



## Board of Directors Compliance Training

Prepared for **Montana Hospital Association**

September 23, 2021

*Presented by:*  
**Traci Waugh, RHIA, CPHS, CHC®**

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## Introduction



**Traci Waugh**  
**RHIA, CPHS, CHC®**  
**Senior Manager – PYA, P.C.**

Traci Waugh brings more than three decades of healthcare experience, which includes more than 15 years serving in compliance leadership roles, such as Director of Outreach Services and Compliance, as well as Senior Director of Compliance and Medical Staff. She also has experience as a director of health information management, medical staff, quality improvement, and risk management.

Traci works collaboratively with PYA clients, helping them develop and leverage robust compliance programs. She often speaks nationally, regionally, and locally on compliance-related topics.

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## Objectives



- Board of Directors Duties
  - Corporate Law
  - Compliance Oversight
- Overview of Fraud and Abuse Laws
  - False Claims Act
  - Anti-Kickback Statute
  - Stark Law
- Settlements
- Compliance Program Fundamentals
  - High-Level Oversight
  - Policies and Procedures
  - Open Lines of Communication
  - Training and Education
  - Response to Detected Errors
  - Consistent Enforcement
  - Auditing and Monitoring
- The Board's Responsibility for Compliance

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## Board of Directors Duties

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## Board of Directors (Board) Duties



- Board responsibilities pursuant to corporate law:
  - Fiduciary duties:
    - **Duty of Care:** good faith; be informed; reasonably prudent person
    - **Duty of Loyalty:** best interest of facility; avoid conflicts of interest
    - **Duty of Obedience:** consistent with facility's purposes
  - A director must act reasonably, prudently and in the best interests of the organization, avoid negligence or fraud, and act to avoid conflicts of interest.

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## Board Duties: Duty of Care



- The Board has a duty to ensure that an adequate organizational compliance program is in place, designed to provide management and the Board with timely and accurate information about the organization's compliance with the law.
- The Board must be reasonably informed about the organization's practices.
  - Including receiving input from legal counsel and other experts on whether practices are compliant with the law

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## Board Duties: Duty of Care



- What must a Board member do to avoid liability?
  - Act in good faith.
  - Ask questions.
    - Do not need to know every detail but need to be reasonably informed.
  - Receive appropriate information about the compliance program.
    - Receive direct reports from the Compliance Officer.
    - Receive compliance-related education.
  - Report any compliance issues you encounter to the Compliance Department and/or Legal Counsel and follow through with the process.
  - Follow proper procedures for conflicts of interest.
    - Failing to disclose a conflict may mean the Board member is not acting in “good faith” and can expose the Board member to personal liability.

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## Expectations for Compliance Oversight



### Measuring Compliance<sup>3</sup> Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 27, 2017  
HCCA-OIG Compliance Effectiveness Roundtable  
Roundtable Meeting - January 17, 2017 | Washington, DC



1. <https://www.justice.gov/criminal-fraud/page/file/937501/download>  
2. <https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2016>

3. <https://oig.hhs.gov>  
4. <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>

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## DOJ Criminal Division Evaluation of Corporate Compliance Programs



- The purpose “*is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation’s compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate*
  - (1) form of any resolution or prosecution;
  - (2) monetary penalty, if any; and
  - (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).”
- Three fundamental questions that the DOJ prosecutors will ask:
  - Is the corporation’s compliance program well-designed?
  - Is the corporation’s compliance program adequately resourced and empowered to function effectively? (*Revised in the 2020 guidance.*)
  - Does the corporation’s compliance program work in practice?

Source: <https://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8>

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## DOJ Criminal Division Evaluation of Corporate Compliance Programs (cont.)



- Organizations (and compliance professionals) must “prove it”.
- “Why has the company chosen to set up the compliance program the way that it has, and why and how has the company’s compliance program evolved over time?”

### Evolution of the DOJ’s Criminal Division Evaluation of Corporate Compliance Programs



Source: <https://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8>

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## Board Duties: Compliance Oversight



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## Overview of Fraud and Abuse Laws

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## False Claims Act (FCA)



- What is the FCA?
  - A civil war era law to provide recourse for the sale of defective goods to the U.S.
  - Imposes liability on persons who “knowingly and willfully...make materially false, fictitious or fraudulent statements...in connection with the delivery or payment of health benefits....”
    - Knowledge
    - Criminal or civil penalties, up to five years imprisonment, and exclusion from participation in federal health care programs
    - Civil penalties include up to \$23,331 per false claim and up to 3x the amount of damages
    - Six-year statute of limitations

Source: The Department of Justice. Found at -- <https://www.justice.gov/jm/criminal-resource-manual-902-1996-amendments-18-usc-1001>

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## FCA (cont.)



- Affordable Care Act: 60-Day Repayment Rule
  - Must report and refund overpayment within 60 days of “identification”
    - “Identification” = quantification
    - FCA definition of “knowledge”
    - Receipt of overpayment can be completely innocent
  - Six-month good faith investigation + 60 days
    - Longer for Stark Law and Anti-Kickback Statute (AKS) issues
  - Six-year look-back period
- Any overpayment retained beyond that point constitutes an “obligation” under the FCA as a reverse false claim.

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## Anti-Kickback Statute (AKS)



- AKS prohibits:
  - Knowingly and willfully
  - Soliciting, receiving, offering or paying (directly or indirectly, overtly or covertly)
  - Any remuneration (anything of value, cash or in-kind)
  - In exchange for or to induce the referral of any item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other government health care programs
- “One Purpose Test”
- Intent-based: requires a “guilty mind”
- Civil and criminal liability

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## AKS (cont.)



- Penalties for violation:
  - **Criminal:** fines of \$25,000 per violation, 5 years imprisonment
  - **Civil:** \$50,000 civil monetary penalties per violation, plus 3 X the damages (treble damages)
  - Risk of exclusion
  - Loss of medical license

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## AKS: Safe Harbors



- Investment interests
- Space rental
- Equipment rental
- Personal services and management contracts
- Sale of practice
- Referral services
- Discounts
- Employees
- Group purchasing organizations
- Waiver of beneficiary coinsurance and deductible amounts
- Ambulance replenishing
- Federally qualified health centers (FQHCs)
- Price reductions offered to health plans
- Practitioner recruitment

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## AKS: Safe Harbors (cont.)



- Investments in group practices
- Ambulatory surgical centers
- Referral arrangements for specialty services
- Price reductions offered to eligible managed care organizations
- Price reductions offered by contractors with substantial financial risk to managed care organizations
- Electronic Health Record items and services
- Pharmacy cost-sharing waivers
- Public ambulance cost-sharing waivers
- Relationships between Medicare Advantage Organizations and FQHCs
- Medicare coverage gap discount programs
- Free or subsidized local transportation services

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## AKS: November 2020 new safe harbors



- HHS finalized rule changes to modernize the AKS and Stark Law and create new flexibilities for value-based arrangements among providers, suppliers, practitioners, and others.
- The rule changes add three new safe harbors to the AKS:
  - Care coordination arrangements to improve quality, health outcomes, and efficiency without requiring the parties to assume risk
  - Value-based arrangements with substantial downside financial risk
  - Value-based arrangements with full financial risk

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## Stark Law



- In General:
  - If a physician has a “financial relationship” with a hospital, then that physician is prohibited from making Medicare referrals to the hospital and the hospital is prohibited from billing Medicare, unless an appropriate exception is met.
    - **Prohibited Referrals:** physician cannot refer
    - **Prohibited Billing:** hospital cannot bill Medicare or anyone else

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## Stark Law: Six Questions



- ✓ Is there a Physician?
  - ✓ Is the Physician making a Referral?
  - ✓ Is the Referral for Designated Health Services (DHS)?
  - ✓ Are the DHS being furnished by an Entity?
  - ✓ Does the Physician (or immediate family member) have a Financial Relationship with the Entity?
  - ✓ Are the DHS payable by Medicare?
- If yes to the above, then an exception ***MUST*** be met.

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## Stark Law: Compensation Exceptions



- Rental of office space
- Rental of equipment
- Bona fide employment relationships
- Personal service arrangements
- Physician recruitment
- Assistance to compensate a non-physician practitioner
- Isolated transactions
- Certain arrangements with a hospital (unrelated to DHS)
- Group practice arrangements with a hospital
- Payments by a physician (for items and services)
- Charitable donations by a physician
- Non-monetary compensation

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## Stark Law: Compensation Exceptions (cont.)

- Fair Market Value compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesy
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic prescribing items and services
- Electronic health records items and services
- Certain timeshare arrangements

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## Stark Law: Compensation Exceptions (cont.)

- Common elements of compensation exceptions (e.g., Medical Director or space lease)
  - In writing
  - Signed by the parties
  - Term of at least one year
  - Specify duties
  - Compensation is “set in advance”
  - Compensation is fair market value and commercially reasonable
  - Compensation does not take into account volume or value of referrals

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## Stark Law Penalties



- Stark sanctions:
  - Denial of payment
  - Repayment: up to 100% of amount paid
  - Civil monetary penalties of up to \$25,820 per item or service
  - Fine of up to approximately \$172,137 for a “circumvention scheme”
  - Risk of exclusion from Medicare and Medicaid
- Hospital has burden of proof

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## Comparison of AKS and Stark Law



AKS	Stark Law
Intent-based	Strict liability
Criminal liability	Civil liability
Broad application: implicates physicians and others	Applies only to a <b>financial relationship</b> with <b>physicians</b>
Safe harbors: “ <i>Should</i> ”	Exceptions: “ <i>Must</i> ”

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## Personal Obligation and the Yates Memo



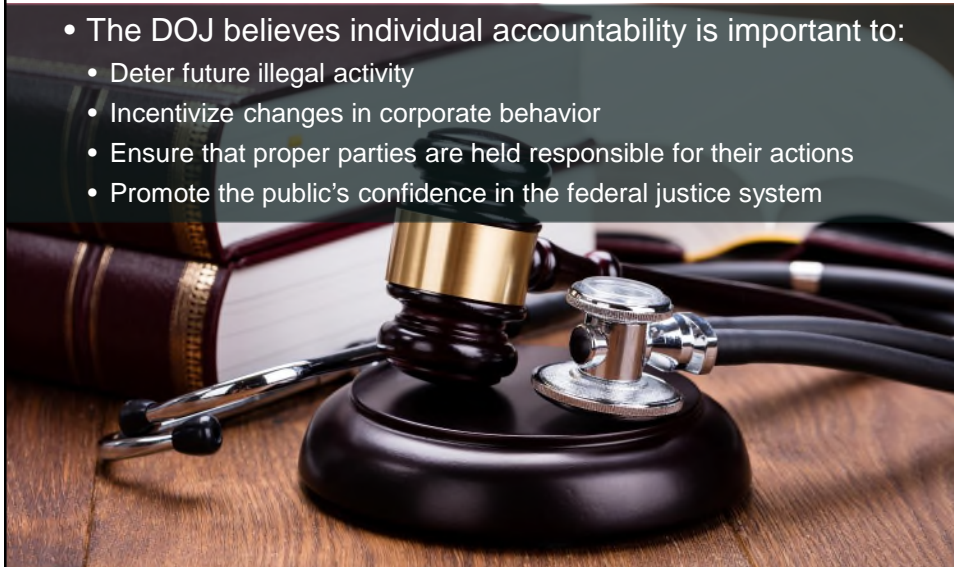
- Every individual involved in the development, approval, management or review of facility's contracts has a personal obligation to understand the applicable laws and facility's internal policies and procedures.
- Yates Memo:
  - On September 9, 2015, Deputy AG Sally Yates of the DOJ released to the public an internal DOJ Memorandum – the "Yates Memo" – addressing individual accountability for corporate wrongdoing.
  - The primary message is that the government will hold individuals accountable who are responsible for corporate misconduct.
  - The government wants to hold key decision-makers responsible.
  - There have been approximately 30 individual liability settlements to date.

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## Yates Memo: Policy Rationale



- The DOJ believes individual accountability is important to:
  - Deter future illegal activity
  - Incentivize changes in corporate behavior
  - Ensure that proper parties are held responsible for their actions
  - Promote the public's confidence in the federal justice system



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# Yates Memo



The U.S. Department of Justice periodically issues memos that give guidance on how it prosecutes corporate crime. Its latest memo, issued in September 2015, focuses on how prosecutors should treat employees and executives that are involved in corporate cases. **Here are the 6 things you need to know about it.**

- 1**  Companies will have to turn over information on involved individuals in order to get cooperation credit.
- 2**  All investigations—both criminal and civil—will start with a focus on individual actors within the company.
- 3**  Criminal and civil attorneys will work in lockstep on corporate cases, sharing information freely.
- 4**  Line prosecutors need written approval from a senior DOJ attorney before offering protection to individuals.
- 5**  Individual actions have to be resolved (or have a resolution plan) before corporate actions can be resolved.
- 6**  Civil actions will be pursued against culpable individuals, even if they can't pay a substantial fine.



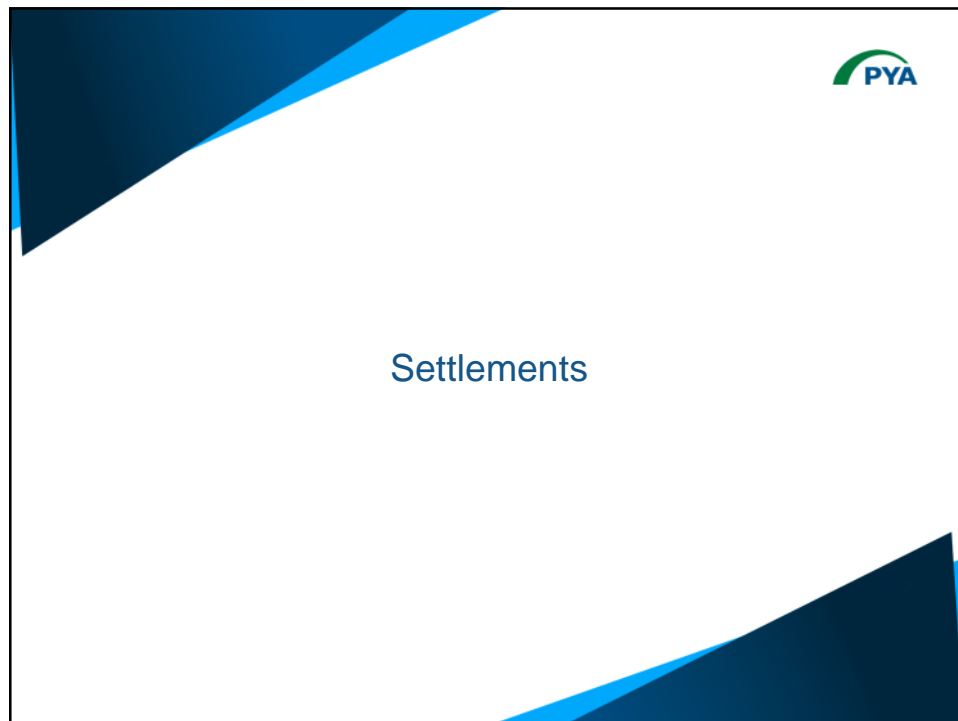
thebroadcat.com

Source: The Broadcat, *The Yates Memo, Simplified* available from [www.thebroadcat.com](http://www.thebroadcat.com), used with permission.

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## Settlements

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## Health Care Fraud is Big Business



- Of the more than \$3 billion in settlements and judgments recovered by the Department of Justice this past fiscal year, \$2.6 billion relates to matters that involved the health care industry, including:
  - Drug and medical device manufacturers
  - Managed care providers
  - Hospitals
  - Pharmacies
  - Hospice organizations
  - Laboratories
  - Physicians
- This is the tenth consecutive year that the department's civil health care fraud settlements and judgments have exceeded \$2 billion.
- The amounts included in the \$2.6 billion reflect only federal losses, but in many of these cases the department was instrumental in recovering additional millions of dollars for state Medicaid programs.

Source: <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>

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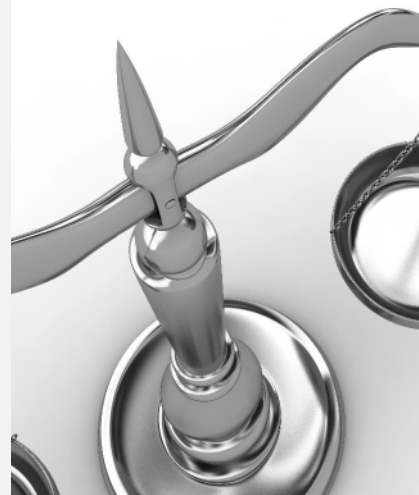
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## Return on Investment



- Prosecuting 'fraud' -
  - In July 2021, a HHS report stated that **for every \$1 invested** in the OIG, Department of Justice (DOJ), and Federal Bureau of Investigation (FBI) investigations related to health care fraud in the past three years, **\$4.30 was returned**.



Source: The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2020 [FY2020 Health Care Fraud and Abuse Control Program Annual Report \(hhs.gov\)](https://www.hhs.gov/health-care-fraud-and-abuse-control-program-annual-report)

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## What do these organizations have in common?



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## Settlements Due to Compliance Violations

<b>\$513M</b>	Tenet Healthcare Corporation (North Fulton Medical Center and Atlanta Medical Center)   October 2016	<b>\$30M</b>	Detroit Medical Center Detroit, MI   December 2010
<b>\$237M</b> <small>judgment settled for</small>	Tuomey Healthcare System Sumter, SC   October 2015 (Hospital sold to third party)	<b>\$25M</b>	Columbus Regional Healthcare System Columbus, GA   September 2015
<b>\$72.4M</b>		<b>\$24M</b>	Kalispell Regional Healthcare System Kalispell, MT   September 2018
<b>\$84.5M</b>	William Beaumont Hospital Detroit, MI   August 2018	<b>\$21.75M</b>	Citizens Medical Center Victoria, TX   April 2015
<b>\$69.5M</b>	North Broward Hospital District Broward County, FL   September 2015	<b>\$20.75M</b>	University of Pittsburgh Medical Center – Hamot Hamot, PA   March 2018
<b>\$55M</b>	Lancaster Regional Medical Center & Heart of Lancaster Medical Center (HMA) Lancaster, PA   September 2018	<b>\$18M</b>	Westchester Medical Center Valhalla, NY   May 2015
<b>\$42M</b>	Pacific Alliance Medical Center Los Angeles, California   June 2017	<b>\$17M</b>	Lexington Medical Center West Columbia, SC   July 2016
<b>\$34M</b>	Mercy Hospital Springfield, MO   June 2015	<b>\$14.25M</b>	Mercy Health Cincinnati, OH   May 2018
		<b>\$10M</b>	Robinson Health System Portage County, OH   March 2015

*Shaded organizations either engaged PYA after settlement, or PYA was selected to serve a Federal Monitor post-settlement.*

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## Key Themes in Government Settlements



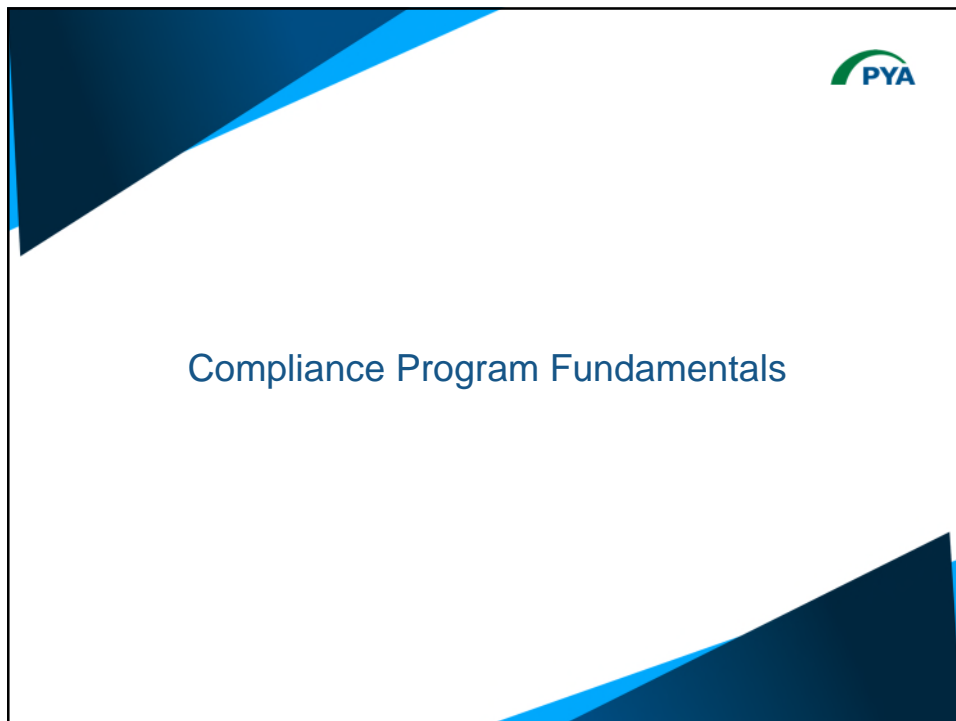
- Breakdown in processes and key controls due to growth
- **Reactive** vs. **Proactive** Compliance Program
- Relationships with referral sources
  - Employed physician compensation
  - Multiple medical directors in same specialty
  - “Stacking Arrangements”
  - Highly compensated physicians
  - Disparities in call coverage arrangements
  - Lack of commercial reasonableness
  - Real estate transactions
  - Paying for services above fair market value
  - No evidence of fair market valuation

Source: <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>

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## Compliance Program Fundamentals



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## High-Level Oversight



- A number of significant legal and regulatory compliance failures have dramatically impacted the economic well-being of various healthcare organizations.
- A compliance plan is a formal statement of a healthcare practice's intention to conduct itself ethically regarding business operations, government regulations, and patient services and care.
- The purpose of a formal compliance plan is twofold:
  - Provides a blueprint for the practice's compliance program and accomplishing the aforementioned goals
  - Encourages employees to report unethical conduct

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## High-Level Oversight (cont.)



- Tone at the Top
  - Employees do not live in a vacuum – they will reflect the importance of ethical business practices shown to them by the managers, executives, and Board members above them.
  - The success of an effective compliance program is highly dependent upon the support provided by an organization's governance and management (the Tone at the Top).
  - The Tone at the Top is the foundation of an effective compliance program and begins with the Board's oversight responsibility, followed by the CEO's commendation of the program, support by the executive management team, and a Compliance Officer that facilitates organization-wide accountability for compliance issues.

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## High-Level Oversight (cont.)



- Board Responsibility
  - A Board must act in good faith in the exercise of its oversight responsibility for its organization:
    - Ensure that a corporate information and reporting system exists.
    - Make certain that the reporting system is adequate to assure that appropriate information related to compliance with applicable laws is given appropriate attention in a timely and logical manner.

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## High-Level Oversight (cont.)



- Compliance Committee (CC)
  - The CC provides oversight, advice, and general guidance to the Board, President/CEO, senior management, facility CEOs/Executive Directors, and facility compliance contacts on all matters relating to corporate compliance and the compliance program.
  - Ongoing analysis and evaluation of corporate values, culture, and potential or high-risk areas of compliance
  - Ensuring compliance program effectiveness via metrics and monitoring
  - Establishing heightened awareness of compliance issues
  - Promote compliance in the work environment
  - Reviewing the Chief Compliance Officer's (CCO) annual Compliance Work Plan
  - Monitoring internal and external audits

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## Policies and Procedures



- Policies and procedures are used to document how to comply with federal and state laws as well as contractual or accreditation standards when conducting its operations
- Having updated and detailed policies and procedures provides workforce with a guide on how to perform their jobs compliantly
- Well-documented and updated policies and procedures allow for detection of possible compliance issues. For example, missed steps in procedures or not following the procedure in the right order can signal possible issues.

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## Policies and Procedures (cont.)



- Essential Compliance Policies and Procedures
  - Compliance program reporting structure, education, and hotline operation
  - Remediation efforts when compliance issues are identified, including timely reporting, and refunding to governmental payers (e.g., the 60-day rule)
  - Fraud, Waste, and Abuse (Deficit Reduction Act)
  - Entities receiving over \$5 million in Medicaid payments must have policies in place to address FCA, Whistleblower protections, and detection of fraud and abuse

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## Policies and Procedures (cont.)



- Essential Compliance Policies and Procedures (continued)
  - Conflicts of interest
  - Gifts and gratuities
  - Non-retaliation for reporting compliance issues
  - Exclusion screenings for all employees, physicians, non-physician practitioners, vendors
  - Standards of conduct and disciplinary actions
  - Relationships with referral sources

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## Open Lines of Communication



- For a compliance program to be effective, the workforce must be able to ask questions and report problems. In some cases, workforce members might have an obligation to report a concern.
- The Compliance Office must be a resource for clarification of policies, procedures and regulations.
- The Compliance Office must partner with business leadership to communicate about issues identified and how they are resolved.
- Effective programs also allow for anonymous reporting of issues and concerns and feedback to these individuals regarding the status of the issues.

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## Training and Education



- General compliance training to all employees that effectively communicates facility's compliance program requirements
  - Initial training for all new employees and members of the medical staff occurring at or near the date of hire
  - Annual training for existing employees and members of the medical staff
- Audits by oversight agencies and payers, as well as litigation cases, require proof of training
  - Content
  - Frequency
  - Target Audience
  - Proof of Attendance
  - Outcomes
- ***Training is not optional***

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## Auditing and Monitoring



- A system for auditing and monitoring must be implemented to:
  - Measure the effectiveness of the compliance program
  - Ensure compliance with legal, regulatory, internal policy and contractual requirements
  - Identify compliance risks
- Difference between Auditing and Monitoring:
  - Monitoring is performing regular reviews as part of normal operations to confirm ongoing compliance
  - Auditing is formal reviews of compliance with a particular set of standards as base measures
- Includes periodic risk assessment and work plans to focus on auditing and monitoring activities

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## Auditing and Monitoring (cont.)



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## Response to Detected Errors



- Response and Investigations
  - An effective compliance program includes a process to respond to program violations
  - Issues that are identified must be reported quickly and then thoroughly investigated and corrected
  - Findings, status of investigations and follow-up, and outcomes must be reported to appropriate governance bodies
  - The organization should have policies and protocols in place to respond to government investigations

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## Response to Detected Errors (cont.)



- Corrective Action
  - When vulnerabilities or non-conformances are investigated, corrective action must be conducted in response to the potential violations.
  - Corrective action can include:
    - Policy and procedure updates
    - Retraining employees
    - Correcting claims submitted or refunding overpayments
    - Disclosure to oversight agencies
    - Information technology changes
    - Employee discipline, where appropriate

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## Consistent Enforcement



- Written policies that apply appropriate disciplinary sanctions on those who fail to comply with applicable requirements and written standards of conduct are required
- Policies should include sanctions for:
  - Non-compliance
  - Failure to detect non-compliance when routine observation or due diligence should have provided adequate information
  - Failure to report actual or suspected non-compliance
- Discipline must be dealt with timely and enforced consistently

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## The Board's Responsibility for Compliance

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### Board Members Should be Asking...

- Do I receive regular compliance reports?
- Do I understand the compliance reports I receive?
- Do I receive regular updates regarding the compliance work plan status and any challenges to complete items?
- Have I received training on relevant compliance issues?
- Is compliance part of strategic and capital planning?
- How is the management team incentivized? Is compliance a component in the "balanced scorecard" or strategic metrics?
- Are adequate resources devoted to staff training and retention?
- Are we knowledgeable of the risks that are **NOT** being addressed on the compliance work plan due to resource constraints?
- Would I be confident in signing a certification regarding the effectiveness of our compliance program?

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## Board Accountability and Mandatory Certifications



“The Board of Directors has made a reasonable inquiry into the operations of [Hospital’s] Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [Hospital] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

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## Board Responsibilities: Summary



- Ensure funds budgeted for the compliance program are sufficient and appropriate, considering the organization’s high risks.
- Review and approve any modifications to the key policies and procedures that define the compliance program framework.
- Request regular reports from the Compliance Officer regarding compliance program activities.
- Recognize that the ownership of the compliance program is the entire organization...not just the compliance department
- Expect compliance reports every quarter and ask questions.
- Request an evaluation of the effectiveness of the organization’s compliance program and the Compliance Officer annually.

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## In Conclusion...



- For each dollar spent on compliance, on average, **\$5.21** is saved by in avoidance of legal liabilities, harm to the company's reputation and lost productivity.

Investment	Savings	ROI
Increase in Compliance Budget \$1.00 →	Decrease in Damages, Settlements, Fines	\$1.37
	Avoidance of Reputational Harm	\$2.74
	Avoidance of Loss of Productivity	\$1.10
	<b>Total Savings</b>	<b>\$5.21</b>
		→ $\frac{5.21}{1.00} - 1 = 421\%$

Source: Seizing the Opportunity – Part One: Benchmarking Compliance Programs. General Counsel Roundtable. Managing Legal Risk Series. Corporate Executive Board.

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## Resources and References



- Office of Inspector General - State False Claims Act
  - <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/>
- Office of Inspector General – Federal Anti-Kickback Statute
  - <https://oig.hhs.gov/newsroom/oig-podcasts/federal-anti-kickback-statute/>
- Office of Inspector General Fact Sheet– Revised Safe Harbors
  - <https://oig.hhs.gov/reports-and-publications/federal-register-notices/factsheet-rule-beneficiary-inducements.pdf>
- Office of Inspector General – Physician Self-Referral Law
  - <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>
- Measuring Compliance Program Effectiveness: Resource Guide
  - <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>

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# Questions?



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Thank you!



**Traci Waugh**  
RHIA, CPHS, CHC®  
Senior Manager  
twaugh@pyapc.com



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