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

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Civil Money Penalty Law

The submission of false and fraudulent claims

Illegal remuneration under the Stark and Anti-Kickback Statutes

Payments to induce reduction or limitation of medically necessary services

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Corporate Integrity Agreements (“CIA’s”)

- ❑ The OIG imposes compliance obligations on health care providers 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.

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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

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Broad Application Against Individuals

- ❑ 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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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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Broad Application 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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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-under review
- 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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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.

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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)
- ❑ Kindred/Rehabcare paid \$125 million (unnecessary nursing home rehabilitation therapy (2016)
- ❑ Pfizer/Wyeth Pharmaceuticals paid \$785 million (failure to provide discounts to Medicaid offered to hospitals-lowest price) (2016)

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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
- ❖ Vibra Healthcare Hospital chain paid \$327 million (improper admissions and medically unnecessary extended hospital stays) (2016)

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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)
- ❑ Violations of enrollment rules not basis for FCA claims
- ❖ *U.S. ex rel. Hobbs v. MedQuest Associates* (CHOW deficiencies not basis for FCA claims)

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Noteworthy Cases (Cont'd.)

- ❖ *U.S. ex rel. Hansen v. Deming Hospital* (CLIA noncompliance not basis for FCA claim).
- ❖ See *Universal Health Services, Inc. v. Escobar* (U.S. Supreme Court, June 16, 2016) (review of "implied certification" theory of liability and "materiality" under the False Claims Act).
 - ❖ FCA may be violated when claims impliedly certify compliance with material underlying statute, regulation or contractual requirement
 - ❖ "Materiality Standard" is "demanding" and government's identification of requirement as a "condition of payment" is relevant, but not dispositive of "materiality" determination
 - ❖ If government regularly pays a particular type of claim despite actual knowledge that certain requirements have been violated it may be strong evidence that requirements are not "material"
 - ❖ The issue of materiality will be at center of False Claims Act litigation and should be followed closely for compliance purposes

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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 reasonable due diligence to determine a "known overpayment"*

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Final Rule on Repayments

- ❖ See Final Rule "Medicare Reporting and Returning of Self-Identified Overpayments," February 12, 2016, 81 Federal Register 7653.
- ❖ Report and return overpayment and the reason for the overpayment within 60 days of identification.
- ❖ Identification of overpayment when organization has or should have, through the exercise of reasonable diligence, determined the receipt of the overpayment and quantified the amount of the overpayment.
- ❖ Reported and returned within six years of the date the overpayment was received ("Look Back Period").
- ❖ SDP or SRDP self-disclosure is considered compliance with requirements of the regulation.

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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)*

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Private Payer Fraud

- ❑ What is private payer insurance fraud?
- ❖ *Fraud against those who pay for private health insurance coverage*

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Federal Statues Prohibiting Private Payer 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

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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.

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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

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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)

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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

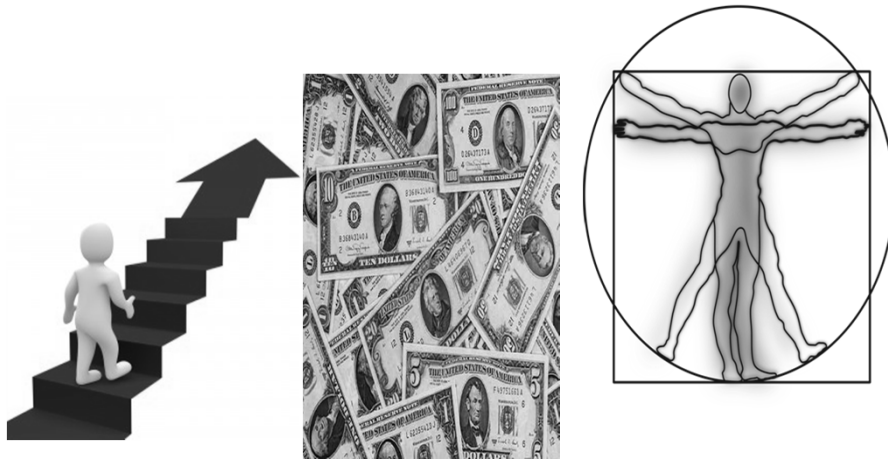
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Type Of Criminal And Civil Cases

- 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

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CONFLICTS-OF-INTEREST



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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.

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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

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Board of Directors, Organizational Management, Employees and Contractors

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



RESEARCH COMPLIANCE

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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.

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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

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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 internal control systems are not necessary
- Poor communications between components

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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.

Characteristics of an Effective System for Research Oversight

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

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.

Self Disclosure Process

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

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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
- ❑ FCA and Civil Money Penalty Law and Regulations (Medicare Reporting and Returning of Self-Identified Overpayments – February 12, 2016, 81 Federal Register 7652) 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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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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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 on Self-Disclosure

- ❑ 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 organization compliance program is to manage compliance risk and take remedial action when necessary.
- ❑ Response to reports of non-compliant activity.
- ❑ New business ventures are evaluated for potential risk.
- ❑ Timely response is made to newly developed rules and regulations.

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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 are not being addressed?
- »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 (con't)

- 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

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