HCCA Healthcare Compliance Essentials Workshop

Combined PDF Presentations

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Compliance Essentials Workshop

Intro and Background to Compliance and Ethics Programs

Steve Lokensgard, Faegre Drinker Biddle & Reath

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Presenter

- Army JAG Corps (1987)
- Minnesota Attorney General's Office (1994)
- Allina Health (2000)
  - Associate General Counsel
  - Chief Compliance Officer
- Faegre Drinker Biddle & Reath (2009)

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2

Welcome!

- This is the first of 13 sessions in the Healthcare Compliance Essentials Workshop
  - Day 1
    - Introduction & background to compliance & ethics programs
    - Standards and procedures
    - Governance, oversight, authority
  - Day 2
    - Risk assessment
    - Due diligence in delegation of authority
    - Hot/ common compliance issues
  - Day 3
    - Communication and Training
    - Monitoring, Auditing, and Reporting Systems
    - Investigations
  - Day 4:
    - Response to wrongdoing
    - Incentives and Enforcement
    - Program Improvement
    - What's next for me and my program?

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Today's Agenda

- History of Health Care Regulation (late 1800's – 2010)
- Evolution of Compliance and Ethics Programs (1980's to present)
- Current HHS Guidance on Compliance Programs
- Current DOJ Guidance on Compliance Programs
- Scope of a Compliance Program
- Value of Compliance and Ethics Programs
- Introduction to the Elements of an Effective Compliance Program

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Article by Mike Adelberg in Compliance Today July, 2007

How did we get here?
A brief history of health care regulation in the United States

By Michael Adelberg, MPP, MA

Editor's note: Michael Adelberg has been in the health care regulatory field for 15 years, including 10 with the Centers for Medicare and Medicaid Services (CMS). At CMS, he was prominent in the development and implementation of different Medicare oversight and public reporting programs. He is presently a health insurance executive. He can be reached via e-mail at madelberg1@hotmail.com.

Even the most enthusiastic supporters of the current U.S. regulatory system shrug over its patchwork nature and the overlapping mandates of its constituent parts. The present U.S. regulatory structure, as regulatory professionals well know, creates a host of regulators—varied federal actors, states, and different quasi and non-governmental organizations. Managed care plans, for example, are financially regulated by state insurance departments, accredited by the National Committee for Quality Assurance (NCQA), and those that participate in government programs (and most do) are further regulated by the various government payers of these programs. On top of these entities sit the prosecutorial powers of state attorneys general, the Department of Health and Human Services (DHHS), Office of the Inspector General (OIG), and the Department of Justice. The various regulators serve different—but rarely entirely distinct—functions.

It is the author's contention that the patchwork of regulators and regulatory activity is the result of a profound lack of consensus over the appropriate role of regulation and government oversight in health care throughout U.S. history. The result is a confusing regulatory patchwork and its piecemeal expansion over time. As political scientist Lawrence Brown notes, expansions of the U.S. regulatory state have tended be reactive, based on upon periodic "market malfunctions." For example, legislations to create and further empower the Food and Drug Administration in 1906, 1938, and 1962, were all the result of high profile drug-market failures the previous year.[1] Equally important are macro-level societal and technological changes that have grown health care exponentially as a segment of the U.S. economy and, in many important ways, as a public entitlement. As such, the health care regulatory state has haphazardly evolved to date, and will continue to evolve based on externalities—market failures, technological advances, and societal changes—rather than because of any great or consistent political vision. As Brown further notes, the U.S. health care regulatory system was built in "bits and pieces" and never "conformed to an economic theory or master plan."[2] Nevertheless, the trend toward a greater regulatory footprint and public sector presence has been the consistent (if accidental) progression. The purpose of this article is to visit important movements in the century-long "bits and pieces" progression to building our present regulatory state, with an eye toward what this means for the foreseeable future.

The pre-regulatory era, 1800s–early 1900s

It is easy to forget how small a role professional health care played in American society just a little over a century ago. At this time, Americans rarely saw a doctor, and most lived out their adult lives without ever stepping into a hospital. Local doctors provided most care in the home, and huckster healers and medicine men toured the nation selling all variety of "snake oil" miracle cures with little risk of reprisal. By today's standards, health care was not very effective, regardless of the patient's ability to pay. The improvements brought about by the public health revolution (e.g. sanitation, hand-washing, vaccinations, quarantines, and improved diet) would make the United States the world's healthiest nation—but not because of the quality of its health care.[3]

In these bad old days for health care, doctor-patient services were negotiated privately, and rarely cost much. Hospitals (which generally provided only surgery and palliative care) were almost entirely financed by religious organizations and private philanthropy, and the wealthy avoided them. There was no health insurance provided by the government or employers because there was little need. By the late 1800s, the American Medical Association and American College of Surgeons were leading efforts to develop standards for doctors and hospitals, but these were unevenly deployed across the states. State medical boards were only gradually professionalizing the licensure requirements for doctors and hospitals; while the professionalizing of other health care providers, such as pharmacists, nurses, and dentists, lagged behind.[4]

To the degree there was any health care regulation in the modern sense of the term, it was at the state level and related to drugs. By the late 1800s, most states had passed laws against the "adulteration" of drugs. But

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5

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History of Health Care Regulation late 1800s

- Health care primarily delivered in the home
- Hospitals were supported by philanthropy, religious organizations
- No federal regulation
  - "Snake Oil" salesman touting miracle cures and elixirs

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History of Health Care Regulation Late 1800s

- 1840s
  - First medical malpractice lawsuits, but infrequent
- American Medical Association
  - Founded in 1847
  - 1849 – interested in publishing articles to warn the public of the dangers of quack remedies and nostrums
- State Boards of Medical Practice
  - 1883 – Minnesota
  - Professionalizing the practice of medicine

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Ethics

The Knick, Season 1, E6

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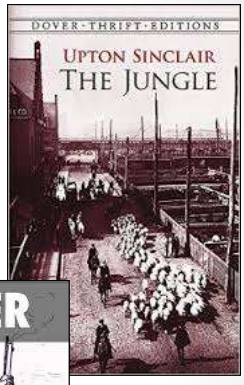
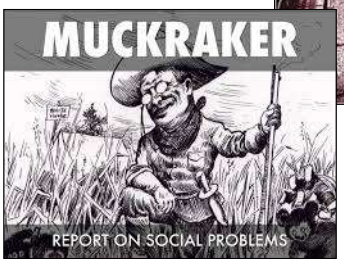
History of Health Care Regulation Early 1900s

- 1905 – Upton Sinclair publishes The Jungle
  - Exposes unsanitary and abusive conditions
- Muckrakers /Progressives seek regulations
- The Meat Inspection Act of 1906
- The Pure Food and Drug Act of 1906
  - Focuses on adulteration of drugs, labelling





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History of Health Care Regulation Early 1900s

- Progressives believed in positivism
  - A belief that unfettered human ingenuity will forever advance the state of art in a given field
  - Envisions a degree of self-governance – a belief that physicians and hospitals will naturally strive to improve quality and safety – no need for government intervention to spur health care innovations
  - American College of Surgeons (now Joint Commission) began inspecting hospitals for compliance with community standards
- Government oversight was necessary to punish bad actors
  - Reign in the quacks and crooks

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History of Health Care Regulation 1930s

- New Deal – growth of government
- First Rulemaking
  - 1930's, in the wake of The New Deal, agencies begin clarifying legislation and issuing rules
  - Administrative Procedures Act of 1946
- Civil Monetary Penalties
  - Federal agencies were given authority to issue penalties to address noncompliance
  - Dramatic reduction of criminal prosecutions for FDA violations between 1930 and 1950
- Focus of government regulation continues to be punishment and financial sanctions to deter misconduct

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History of Health Care Regulation WWII

- World War II impacts health insurance
- 1942 War Labor Board Ruling
  - Wage freeze in effect
  - Fringe benefits of up to 5% didn't count
  - Employers started offering health insurance
- 1950's – Unions organize
  - Many bargain for health insurance

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History of Health Care Regulation 1960s

- 1965 Medicare is enacted
  - Government becomes a payer
- Federal Government begins its role as change agent
  - 1973 HMO Act
    - $300 million to start up managed care organizations
    - Requires many employers to offer HMO coverage to employees
- Creates new federal agencies
  - Centers for Disease Control
  - National Institutes of Health
  - Agency for Health Research and Quality

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History of Health Care Regulation 2010-present

- EHR Incentive Payments
  - Payments for making "meaningful use" of an electronic health record
- Affordable Care Act
  - Established the CMS Innovation Center
    - Models to pay for value rather than volume
  - Accountable Care Organizations
  - Plans available on the Health Care Exchange

14

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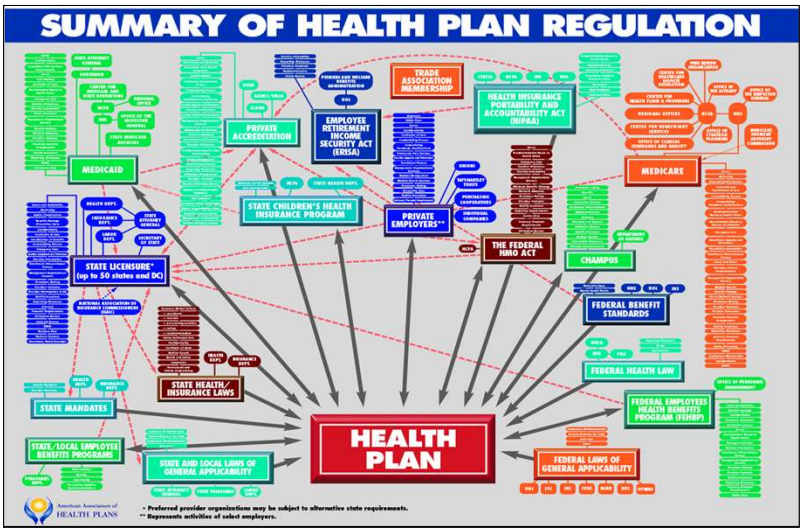
History of Health Care Regulation



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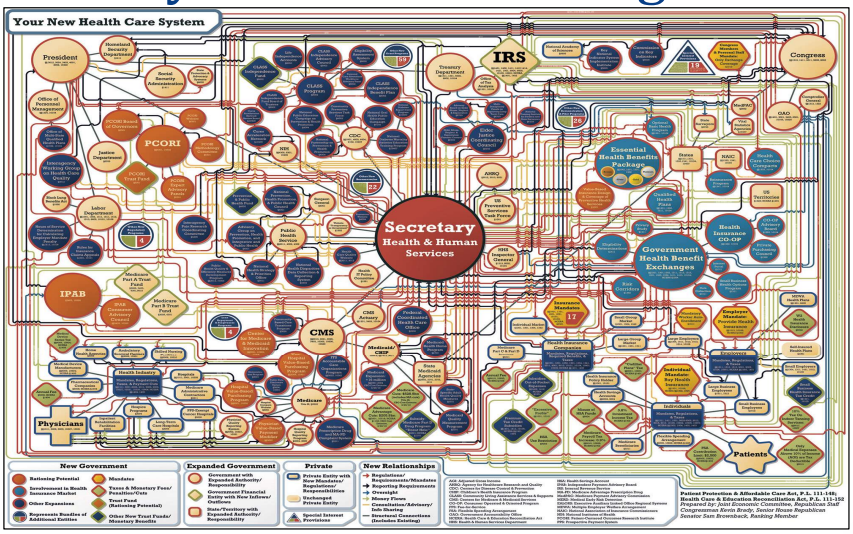
History of Health Care Regulation



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History of Health Care Regulations Summary

- Late 1800s
  - Little to no regulation, growth of professional associations with aspirational goals
- Early 1900s
  - Health care regulation begins
  - Criminal sanctions, focused on quackery
- 1930s
  - Growth of agencies and administrative sanctions
- 1960s to present
  - Regulations expand rapidly after 1965
  - Complex – multiple agencies with enforcement authority
  - Traditional government role as the enforcer continues
  - New government role as a change agent
    - Incentives for higher quality, lower cost, population health

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Evolution of Compliance Programs

- Influence of the Defense Industry
  - Operation Ill Wind leads to convictions of 9 government officials, 42 consultants, 7 military contractors
  - February 1986 Packard Commission Interim Report
    - Urged defense contractors to improve the defense acquisition process through greater self-governance
    - "To assure that their houses are in order, defense contractors must promulgate and vigilantly enforce codes of ethics that address the unique problems and procedures incident to defense procurement."
    - "They must also develop and implement internal controls to monitor these codes of ethics and sensitive aspects of contract compliance."
- Leads to creation of the Defense Institute Initiative on Business Ethics and Conduct

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Evolution of Compliance Programs

- Original DII Principles
  - Have and adhere to written Codes of Conduct;
  - Train employees in those Codes;
  - Encourage internal reporting of violations of the Code, within an atmosphere free of fear of retribution;
  - Practice self-governance through the implementation of systems to monitor compliance with federal procurement laws and the adoption of procedures for voluntary disclosure of violations to the appropriate authorities;
  - Share with other firms their best practices in implementing the principles, and participate annually in "Best Practices Forums"; and
  - Be accountable to the public.

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Evolution of Compliance Programs

- Sentencing Reform Act of 1984
  - Created the Federal Sentencing Guidelines
    - Eliminate sentencing disparities
    - Sentencing to be based on guidelines that would bind federal judges
  - U.S. v. Booker, 2005
    - Guidelines are considered advisory only

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Evolution of Compliance Programs

- 1991 – the U.S. Sentencing Commission publishes its first set of guidelines applicable to organizational offenders
  - Purpose for punishing individuals: retribution, incapacitation
  - Purpose for punishing organizations: deterrence
- Guidelines give credit to organizations who have an effective program to prevent and detect violations of law

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Evolution of Compliance Programs

- Seven Elements of an Effective Compliance Program
  - Standards and procedures
  - Involvement of high-level personnel
  - Discretionary authority carefully delegated
  - Standards and procedures communicated to employees
  - Monitoring and auditing
  - Standards consistently enforced
  - Response and prevention
- Compliance program can vary based on the size of the organization
- Guidelines incorporate many concepts from the Defense Industry Initiative

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Evolution of Compliance Programs

- Growth of compliance programs since the sentencing guidelines were published
  - 1991 – Ethics & Compliance Officers Association
  - 1996 – Health Care Compliance Association (HCCA)
    - 2,000 members in 2000
  - 2005 – Society of Corporate Compliance and Ethics (SCCE)
  - 2018 – topped 20,000 members in HCCA and SCCE

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Evolution of Compliance Programs

- Compliance Programs Become Mandatory
  - 1998 – CMS requires such organizations to establish a "plan for complying with all applicable Federal and State standards"
    - 63 Fed Reg 34968 (June 26, 1998); 42 CFR 422.503(b)(4)(vi)
  - 1998 – OIG publishes its Compliance Program Guidance for Medicare+Choice Organizations
    - "the OIG's program guidance is voluntary and simply is intended to provide assistance for Medicare+Choice organizations looking for additional direction in the development of internal controls that promote adherence to applicable Federal and State law."
- Similar regulatory requirements for Medicare Prescription Drug Plans
  - 70 Fed Reg 4194 (January 28, 2005); 42 CFR 423.504(b)(4)(vi)

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Evolution of Compliance Programs

- Compliance Programs Become Mandatory
  - 2005 – Deficit Reduction Act of 2005
    - Requires entities that receive or make payments under a state Medicaid plan of at least $5 million to have a compliance program
      - Actually, must have detailed policies and procedures for detecting and preventing fraud, waste and abuse
  - 2010 – Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148)
    - Requires all entities participating in Medicare to establish a compliance program

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Evolution of Compliance Programs Summary

- 1980s - Voluntary principles adopted by the defense industry
  - Prevent and detect crime, promote and ethical culture
- 1990s – Federal Sentencing Guidelines
  - Still voluntary, incentive to adopt an effective compliance program
  - Expand from defense industry to health care industry
  - Compliance associations are formed and begin to grow
- 2000s – Compliance programs become mandatory
  - Starts with managed care plans in 1998

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Current Compliance Standards

- 42 CFR 503(b)(4) Compliance Program for Medicare Advantage Organizations
  - "Governing Body" and senior leader oversight
  - Written policies, procedures and standards
  - Designation of a Compliance Officer
  - Annual training and education
  - Effective communication, including compliance hotline
  - Timely, consistent and effective enforcement of the standards
  - Routine monitoring, auditing and risk analysis
  - Response and prevention, including procedures to voluntarily self-report potential fraud or misconduct

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Current Compliance Standards

- CMS Guidance – "The Twins"
  - Medicare Managed Care Manual, Ch. 21 – Medicare Advantage Part C Compliance Program Guidelines
  - Prescription Drug Benefit Manual, Ch. 9 – Medicare Advantage Part D Compliance Program Guidelines
- Elements of an Effective Compliance Program – OIG Sentencing Guidelines
  - I: Written policies, procedures and standards of conduct
  - II: Compliance Officer, Compliance Committee and High Level Oversight
  - III: Effective Training and Education
  - IV: Effective Lines of Communication
  - V: Well publicized disciplinary standards
  - VI: Routine Monitoring, Auditing, Risk Assessment
  - VII: Prompt Response to Compliance Issues

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Current Compliance Standards

- Medicaid Managed Care Rule – May 6, 2016
  - 42 CFR 438.608(a)(1)
- Requirements of a Compliance Program
  - I: Written policies, procedures and standards of conduct
  - II: Compliance Officer
  - III: Compliance Committee and Board Oversight
  - IV: A System for Training and Education
  - V: Effective Lines of Communication
  - VI: Enforcement of Standards Through Well publicized disciplinary guidelines
  - VII: Routine Monitoring, Auditing, Risk Assessment, and Prompt Response to Compliance Issues

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HHS Guidance

- HHS OIG Issues Compliance Program Guidance
  - Hospitals (1998 and 2005)
  - Physicians and Small Group Practices (2000)
  - Home Health (1998)
  - Hospice (1999)
  - Laboratories (1998)
  - Durable Medical Equipment Companies (1999)
  - Ambulance Suppliers (2003)
  - Nursing Facilities (2000 and 2008)
  - Pharmaceutical Manufacturers (2003)
  - Medical Device Companies (none, but see Pharmaceutical Manufacturers)
  - Third Party Billing Companies (1998)

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HHS Guidance

- HHS OIG Issues Compliance Program Guidance
  - All have common elements
  - Differs by Risk Issues/ Scope of Compliance Program

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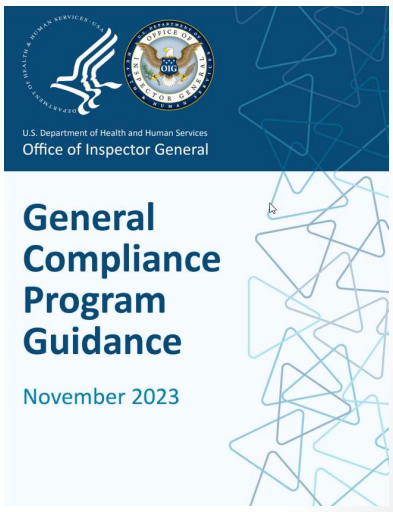
HHS Guidance

- 2023 Compliance Program Guidance
  - Applies to all organizations
  - Voluntary guidance – not a regulation
  - Identifies common risk issues
    - AKS, Stark, False Claims Act, HIPAA
    - CMPs, Exclusion Authorities
    - Private Equity
  - Compliance Adaptations for Small and Large Entities



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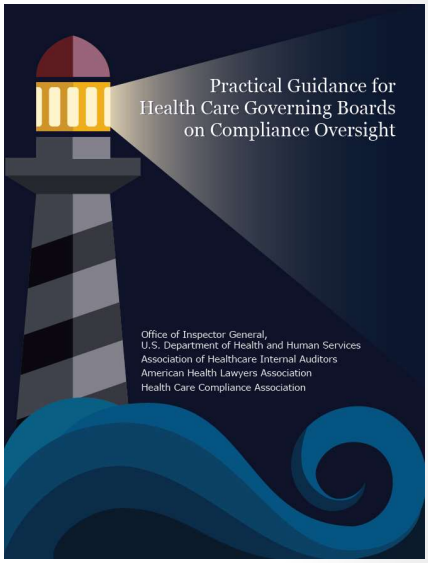
HHS Guidance

- 2015 Guidance Document on Board Oversight of a Compliance Program
  - OIG/ AHLA/ HCCA
- Addresses issues relating to the Board's oversight and review of compliance
  - Expectations
  - Roles and responsibilities
  - Issue reporting
  - Regulatory risk
  - Accountability



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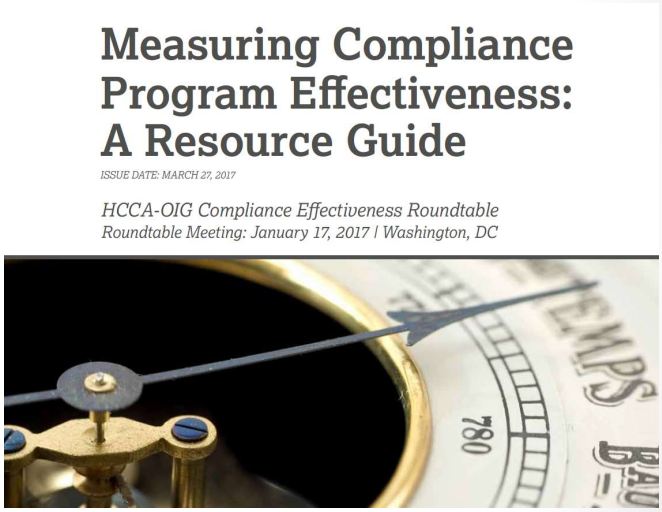
HHS Guidance

- 2017 Resource Guide on Measuring Compliance Effectiveness
  - OIG and HCCA
  - 54-page detailed guide



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DOJ Guidance

- Current Federal Sentencing Guidelines
  - Posted at: https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8
- Lists Factors to Consider:
  - The applicable industry practice or the standards called for by any applicable government regulation (i.e. regulations applicable to Medicare Advantage plans)
  - The size of the organization
  - History of similar misconduct
- 2022 Report on the Organizational Sentencing Guidelines
  - In 30 years there were 4,946 organizational offenders
    - 89.6% of had no compliance program
    - Only 11 organizations received credit for having an effective compliance program

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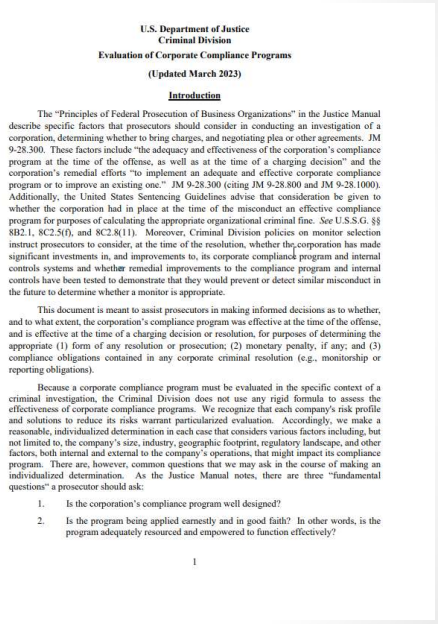
DOJ Guidance

- DOJ Guidance (March 2023)
  - Is the corporation's compliance program well designed?
  - Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
  - Does the corporation's compliance program work in practice?

Posted at: https://www.justice.gov/criminal-fraud/page/file/937501/download



U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

(Updated March 2023)

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. *See* U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, Criminal Division policies on monitor selection instruct prosecutors to consider, at the time of the resolution, whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems and whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future to determine whether a monitor is appropriate.

This document 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).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three "fundamental questions" a prosecutor should ask:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?

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Scope of a Compliance Program

- ~~Compliance with All Laws~~
- Purpose: Prevent and detect crime and promote an ethical culture
- Focus on high risk issues
  - Consider OIG guidance documents
  - Typically for a health care organization:
    - Ethics (a Code of Conduct)
    - HIPAA Privacy and Security
    - Fraud and Abuse Laws (Anti-Kickback Statute, Stark Law, Unlawful patient inducement)
    - Billing Compliance (False Claims Act)
    - Antitrust
    - Foreign Corrupt Practices Act
    - Accreditation Standards (sometimes)

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Benefits of a Compliance Program

- Employee Engagement
  - Being part of an ethical organization
- Continuous Process Improvement
  - Compliance discipline translates well to other areas
- Good business practices to identify and prevent risks
  - Required by some banks

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Overview of the "Seven Elements"

- Standards and Procedures
- Governance, Oversight, and Authority
- Due Diligence in Delegation of Authority
- Communication and Training
- Monitoring & Auditing and Reporting Systems
- Incentives and Enforcement
- Response to Wrongdoing
- Risk Assessment
- Program Improvement

39

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Questions

40

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Compliance Essentials Workshop

Written Standards of Conduct, Policies and Procedures

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Agenda for this Training

- Foundational principles of written standards of conduct and policies and procedures
- Formulating your Code of Conduct
- Comparing, contrasting and managing your compliance policy and procedure program

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Foundational principles of written standards of conduct and policies and procedures

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Why We Need Written Standards

- **Set clear expectations:** Define consistent rules of behavior.
- **Provide consistency:** Written standards ensure uniform application across the organization.
- **Establish policies:** Clarify our organizational approach to key issues.
- **Guide procedures:** Outline step-by-step actions for daily tasks.
- **Measure performance:** Create a baseline for accountability and auditing.

Standards and policies "promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law." – *U.S. Sentencing Guidelines Manual Nov 1, 2018, p. 517.*

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Why Written Standards, Policies & Procedures Really Matter

- **First thing auditors ask for:** Copies of your standards and policies.
- **Expect a long request list:** They'll likely ask for more than they need.
- **Time travel required:** You'll need proof of what policies were active when events occurred.
- **Compliance matters:** A policy not followed is worse than no policy at all.
- **Clarity counts:** Everyone must know the rules—and actually follow them.
- **Weak link alert:** Poor policy management can sink your program.
- **Strong defense:** Well-managed policies protect your organization when it matters most.

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Foundational Principles

POLLING QUESTION

How confident are you in your organization's policy and procedure management process?

A. **Our organization does not have policies and procedures.**
B. **We have policies and procedures, but no management process.**
C. **We have a policy and procedure management process in place, but it needs improvement.**
D. **Our policy and procedure management system is in place and well implemented.**
E. **Our policy and procedure management system and process would be considered best practice in the industry.**

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Formulating your Code of Conduct

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Code of Conduct: Your Everyday Compass

- **Our ethical GPS:** Lays out the principles, values, and expectations that guide our decisions.
- **For everyone, no exceptions:** Board members, frontline staff, volunteers, vendors—you're all in.
- **The standard we all share:** Aligns every role to the same high bar for ethical behavior.
- **More than rules—it's our "why":** Explains not just what we do, but why we do it the right way.

The code of conduct "should function in the same fashion as a constitution, i.e., a document that details the fundamental principles, values, and framework for action within an organization." – *Office of Inspector General, Supplemental Compliance Program Guidance for Hospitals, FR, Vol. 70, No. 19, January 31, 2005.*

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Elements of a Strong Code of Conduct

- **Tone at the top:** Endorsed by the CEO and Board.
- **Speaks our language:** Tied to mission, vision, values, and culture (not lawyer-speak).
- **Crystal clear:** Easy to read, easy to follow, no decoder ring required.
- **Covers everyone:** Applies across the organization—not just certain roles.
- **Practical + Relatable:** Uses real examples and FAQs to show what "right" looks like.
- **Inspires action:** Encourages commitment, not just compliance.

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9

How to Bring Your Code of Conduct to Life

- **Distribute widely:** Make accessible to employees, board, physicians, volunteers, vendors.
- **Multiple formats:** Paper and electronic copies; include on intranet/public website—make it impossible to miss.
- **Incorporate into training:** Introduce during onboarding and revisit in annual compliance refreshers.
- **Keep it simple:** Write so it's clear to everyone (8th-grade reading level is ideal).
- **Connect the dots:** Link to related policies for deeper guidance when needed.
- **Stay current:** Review and update at least annually—or sooner if rules change.
- **Language access:** Provide translations for a diverse workforce.

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Code of Conduct Best Practices

- **Visual appeal:** Use modern design — more like a brochure, less like a court filing.
- **Organizational identity:** Use your colors, logo, and even real staff photos (relatable > stock photos).
- **Key contacts:** Compliance hotline, officer, and external reporting options—easy to find, no digging required.
- **Relevant topics:** Billing, privacy, workplace behavior—your high-risk areas front and center.
- **Frequent reference:** Refer to the Code in meetings, training, and daily conversations—not just during onboarding.
- **Annual attestation:** Require acknowledgment of understanding and agreement to comply.

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Case Study: Missing Code of Conduct

Janet just joined as the new Compliance Officer. During her first program review, she discovers the organization has **no formal Code of Conduct**.

What's her first move? Where should she start?

- Should she build it from scratch or adapt an existing template?
- Who needs to be involved—leadership, HR, legal, frontline staff?
- How will she roll it out and make it stick?

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Building a Code of Conduct: Step by Step

Creation → **Publication** → **Management**

- Start With Reality Check
- Bring in the Right Voices
- Tie It to Who You Are
- Spot the Risks
- Make It Practical

- Look Professional
- Plan Distribution
- Shout It Out

- Keep It Fresh
- Set Clear Ownership
- Embed in Daily Life

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Building a Code of Conduct: Step by Step

- **Creation**
  - **Reality check:** Acknowledge what's missing (or outdated).
  - **Involve stakeholders:** Leadership, HR, Legal, operations—get buy-in early.
  - **Align:** Mission, vision, values, culture = foundation of your Code.
  - **Identify risks:** Use a risk assessment to address high-stakes areas first.
  - **Make it practical:** Add real examples or FAQs to help staff connect the dots.
- **Publication**
  - **Look professional:** Partner with Marketing for design and branding.
  - **Storage and distribution:** Decide on digital, print—or both—and make it accessible.
  - **Shout it out:** Communicate widely to employees, board, and key partners.
- **Management**
  - **Keep it fresh:** Review annually or when laws change.
  - **Ownership:** Define who approves updates and revisions.
  - **Embed in daily life:** Use in training, refreshers, and compliance touchpoints.

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Foundational Principles

POLLING QUESTION

How would you classify your organization's Code of Conduct?

A. **Our organization does not have a Code of Conduct.**
B. **Our Code of Conduct is a very brief document and not well known.**
C. **Our Code of Conduct is comprehensive, but not visually appealing or well known/understood.**
D. **Our Code of Conduct is in place and is a good document.**
E. **I consider our Code of Conduct best practice in the industry.**

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Comparing, contrasting and managing your compliance policy and procedure program

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Ethical Principles to Everyday Practice

- **Shift in focus:** Moving from high-level principles to detailed guidance
- **Different realities:** Some organizations use robust management systems; others rely on paper or shared drives
- **Universal goal:** Regardless of format, policies should be clear, accessible, and aligned with compliance objectives
- **Key takeaway:** Effective policy management supports consistent, compliant operations

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Definitions: Standards, Policies, and Procedures

Standards

- Our agreed-upon benchmarks for doing things consistently.
- Think of these as the "north star" everyone aligns to.

Policies

- Explain the organizational philosophy—what we do and why we do it.
- Big-picture rules, not step-by-step instructions.

Procedures

- The play-by-play: step-by-step instructions to get it done.

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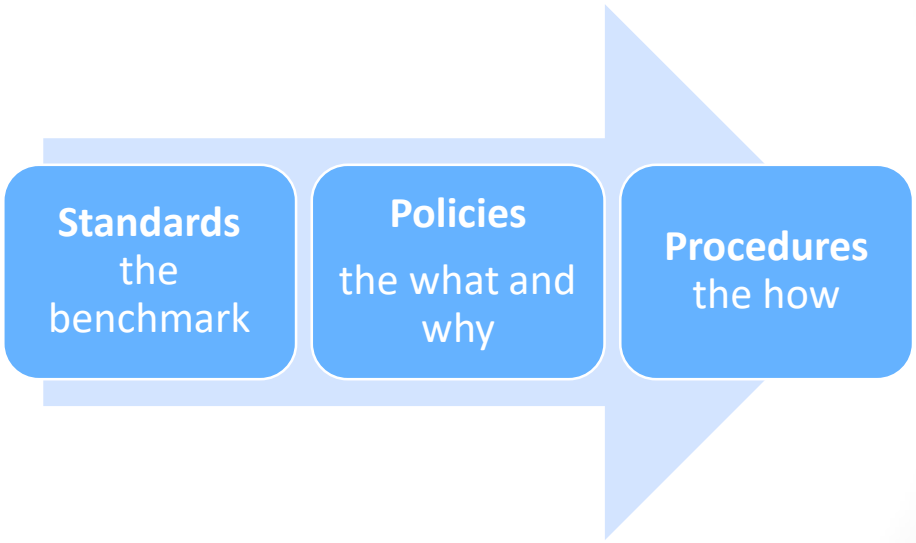
Key Differences



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Policies & Procedures: How They Work Together

- **Policies = The Big Picture:** Broad statements of approach that guide decisions and strategy.
- **Procedures = The Playbook:** Detailed steps that show exactly how tasks get done consistently.
- **How They Connect:** Policies set the goals; procedures make them happen.
- **Quick Analogy:** Think leadership (vision) vs. management (execution).
- **Best Practice:** They can stand alone but often work best when combined for clarity and ease of use.

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Building a Strong Policy Management Framework

- **Centralized Access:** Store policies in one system for easy search and use.
- **Clarity & Readability:** Write in plain language; translate if needed for your workforce.
- **Routine Review:** Evaluate policies annually or as regulations change.
- **Regulatory Alignment:** Update when laws or standards are revised.
- **Role-Based Access:** Ensure relevant stakeholders can view and apply policies.
- **Technology Tools:** Use policy management software for version control and reminders.
- **Leadership Training:** Train policy owners and leaders on policy development and management best practices.

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Ownership Matters: Compliance vs. Department vs. Shared

- **Department-owned:**
  - Best when the process is operational
  - Risk: Updates may drift from compliance requirements
- **Compliance-owned:**
  - Ensures alignment with regulations
  - Risk: Less operational buy-in from frontline teams
- **Joint ownership:**
  - Combines expertise and oversight
  - Requires clear roles to avoid confusion during updates
- **Key takeaway:**
  - Choose an approach that fits your organization, but ensure clear accountability and adherence

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Foundational Principles

POLLING QUESTION

As a rule, who owns compliance-related policies and procedures in your organization?

A. **The department conducting the process.**
B. **The Compliance Department.**
C. **It's a mixed bag, some owned by Compliance and some owned by the process owner of the procedures outlined in the policy.**

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Policies and Procedures

- **Structural policies:** Define how the compliance program itself operates
  - Examples: hotline operations, investigations, auditing, training
- **Substantive policies:** Address specific compliance risks in day-to-day operations
  - Examples: HIPAA privacy, EMTALA, conflicts of interest, gifts and gratuities

> "The OIG believes that [and organization's] written policies and procedures should take into consideration the regulatory exposure for each function or department of the [organization]. Consequently, we recommend that the individual policies and procedures be coordinated with the appropriate training and educational programs with an emphasis on areas of special concern that have been identified by the OIG through its investigative and audit functions." – *Office of Inspector General, Compliance Program Guidance for Hospitals, FR, Vol. 63, No. 35, February 23, 1998.*

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Structural Policies: Building the Compliance Framework

- **Compliance Program Plan:** Outlines the program's core elements and functions—your "playbook" for compliance.
- **Hotline & Reporting:** How staff can raise concerns—and what happens next.
- **Education & Training:** Ensuring everyone knows the rules (and why they matter).
- **Auditing & Monitoring:** Spot issues early with routine checks and follow-up.
- **Investigations:** Clear, consistent steps for handling potential noncompliance.
- **Disciplinary Standards:** Fair and consistent consequences, often in partnership with HR.

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Substantive Policies: Addressing Key Risk Areas

- **Gifts & Gratuities:** Managing what can (and can't) be given or received by patients, vendors, or referral sources.
- **Conflicts of Interest:** Addressing potential issues for Board members, leadership, and employees.
- **Coding & Billing:** Ensuring claims are accurate, defensible, and compliant.
- **Physician Arrangements:** Structuring contracts and financial relationships within regulatory limits.
- **EMTALA & Transfers:** Safeguarding patient rights during emergency care and transfers.
- **HIPAA Privacy & Security:** Protecting patient information—access, use, and disclosure rules.

"Every compliance program should require the development and distribution of written compliance policies that identify specific areas of risk to the [organization]." – *Office of Inspector General, Compliance Program Guidance, FR, Vol. 63, No. 35, February 23, 1998.*

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Key Elements of Policy Content and Format

- **Applicability:** Who the policy applies to (employees, vendors, etc.)
- **Effective and revision dates:** Track adoption and updates over time
- **Purpose:** Why the policy exists and what it aims to accomplish
- **Policy statement:** High-level expectations or guiding principle
- **Operational definitions:** Clarify key terms used in the policy
- **Procedure:** Step-by-step instructions for carrying out the policy
- **Attachments and links:** Related documents, forms, and supporting materials
- **References:** Supporting regulations or other guidance documents

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Staying Current with Evolving Regulations

- **Track government updates:** Monitor OIG alerts, advisory opinions, and CIAs for emerging best practices
- **Respond to new laws:** Update policies when regulations change (e.g., information blocking, Stark updates, HIPAA proposals)
- **Manager accountability:** Hold supervisors responsible for ensuring staff understand and follow policies
- **Regular review:** Reassess policies to address internal audit findings or changing practices
- **Benchmarking:** Compare with similar organizations to align with industry standards

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Aligning Policies with Trends and Recordkeeping Requirements

- **Update based on findings:** Revise policies when internal or external audits reveal gaps
- **Retention standards:**
  - Compliance and HIPAA policies — minimum 6 years
  - Medicare Advantage documents — 10 years
  - Governing board minutes — permanent
- **State laws:** Check for state-specific retention requirements, which may exceed federal rules
- **Access and retrieval:** Ensure historical policies can be located quickly during audits

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Other Written Standards That Support Compliance

- **Committee charters:** Define roles and responsibilities for compliance and board committees
- **Guidance documents/instruction sets:** Provide detailed task-level steps that may not rise to the level of formal policy
- **Decision framework:** Establish criteria for when a process needs a formal policy vs. guidance document
- **Code of Conduct:** Keep in the same repository as policies for easy reference by employees and stakeholders

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Pitfalls and Challenges

- **Lack of awareness:** Staff don't know policies exist or where to find them
- **Outdated content:** Policies are not regularly reviewed or revised
- **Inconsistent formats:** Difficult for staff to navigate across multiple templates
- **Scattered storage:** Policies stored in multiple locations (e.g., SharePoint, drives, paper)
- **Conflicting guidance:** Multiple policies provide contradictory instructions
- **Poor accessibility:** Unable to retrieve policies quickly during audits
- **Noncompliance:** Policies are written but not followed in practice

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Making Policies Useful and Sustainable

- **Routine review:** Establish a regular cadence (e.g., annual or biennial) to keep policies current
- **Communicate changes:** Ensure updates are shared and integrated into staff education
- **Approval workflow:** Define who approves compliance policies (e.g., Compliance Officer, committees, Board)
- **System considerations:** Account for timelines and approval requirements across departments or system-level policies
- **Monitor adherence:** Use audits and monitoring to confirm policies are followed in practice

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Next Steps – Strengthening Your Compliance Framework

- **Evaluate your Code of Conduct**
  - Is it clear, readable, and accessible to everyone who needs it?
- **Assess your policy management system**
  - Are policies easy to find and consistently formatted?
  - Would you be audit-ready today?
- **Check compliance policy completeness**
  - Compare against government guidance, risk assessments, and recent trends
- **Search for duplicates or conflicts**
  - Use keyword searches to uncover overlapping or contradictory policies
- **Simplify and clarify**
  - Remove confusion to strengthen confidence and compliance

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Right-Sizing Policies for Your Organization

- **Large systems:** Multi-hospital networks are expected to implement best-practice compliance structures
- **Smaller facilities:** Standalone or rural hospitals can scale policies appropriately but still meet core requirements
- **Benchmarking:** Compare with similar organizations to gauge appropriate level of detail and sophistication
- **Goal:** Demonstrate good-faith efforts to maintain an effective compliance program, regardless of size

> The formality and scope of actions that an organization shall take to meet the requirements of [the U.S. Sentencing Guidelines], including the necessary features of the organization's standards and procedures, depend on the size of the organization. – *U.S. Sentencing Guidelines Manual Nov 1, 2018, p. 520.*

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Case Study: The Policy Gaps

Mark, the Compliance Officer, just completed a compliance program effectiveness review. His big finding? **Several high-risk areas aren't covered by any policy at all.**

Where should Mark start?

- Which gaps are highest priority to address first?
- Who needs to be involved in drafting and approving these new policies?
- How can Mark prevent future gaps from happening?

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Bridging the Policy Gap

- **Identify the Type of Gap:** Is it structural (program-wide) or substantive (specific to a risk area)?
- **Prioritize by Risk:** Use risk assessments and enforcement trends to focus efforts.
- **Tackle High-Risk First:** Address gaps flagged in audits or those with regulatory heat.
- **Collaborate with Experts:** Bring in process owners and SMEs for accuracy and buy-in.
- **Educate & Roll Out**: Make sure new policies are communicated, understood, and easy to find.

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Foundational Principles

POLLING QUESTION

What area do you want to improve on *most* based on what was discussed in today's learning session?

A. **Improving our Code of Conduct.**
B. **Improving our overall policy and procedure management process.**
C. **Improving and updating our compliance policies.**
D. **Improve in all areas discussed!**

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Questions and Comments

Contact info:
thagan@greatriverhealth.org

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Compliance Essentials Workshop

HCCA Compliance Basics: Governance, Oversight, Authority

Sarah Couture, RN, CHC, CHRC, CHPC

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The 7 Elements

1. Written policies and procedures
2. Compliance leadership and oversight
3. Training and education
4. Effective lines of communication with the compliance officer and disclosure programs
5. Enforcing standards: consequences and incentives
6. Risk assessment, auditing, and monitoring
7. Responding to detected offenses and developing corrective action initiatives

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The 7 Elements

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What is Governance?

- (2) (A)The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.
- (B) High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.
- (C) Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.

https://www.justice.gov/criminal-fraud/page/file/937501/download

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The Structure of the People in Charge

- The board of directors. The board has oversight of the program.
- The CEO. The CEO is at the highest high-level and is ultimately responsible for the program's effectiveness.
- The Chief Compliance Officer (CCO). This is the high-level person selected by the CEO and board to administer the program.
  - Should have direct access to the CEO and board and adequate resources to fulfill duties.
- The Compliance Committee. The operations personnel with whom the CCO works to carry out the compliance program.
  - Two-way street: help CCO with program, and engagement with compliance.

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The Board and Compliance

- What is the board of directors and what do they do?
- Board compliance responsibility: knowledgeable about content and operation of compliance program and program oversight.
  - Understand what compliance is and why it matters
  - Help set "tone at the top"
  - Recognize the CCO's role and have regular interaction with CCO
  - Ask the right questions to assess if the program is working
  - Understand importance of program effectiveness, and provide more resources if needed
  - Hold CEO accountable for compliance
- The board can delegate its compliance oversight responsibility to a board sub-committee.

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Why the Board Matters to Compliance

- The board will be held responsible for a program's failure.
- Board members, like the CEO, have skin in the game.
- On occasion, board members are *personally* liable for compliance fiascos.
- The board has enormous impact on "tone at the top." Culture starts here!
- Board members have influence over the CEO and other senior executives.
- The board can execute management changes or insist on a course of action in *lieu* of a change.

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The Board's Duties and Responsibilities

- The board should have specific knowledge of what the program is and how it operates day-to-day.
- Competent oversight (see above).
- The board keeps up-to-date on compliance matters and changes to laws and regulations affecting compliance.
- CCO should be granted direct access to board.
- Board receives, at minimum, quarterly compliance reports from CCO.
- If needed, board delegates CCO reporting to a compliance sub-committee.

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Questions the Board Should Be Asking

- How will the board be kept up-to-date on regulatory changes?
- Does the organization have a compliance reporting process? Is it effective?
- Is the compliance program adequate considering the size and complexity of the organization?
- What are the benchmarks the program uses to measure effectiveness?
- Does the board need annual resolutions?

https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

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Access to the Board

- The CCO should have direct access to the board.
- Regular meetings between the CCO and the board.
  - Consider regular meetings with board chair.
- Regular executive session without management.

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Reporting to the Board: Concepts

- Should be by the CCO and, at minimum, quarterly.
- To the board as a whole or to a sub-committee.
- Board should receive information that is useful, timely, and understandable.
- Depth of information – how much does your board want to know?
- Reports should not be edited by leadership before presentation to the board.
- Tailored to size and complexity of your organization.
- Consider dashboards.

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Reporting to the Board: Content

- Oversight
  - Assessments, budgeting, staffing, etc.
  - Program effectiveness
  - Program improvement plans or needs
  - Need for escalation and accountability

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Reporting to the Board: Content

- Risk assessment and work plans
  - Process and results
  - Work plan based on risk
  - Changes to work plan
  - Status reports/updates
  - Completion

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Reporting to the Board: Content

- Code of Conduct
- Policies and Procedures
- Compliance reports/complaints
  - Significant issues
  - Trends
- Investigations
  - Noteworthy investigations and outcomes
- Audits
  - Audit plan, trends, CAPs, issues

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Reporting to the Board: Content

- External activity
- Education and training
- Culture survey
- Exclusion screening
- Discipline
- Incentives

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Board Education Basics

- Include board education in compliance education and training plan.
- Onboarding
- At least annual general training, then other specific education as needed.
  - Oversight responsibility
  - Compliance risks
  - Recent industry changes and enforcement
  - Compliance program specifics
- Training attestations

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Board Education Advanced Steps

- Depth of education (and conversation) will deepen over time.
- As compliance engagement and understanding increases, board member questions and perspectives on business implications will evolve.
- Consider outside education, such as live training by an outside expert, webinars, HCCA board events, etc.

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Board Oversight & Effectiveness

- Regular, at least annual, internal effectiveness review
- Intermittent outside expert review for objective perspective
- Compliance expertise availability to the board

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Challenges to Board Engagement

- Effective CCO engagement with board
- Appropriate amount of information to the board
- Access to and sufficient time with board
- Board compliance understanding and engagement
- Centralized board over multiple entities
- Value and importance of compliance to organization and to board

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Strategies for Effective Engagement

- Take time to develop a good relationship with the board.
- Trust and rapport built as board sees CCO expertise and learns value of compliance.
- Make a plan for progressive board engagement.
- Seek outside input.

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The Chief Compliance Officer

- The CCO is the person delegated with responsibility to establish and implement the compliance program.
- Implements and maintains compliance policies.
- Should report to CEO and board.
- Must have adequate resources and authority.

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Why the CCO Matters

- Compliance program will not be as effective without the right kind of leader.
- Compliance program will not be as effective with insufficient resources (i.e., budget, staffing).
- Compliance program will not be as effective if the CCO has insufficient authority, independence, and access.

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What is a CCO?

- The CCO is the organization's compliance expert.
  - Keeps abreast of regulatory changes and risk profile.
  - Keeps executive and board up-to-date.
  - Gets operations engaged with compliance.
- Develops and implements the compliance program.
- Maintains the credibility and integrity of the program.
- See also "The Compliance Officer's Primary Responsibilities" on pp. 38-39 of https://oig.hhs.gov/compliance/general-compliance-program-guidance/.

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What Makes a Great CCO?

- Experience! CCOs come from many different backgrounds.
- Expertise. A good CCO brings knowledge, maintains it, and adds to it.
- Personality: strong yet collaborative, personable and approachable.
- "Know" vs. "No" – not just enforcer, also partner!
- Keeps an open door.
- Job description- aligned with board expectations?

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CCO Independence and Authority

- Reports directly to CEO (and/or board). Should not report to a business division or general counsel.
  - OIG General Compliance Program Guidance November 2023
    - P. 37 - "The compliance officer should: report either to the CEO with direct and independent access to the board or to the board directly; [and] have sufficient stature within the entity to interact as an equal of other senior leaders of the entity;"
    - P. 39 – "The compliance officer should not lead or report to the entity's legal or financial functions, and should not provide the entity with legal or financial advice or supervise anyone who does. The compliance officer should report directly to the CEO or the board. Usually, leaders of these functions are the general counsel and the chief financial officer…"
  - OIG Measuring Compliance Program Effectiveness: A Resource Guide
    - 2.26, 2.27 - "report directly to CEO, board (not CFO or Legal)"
  - DOJ Evaluation of Corporate Compliance Programs
    - Section II. B- Autonomy and Resources - "sufficient autonomy from management"
  - OIG Compliance Program Guidance for Hospitals
    - Section II, 2 - "report directly to the CEO and the governing body"
  - OIG Practical Guidance for Health Care Governing Boards on Compliance Oversight
    - P. 7 – "OIG believes an organization's Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner."

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CCO Authority

- Seated with senior leadership.
- Reporting and access to the board.
- Authority needed to effectively prevent and detect misconduct.
  - Authority to gain cooperation
  - Access to data
  - Ability to start working groups as needed
  - Authority to independently retain outside counsel

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The All-Rounder

- Oversight and purview
- "Paper program" versus effective and impactful
- Accountability for CCO performance and program effectiveness
- Working with expertise outside compliance:
  - Legal,
  - Risk management,
  - Internal audit,
  - Outside counsel, and
  - Outside consultants.

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Compliance Program Staff

- Hire the right people (may be easier said than done).
  - Should have right expertise, education, and **personality** for the job.
- How should staff be allocated?
  - According to the 7 Elements?
  - By risk area?

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Compliance Program Staff

- Sufficient staff and resources.
  - How much do you need relative to risk?
  - Always more work to do!
  - Being creative on a limited budget: highest risk focus
  - Asking for more
- Investment in compliance program staff
- Perception of staff, respect, turnover rate
- How are compliance staff assessed?

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Compliance Program Staff Challenges

- Staff not given enough authority; lack of respect from operations
- Wrong personality fit
- Not enough diversity of skill set
- Lack of access to data or people
- Physical presence of staff considerations:
  - Off-campus compliance offices, and/or
  - Remote work

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Engagement with Operations

- Federal sentencing guidelines: governance model
- DOJ: expectation that leaders, managers, and individuals are accountable for compliance
- Compliance is everyone's job!
- There are 3 vantage points ("Three Lines") to consider (plus board and executive oversight):
  - Individual accountability for compliance;
  - Operations ownership of compliance; and
  - Auditing by compliance, internal audit, or third party.

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Engagement with Operations

Owners: Board and CEO/Executive Team
Audit/Compliance Committee of the Board
Enterprise Risk and Compliance Committees
Responsible for managing overall enterprise risk

Owners: Internal Audit, Compliance Audit, and External Audit Engagements
Activities, such as audits, risk assessments, and assessing corrective action effectiveness, are conducted independently from operations

Owners: Responsible Executives and Managers
Monitor effectiveness of controls and develop corrective action for detected deficiencies; conducted by, or under the direction of, department operations

Owners: Each employee
Management establishes requirements (e.g. policies) and provides training to employees to manage risk in their areas

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What Does Meaningful Operations Engagement Look Like?

- Corporate compliance strategy should result in an individual commitment to compliance.
- How to do this? The 7 Elements is your guide!
- BUILD A CULTURE OF COMPLIANCE.

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Why Operations Engagement Matters

- The Department of Justice expects compliance buy-in.
  - Looking for accountability at all levels.
  - Looking for compliance being promoted at all levels.
- Demonstrates that program is working – not just a paper program.
- Develop dual compliance/operations experts to assist with concerns or investigations.

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The Compliance Committee

- Best approach depends on your organizational specifics.
  - Size, organizational chart, engagement, risk areas.
- How will you best leverage leaders and managers?
  - Executive level committee
  - Management level committee
- Consider physician involvement.

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The Compliance Committee

- Charter: goals, vision, functions, members, and expectations.
- Who should attend?
  - Consider regulatory risk areas: billing, coding, privacy, legal, purchasing, HR, research, etc.
- What should they do?
  - Assist in development, implementation, and assessment of compliance program.
  - Display accountability for compliance in their area(s) of purview.

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The Compliance Committee

- Attendance
- Education and engagement
- Meeting participation
  - Is the CCO the only person presenting?
  - Are members tasked with projects?
  - Are members asked to advise the program?
  - How is CCO working with committee to evaluate risk?
- Documentation
- See also "The Compliance Committee's Primary Duties" on pp. 40-41 of https://oig.hhs.gov/compliance/general-compliance-program-guidance/.

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Other Operations Engagement

- What is the plan for engagement and operations accountability? Make a plan!
- Inclusion of compliance requirements in job descriptions and performance evaluations.
- Compliance as a condition for promotion and raises.

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Engagement with Executives

- The CEO should ensure there is an effective compliance program.
- C-Suite Expectations: Compliance example
  - Unambiguous communication about compliance
  - Rigorous example of compliance
  - Involvement in remediation
- Direct communication from CCO regarding compliance
  - Compliance presence and tie-ins at meetings (culture of compliance)
- Compliance meet and greet with new executives
- Regular one-on-ones with risk area leaders

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Engagement with Management

- Become champions for executive compliance efforts
- Active participation in remediation efforts and corrective action plans
- Hold staff accountable for compliance
- They, in turn, are held accountable by senior executives

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Operations Engagement Challenges

- Is compliance a one person show in your organization, or is operations engaged and helping drive?
- Is the compliance committee valuable?
- Does the CCO have access to senior leaders?
- How does the CCO get out and engage with operations?
- Do employees think that compliance is the responsibility only of the compliance program?
- Are compliance expectations built into the culture, with operations, senior leadership – everyone?

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Governance: Final Thought

- The Foundational Element – if you get governance right, you are well on your way to getting:
  - The structure right,
  - The people right,
  - The culture right, and
  - The strategy right.

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Questions?

sarah@couturecompliance.co

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Compliance Essentials Workshop

Compliance Risk Assessment

Kenneth Zeko, Esq., CHC
Founder/President
Zeko LLC

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Agenda

1. Why perform a formal compliance risk assessment?
2. How to develop organizational support and sponsorship?
3. How to conduct a compliance risk assessment?
4. Reporting the results: leadership and the Board
5. Corrective action planning and implementation
6. Sample compliance risk assessment discussion template

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Chapter 1

- Why perform a formal compliance risk assessment ?
  - The learning objective is to provide an understanding of why the current regulatory and competitive landscape requires organizations to undertake a compliance risk assessment
    - Regulatory influences
    - Benefits to the organization

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Why Perform a Formal Compliance Risk Assessment?

Regulatory Influences and Guidance Documents

- U.S. Federal Sentencing Guidelines (1991)
- OIG Supplemental Compliance Program Guidance for Hospitals (2005)
- Practical Guidance for Health Care Governing Boards on Compliance Oversight (2015)
- Measuring Compliance Program Effectiveness: A Resource Guide (2017)
- U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (Updated September 2024)
- General Compliance Program Guidance (November 2023)

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Why Perform a Formal Compliance Risk Assessment?

U.S. Federal Sentencing Guidelines

- (c) [T]he organization **shall periodically assess the risk** of criminal conduct…"
- (A) Assess periodically the risk that criminal conduct will occur, including assessing the following:
  - (i) The nature and seriousness of such criminal conduct.
  - (ii) The likelihood that certain criminal conduct may occur because of the nature of the organization's business.
  - (iii) The prior history of the organization. The prior history of an organization may indicate types of criminal conduct that it shall take actions to prevent and detect.

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Why Perform a Formal Compliance Risk Assessment?

OIG Supplemental Compliance Program Guidance for Hospitals

- Has the hospital developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?
- Does the risk assessment tool include an evaluation of Federal health care program requirements, as well as other publications, **such as the OIG's CPGs, work plans, special advisory bulletins, and special fraud alerts?**

Practical Guidance for Health Care Governing Boards on Compliance Oversight

- "**The Board should ensure that management and the Board have strong processes for identifying risk areas**."
- "Risk areas may be identified from internal or external information sources."

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Why Perform a Formal Compliance Risk Assessment?

Measuring Compliance Program Effectiveness: A Resource Guide

(there are whole sections dedicated to Risk Assessment)

- Policies, standards and procedures are based on assessed risks
- Verify compliance risk assessments are conducted periodically.
- Adequacy of compliance staff based on risk assessment
- Risk Assessment Cycle
- Work plan development based on risk assessment
- Prioritization of risk and consultation with applicable risk partners
- Risk Assessment Process

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Why Perform a Formal Compliance Risk Assessment?

U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (Updated September 2024)

(there's a whole section dedicated to Risk Assessment)

- **How often has the company updated its risk assessments** and reviewed its compliance policies, procedures, and practices?
- **Prosecutors should also consider "[t]he effectiveness of the company's risk assessment and the manner in which the company's compliance program has been tailored based on that risk assessment"** and whether its criteria are "periodically updated."
- Prosecutors may **credit the quality and effectiveness** of a risk-based compliance program that devotes appropriate attention and resources to high-risk transactions, even if it fails to prevent an infraction.

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Why Perform a Formal Compliance Risk Assessment?

HHS-OIG General Compliance Program Guidance (Nov. 2023)

- "[I]n recent years OIG, the compliance community, and other stakeholders have come to recognize and place increasing emphasis upon the importance of a **formal compliance risk assessment process as part of the compliance program**."
- "**Periodic compliance risk assessments** should be a component of an entity's compliance program and should be conducted **at least annually**."
- "A formal compliance risk assessment process **should pull information about risks from a variety of external and internal sources, evaluate and prioritize them, and then decide which risks to address and how to address them**. The **Compliance Committee should be responsible for conducting and implementing the compliance risk assessment**. The Compliance Committee may find it helpful to have compliance, audit, quality, and risk management functions coordinate to conduct a joint risk assessment to maximize the use of entity resources and reduce the number and potential redundancy of such assessments."

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Benefits of a Formal Compliance Risk Assessment

- You don't know what you don't know
- Gets the attention and interest of top management and the Board (interviewees)
- Indirectly provides compliance training for top management and the Board
- Post Yates Memo, Board members may be significantly more concerned about their personal liability and responsibility as Board members
- Board members don't want to be viewed as willfully ignorant or condoning

10

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The Yates Memo and DOJ Updates

- In speeches on October 28, 2021, and September 15, 2022, Deputy Attorney General Lisa O. Monaco issued additional guidance regarding the Yates Memo and holding individuals accountable.
- Monaco stated:
  - "To hold individuals accountable, prosecutors first need to know the cast of characters involved in any misconduct. To that end, today I am directing the department to restore prior guidance making clear that to be eligible for any cooperation credit, companies must provide the department with all non-privileged information about individuals involved in or responsible for the misconduct at issue. To be clear, a company must identify all individuals involved in the misconduct, regardless of their position, status or seniority."
  - "Let me start with our top priority for corporate criminal enforcement: going after individuals who commit and profit from corporate crime."

See: https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-gives-keynote-address-abas-36th-national-institute and https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-delivers-remarks-corporate-criminal-enforcement

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Chapter 2

- How to develop organizational support and sponsorship
  - The learning objectives are to provide an understanding of key organizational dynamics that enhance or serve as obstacles to getting the Risk Assessment process approved and implemented
    - Past experiences
    - Timing
    - Available resources
    - Alignment with key organizational objectives
    - Budgeting & other considerations

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Developing Organizational Support

- Past Experiences to Consider
  - Is this the first risk assessment?
  - What is the organizational appetite for risk assessment?
  - When was the last risk assessment?
  - How was the last one received?
  - Were you the person that initiated the last one?
  - Is the same management team at the helm?
  - Did the organization effect necessary change?
  - Do you sense organizational resistance?
- Timing
  - Where are you in the fiscal year?
  - Are there competing initiatives?
  - Are there other outside initiatives?
  - Are key players going to be available?
  - What is the attention span of the organization?
  - When are the next board meetings?
  - Are there any major internal inquiries ongoing?

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Developing Organizational Support

- Available resources
  - What is the availability of internal participants?
    - The Board, CEO, CFO, COO, GC, Med Director, others
  - If performing the assessment internally, do you have:
    - Independent objectivity?
    - Knowledge to establish a broad risk profile?
    - An understanding of the relative risks?
    - The availability of a regulatory resource?
    - A methodology that has been validated?
    - The time to perform the assessment?
    - The organizational presence?
    - The interview skills?
    - The facilitation skills?

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Developing Organizational Support

- Alignment with key organizational objectives
  - Where is the organization from a strategic perspective?
  - Is the organization pro-active or re-active?
  - Is your program a "real" program?
  - Is your organization obsessed with growth?
  - Are you included in key strategic planning sessions?
  - Do you *really* have support from the top?
  - Do you *really* have the resources you need?
  - Are your compliance committee meetings well attended?
- Budgeting and other considerations
  - How much can you spend on external consultants?
    - You get what you pay for – make sure you get what you *need*
  - Do you have the resources you need to do it internally?
    - Regulatory resource / internal counsel / access to counsel
  - Be careful what you ask for….you may find it!
  - Now what?
  - Is the organization ready for required next steps?

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Chapter 3

- How to conduct a compliance risk assessment
  - The learning objective is to provide an understanding of key steps to designing and implementing an effective risk assessment
    - Planning and kick off
    - Document review
    - Conducting management interviews
    - Rating and ranking methodologies
    - Compiling the risk profile
    - Analyzing and sharing the data
    - Prioritizing the risk profile

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Conducting the Risk Assessment

- Planning and kick off
  - Scheduling interviews
    - How much time do you need and when do you need it?
  - Targeting the right areas (80/20)
  - Effectively communicating the objectives
    - Who, what, why, where, when
    - What do you need ME to do?
  - What is your plan and how are you staying on plan?
  - Consistent treatment across the board
  - Ensuring people are prepared when you arrive
  - Privilege or not privilege?
  - If external – how should you be involved?

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Conducting the Risk Assessment

- Document review
  - Why do you need to review documents?
  - What documents do you need?
    - Previous audits
    - Hotline reports
    - External evaluations
    - Previous risk assessment reports
    - Documentation of controls
    - Corrective action plans
    - Policies and procedures
  - Detail or high-level review?
- Conducting management interviews
  - Who do you need to speak with?
  - Alone or assisted?
  - Communicating the objectives
  - Ensuring the interviewee is prepared
  - A level playing field....if you build it they will come
  - Are you a capable interviewer?
  - What are you going to ask?
  - Asking the tough questions
  - Getting a tough answer
  - Keeping the conversation on track and meaningful

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Conducting the Risk Assessment

- Rating and ranking methodologies
  - Consistency is critical
  - Likelihood of the risk
  - Significance or impact if the risk occurs
  - Mitigating factors to consider
  - Red, Yellow, Green
  - One through Ten
  - High, Medium, Low
  - Embracing the organizational vernacular
- Compiling the risk profile
  - How to organize the data
    - By functional area
    - By risk categories
    - By High, Medium, Low
    - All of the above?
    - None of the above?

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Conducting the Risk Assessment

- Analysing and sharing the data
  - Understanding the data
  - Anticipating the reaction to the data
  - Is this really what you said?
  - Is this really what you meant?
  - Who needs to see the results (at this point)?
  - Avoiding data overload
- Prioritizing the risk profile
  - So many risks…so little time
  - Which high risks are really high risks?
    - Why is THAT a high risk?
    - What does high risk really mean?
    - He said low risk, she said high risk…now what?
    - Understanding your vulnerabilities
    - Protecting the innocent

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Chapter 4

- Reporting the results: Leadership and the Board
  - The learning objective is to understand how to properly lay the groundwork for presenting the findings
    - Understanding potential pitfalls
    - Reporting to interviewees
    - Reporting to your compliance committee
    - Reporting to executive leadership
    - Reporting to the Board
    - Selling the message to the Board
    - Obtaining necessary endorsements and resources

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Reporting the Results

- Understanding potential pitfalls
  - Vetting the data – "I didn't say that"
  - Changing of the guard
  - The messenger
  - You can't "*unring* the bell"
  - I am trying to run a business here
  - Now what do you want me to do?
- Reporting to interviewees
  - When will I see the report?
    - You may or may not
  - What do you need me to do next?
    - Please stand by
  - Keeping constituents appropriately informed
    - Big picture objective
    - Probable next steps
    - Specific responsibilities

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Reporting the Results

- Reporting to your compliance committee
  - Vetting the data
  - Distilling key information
  - Strategic planning of next steps
    - What are realistic objectives?
    - What are you trying to achieve?
    - How are you going to get there?
  - Setting time frames for next steps
- Reporting to executive leadership & the Board
  - Understanding the dynamics
  - Understanding the big picture
  - Understanding your obligations and responsibilities
  - Real life examples
  - What are the implications?
  - What do you need me (us) to do?
  - What if it does not go well?
    - What's your back up plan?
  - Educating the Board
  - Getting commitment on next steps

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Chapter 5

- Corrective action planning and implementation
  - The learning objectives will be to provide an understanding for necessary steps to manage the identified risks
    - Establishing accountability
    - Trust but verify….What's your corrective action plan?

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Corrective Action Planning and Implementation

- Establishing accountability
  - Who owns it?
  - Who controls it?
    - Understanding “upstream and downstream implications”
  - Where is it broken?
  - Documenting the ownership
- Trust but verify …. What’s your corrective action plan?
  - Where is it broken?
  - Policy and procedure development
  - Developing and delivering effective training
  - Developing and implementing auditing and monitoring plans

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Chapter 6

- Sample Compliance Risk Assessment Discussion Template
  - Outline
  - Three Lines of Defence
  - Likelihood
  - Financial Impact
  - Mitigation efforts
  - Residual risk

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Outline for Compliance Risk Assessment Discussion

- Introduction to Compliance Risk Assessment
- Identifying Compliance Risks
- Rating, Ranking and Prioritizing Compliance Risks

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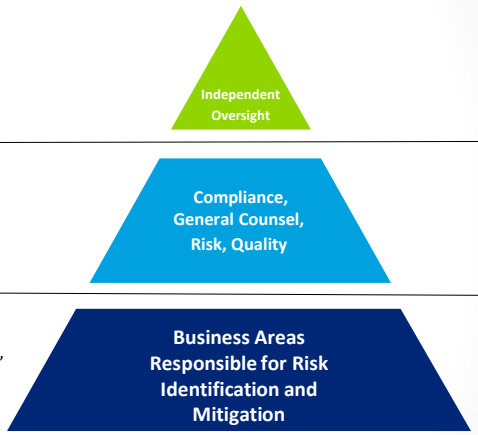
Three Lines Model

"The Third Line"
Internal Audit and sometimes Compliance or consultants will provide independent oversight and audits.

"The Second Line"
Compliance, General Counsel, Risk and Quality will provide compliance management, framework and policies to guide the Organization (can also be 1st line departments).

"The First Line"
Management is accountable for identification of risks, internal controls, compliance activities and monitoring in order to be compliant with laws and regulations (can also be Compliance).



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Compliance Risk Assessment Discussion

- Rating Risks: What's the **Likelihood** of the risk occurring? Include the potential financial and reputational impact. What are the current controls in place to mitigate each risk. Final risk rankings should reflect total residual risk, or the risk that's left after risk mitigation efforts.
- The following chart provides examples of factors that should be considered in rating risks based on their likelihood:

Inherent Likelihood Factors
Known instances/allegations
Previous history
Pervasiveness of the risk across operations
Complexity of the risk
Internal business culture
Violations by other companies or industry peers
Industry/competitor litigation trends
Government enforcement priorities
Criticisms by the Media
Other internal considerations

Rating	
High / Probable	Event could probably occur in most conditions Greater than 25% probability of occurrence
Moderate / Reasonably Possible	Event might occur in some circumstances 5% to 25% probability of occurrence
Low / Remote	Event could only occur in certain exceptional circumstances Less than 5% probability of occurrence

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Discussion Continued

- The risk rating process should consider **Financial Impact** as a factor in the risk ranking process. Create financial impact thresholds in order to rate compliance risks identified by management:

Considerations to Rank Financial Impact	Rating
• Material Impact on financial performance ($X00,000 or more). • Event requires Senior Management or Board attention.	**High**
• Potential material impact on financial performance ($X0,000 to $X99,000). • Consequences may require Senior Management intervention.	**Moderate**
• Minor Impact on financial performance ($X9,999 and under). • Consequences can be absorbed under normal operating conditions.	**Low**

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Discussion Continued

- The risk rating process considers the extent to which the entity currently monitors risk. Develop descriptions for the level of monitoring currently performed by management:

Levels of Monitoring Performed by Management	Rating
• No monitoring no procedures, limited to no policies. • Non-compliance would probably not be detected.	Low
• Some monitoring, some procedures, some training and policies. • Non-compliance would possibly be detected by monitoring already in place.	Moderate
• Consistent, effective monitoring, risk specific training, strong policies and procedures. • Non-compliance would be detected by monitoring already in place.	High

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Discussion Continued

The following describes the steps involved in assessing residual risk:

Step 1	**Assess inherent likelihood and financial impact of compliance risks**
Step 2	**Assess the level of monitoring in place to reduce inherent risk**
Step 3	**Identify the residual risk**

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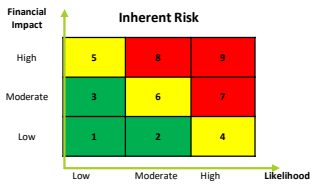
Discussion Continued

The following describes the steps involved in assessing residual risk based (the higher the number the higher the risk - green corresponds to low risk, yellow to moderate and red to high):

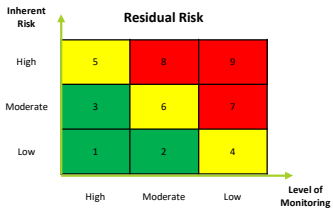
Step 1

Assess inherent likelihood and financial impact of compliance risks



Step 2

Assess the level of monitoring in place to reduce inherent risk



Step 3

Create report detailing observations and recommendations regarding identified risks

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Sample Compliance Risks

Identified Risks	Residual Risk
Insufficient clinical documentation	H
Inappropriate Physician Relationships - Providing inappropriate incentives to physicians	H
Physician Contracting	M
Pain Management	M
Licensure/Credentialing	L
Gifts and Gratuities	L

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Web Pages

Federal Sentencing Guidelines, Chapter 8

https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8

DOJ Evaluation of Corporate Compliance Programs (Updated September 2024)

https://www.justice.gov/criminal/criminal-fraud/compliance

Measuring Compliance Program Effectiveness: A Resource Guide

https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf

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Web Pages

Yates Memo

https://www.justice.gov/archives/dag/file/769036/download

OIG Supplemental Compliance Program Guidance for Hospitals

https://oig.hhs.gov/fraud/docs/complianceguidance/012705hospsupplementalguidance.pdf

Practical Guidance for Health Care Governing Boards on Compliance Oversight

https://oig.hhs.gov/compliance/compliance-guidance/docs/practical-guidance-for-health-care-boards-on-compliance-oversight.pdf

General Compliance Program Guidance

https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf

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Questions?

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Contact Information

Ken Zeko, Esq., CHC

Founder/President

Zeko LLC

kenneth.zeko@gmail.com

214-458-3457

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Compliance Essentials Workshop

Primary Federal Fraud and Abuse Laws and HIPAA

Steve Lokensgard and Dori Cain
Faegre Drinker Biddle & Reath

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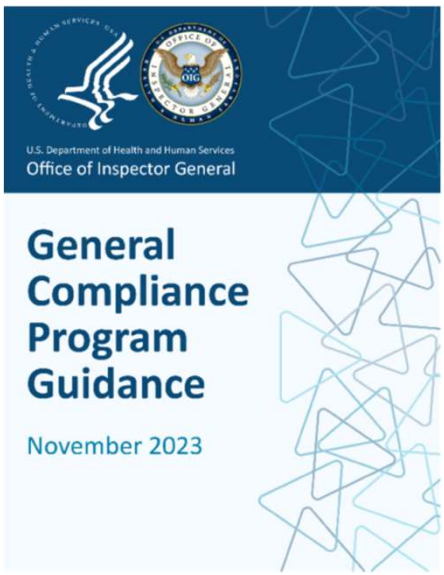

Agenda

Section II:

- False Claims Act
- Anti-Kickback Statute
- Stark Law
- Exclusion Authorities
- Health Care Fraud Statute
- Beneficiary Inducements CMP
- Grant Fraud CMP
- Information Blocking CMP
- HIPAA Privacy and Security

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"These are laws that you need to be familiar with if you even dip your toes into the waters of health care compliance."

Amanda Copsey, Senior Counsel,
HHS Office of Inspector General

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Compliance Department Role

Manage, Investigate Resolve

Assist with Investigation and Resolution

Issue spot and refer to legal

Compliance Responsibility

- Exclusion Authorities
- HIPAA Privacy and Security
- False Claims Act
- Beneficiary Inducements CMP
- Information Blocking CMP
- Grand Fraud CMP
- Health Care Fraud Statute
- Anti-Kickback Statute
- Stark Law

Legal Responsibility

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False Claims Act

- Compliance Department audits three departments
- Audit error rates for the departments are as follows:
  - #1: 4% reimbursement error rate
  - #2 25% reimbursement error rate
  - #3 100% reimbursement error rate
- Are any of these error rates evidence of a violation of the False Claims Act?

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False Claims Act

- Designed to address fraud by contractors in the Civil War
  - Shipments of guns contained only sawdust
  - Food delivered was already rotten
  - Passed March 2, 1863
- 1986 Amendments
  - Treble Damages
  - Increased share for whistleblowers
  - $72 billion recovered since 1987

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False Claims Act

- Contains a "qui tam" provision
  - Allows private citizens to prosecute an action on behalf of the government
  - Whistleblower gets a share of the recovery (15-30%)
  - Whistleblower can move ahead even if government declines to intervene
- FY2023
  - Over $2.68 billion recovered from FCA cases
    - 86% related to qui tam actions filed
    - $1.8 billion related to health care
  - 543 settlements with DOJ
    - Highest number of settlements and judgements in a single year
  - $75 billion recovered since 1986
  - 712 qui tam actions filed

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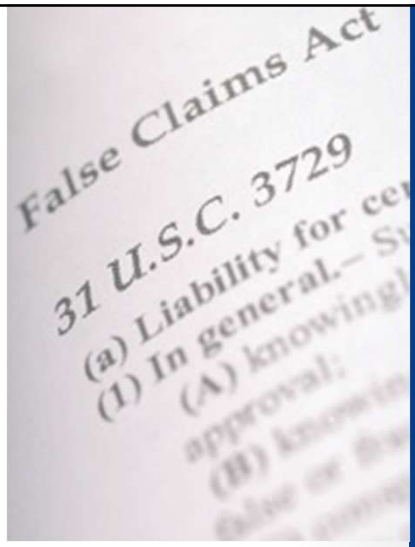
False Claims Act *(31 U.S.C. § 3729-33)*

- Elements of a False Claims Act Violation:
  - Defendant presented, or caused to be presented, a "claim" for payment to the United States;
  - The claim was "false or fraudulent"
  - The defendant acted "knowingly"



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"Knowingly" is not what you think

- False Claims Act definition of "knowingly" includes:
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
- Simple error is not enough

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Types of False Claims

- Factually False Claim – the payee as submitted
  - an incorrect description of the goods or services provided or
  - a request for reimbursement for goods or services never provided
- Legally False Claim
  - Express false certification
    - the payee falsely certifies compliance with a particular statute, regulation or contractual term where compliance is a prerequisite to payment

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False Claims Act

- Are any of these error rates evidence of a violation of the False Claims Act?
  - Intentional v. Reckless v. Simple Negligence (Mistake)

#1: 4% reimbursement error rate
- Typically errors of 5% or less are OK
- But what if we intentionally billed for a service that wasn't provided?

#2 25% reimbursement error rate
- Did one claim skew the sample?
- Are errors similar, or just various random documentation errors?
- History of failed corrective actions?

#3 100% reimbursement error rate
- System charging issue?
- How long has the problem been going on?

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False Claims Act

- Was the error investigated and resolved in a timely manner?
  - "Reverse False Claim"
- Old rule: violated if you affirmatively conceal an overpayment
- New Rule: Affordable Care Act: 60-Day Repayment Rule
  - Providers have a duty to disclose and repay overpayments within 60 days of "discovery"
  - Failure to do so could convert an erroneous claim to a false claim
  - Must investigate issues with "reasonable diligence"
  - 6-year lookback period

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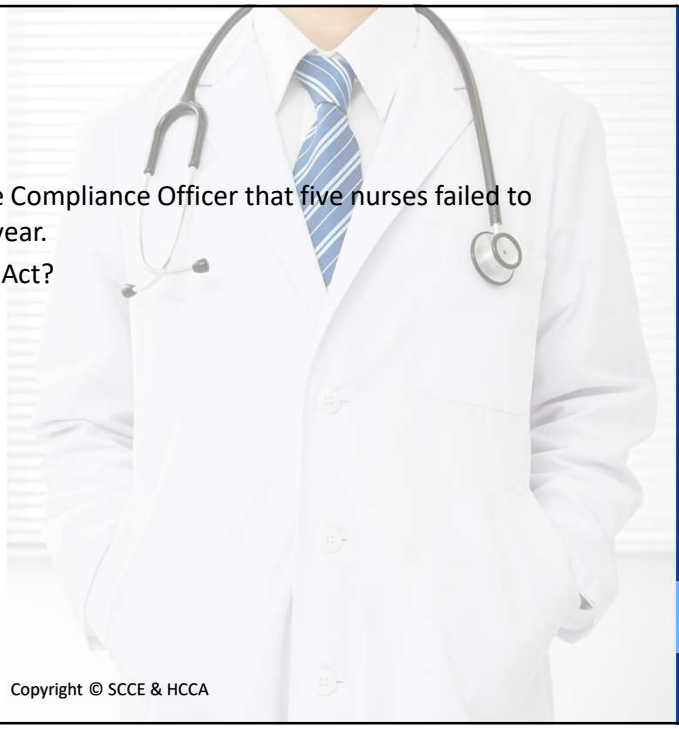
False Claims Act



- The Chief Medical Officer tells the Compliance Officer that five nurses failed to renew their nursing licenses this year.
- Does this violate the False Claims Act?

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Types of False Claims

- Legally False Claim
  - Implied false certification (Escobar, 2016)
    - the payee makes misleading omissions in submitting a claim, such as omitting a violation of a statutory, regulatory or contractual requirement, and the omissions render the payee's representations misleading with respect to the goods or services provided
    - The failure to disclose this noncompliance was material to the government's decision to pay
- Suggests the False Claims Act is implicated by violations of the Conditions of Participation if materiality threshold is satisfied

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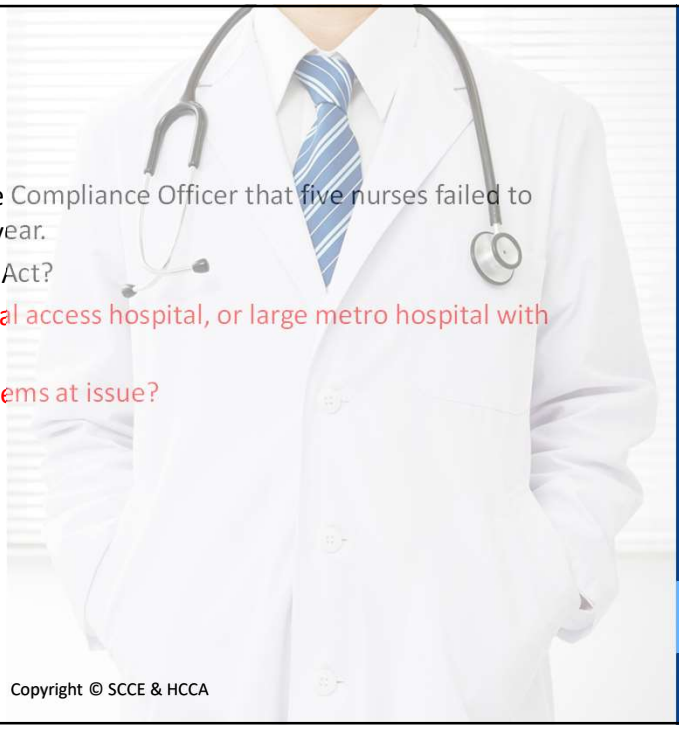
False Claims Act



- The Chief Medical Officer tells the Compliance Officer that five nurses failed to renew their nursing licenses this year.
- Does this violate the False Claims Act?
  - is this a nursing facility, critical access hospital, or large metro hospital with hundreds of nurses?
  - are there other quality problems at issue?

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False Claims Act Penalties

- Treble damages
- $27,018 fines per "false claim" submitted
- Attorneys' fees
- Permissive or mandatory (if criminal FCA) exclusion from Medicare

The math adds up!

1,000 claims of $100 each = $100,000 x 3 = $300,000 (treble damages) + $27,018,000 (fines) = $27,318,000

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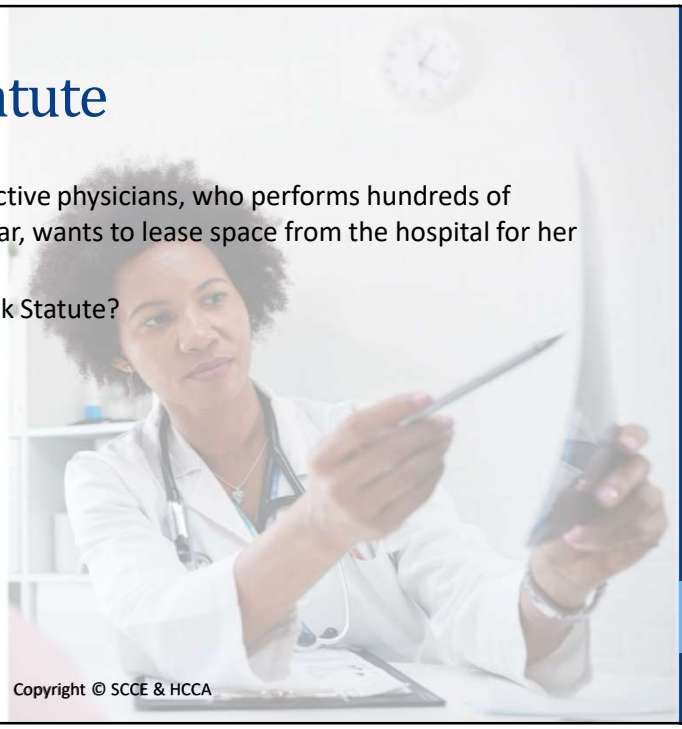
Anti-Kickback Statute

- One of the hospital's most productive physicians, who performs hundreds of surgeries at the hospital every year, wants to lease space from the hospital for her own practice.
- Does this violate the Anti-Kickback Statute?



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Anti-Kickback Statute *(42 U.S.C. § 1320a-7b(b))*

It's a **crime** to knowingly and willfully **offer**, **pay**, solicit, or receive **anything of value**, directly or indirectly, in return for referrals or to induce referrals for which payment may **ultimately** be made **in part** under a federal health care program.

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Anti-Kickback Penalties

- Criminal Sanctions for Anti-Kickback Act violations:
  - Criminal felony conviction
  - 5 years in jail
  - $25,000 fines
- Administrative Penalties for Anti-Kickback violations:
  - Exclusion from participation in Medicare and Medicaid
  - $50,000 fine
- Civil False Claims Act Exposure
  - Claims submitted pursuant to an illegal kickback = false claims

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Anti-Kickback Statutory Safe Harbors

- Statute is very broad
- Could have a "chilling effect" on permissible activity
- Statutory Safe Harbors
  - Discounts
  - Employees
  - Group Purchasing Organizations
  - Waivers of certain co-payments
  - Risk sharing arrangements
  - Waivers of Part D Cost Sharing
  - FQHCs

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Anti-Kickback Safe Harbors

- Regulatory Safe Harbors
- Since 1991, HHS has promulgated 26 “safe harbors”
- Safe harbors are optional
  - Space rental
  - Personal services and management contracts
  - Discounts/rebates
- New/ Revised Safe Harbors (2020)
  - Patient engagement tools and supports
  - Value-based enterprise
  - EHR/ Cybersecurity donations
  - Local transportation

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Anti-Kickback Safe Harbors

- Space Rental Safe Harbor, 42 C.F.R. §1001.952(b)
  - Set out in writing and signed by the parties
  - Specifies all the space subject to the lease
  - Specifies the schedule for use if not 24/7/365
  - Term for at least one year
  - Rental charge is:
    - Set in advance
    - Fair Market Value
    - Not determined in a manner that takes into account the volume or value of referrals
  - The space rented is commercially reasonable

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Anti-Kickback Safe Harbors

- What if the facts don't satisfy the entire safe harbor?
  - Not signed by both parties
  - Term is not a year
  - Doesn't specify the premises to be rented
- Not a violation per se, but because the safe harbor isn't satisfied, it will receive greater scrutiny
- If a violation:
  - OIG Self-Disclosure Protocol
  - OIG Advisory Opinion

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Advisory Opinions

- Application of AKS to specific facts
- Only applies to requesting party
- Published on OIG website

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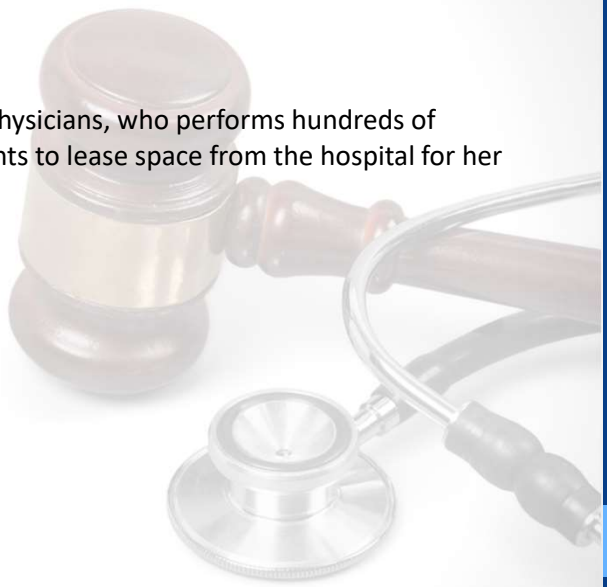
Stark Law

- One of the hospital's most productive physicians, who performs hundreds of surgeries at the hospital every year, wants to lease space from the hospital for her own practice.
- Does this violate the Stark Law?



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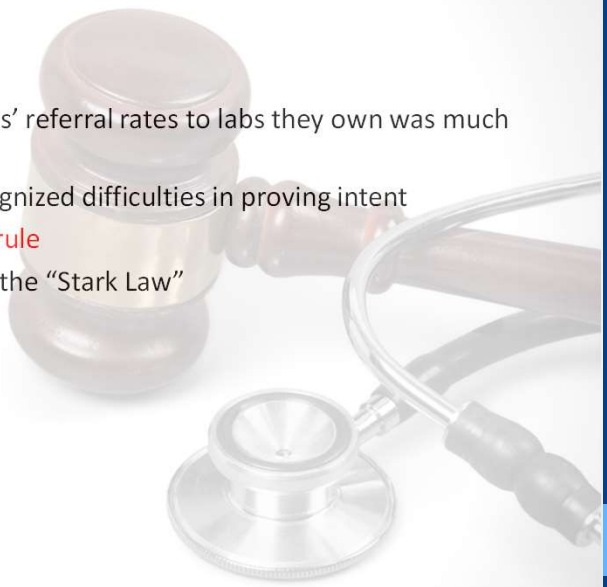
Stark Law

- DHHS, Florida studies showed physicians' referral rates to labs they own was much greater than to independent labs
- Congressman Fortney "Pete" Stark recognized difficulties in proving intent
- Desire to establish so-called bright line rule
- Ethics in Patients Referrals Act of 1989: the "Stark Law"



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Stark Law

- Stark prohibits a physician from referring a patient to an entity for certain designated health services if the physician has a financial relationship with the entity that does not satisfy a statutory or regulatory exception to Stark.
- Note:
  - Applies only to physicians
  - Can apply to employed NPs and PAs if the physician directs their referrals
  - "Entity" – like a hospital, an entity that bills Medicare

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"Designated Health Services"

- Radiology
- Inpatient and outpatient hospital services
- DME
- Parenteral and enteral
- Equipment and supplies
- Prosthetics and Orthotics
- Lab
- Home Health
- Physical Therapy
- Outpatient prescription drugs
- Occupational Therapy

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Stark Law Elements

- Elements of a Stark Law Violation:
  1. A ***financial relationship*** between a physician (or immediate family member) and an entity (e.g., a hospital), including either ownership or investment interest, or compensation arrangement
  2. A ***referral for certain "designated health services" (DHS)*** of a Medicare patient by the physician to the entity (e.g., an order for an MRI; order = referral; MRI = DHS)
  3. The ***absence of an exception***

NO INTENT IS REQUIRED

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Stark Exceptions

- 38 exceptions apply to ownership interests and/or compensation arrangements
- Stark exceptions are like gravity
  - Not just a good idea, it's the law
  - Not like safe harbors
  - If not satisfied, it's a violation

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Stark Exceptions

- Ownership Exceptions:
  - Public Companies
    - $75 million in stockholder equity
    - Listed on an exchange
  - Hospitals
    - Interest in whole hospital (subject to ACA freeze)
  - Rural providers
    - >75% DHS furnished in rural area as defined for Medicare purposes

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Stark Exceptions

- Compensation Exceptions:
  - Space leases
  - Personal Services
  - Recruitment incentives
  - Medical staff incidental benefits
  - EHR subsidies
  - Timeshares
- 2020 New Exceptions
  - Value-based arrangements
    - With no downside risk
    - With meaningful downside risk
    - With full financial risk

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Stark Law Exceptions

- Rental of Office Space Exception, 42 C.F.R. §411.357(a)
  - Lease is set out in writing and signed by the parties
  - Term is at least one year
  - Space rented is commercially reasonable and is for exclusive use of the space
  - Rent is set in advance at fair market value
  - Rent is not determined in a manner that takes into account the volume or value of referrals
  - If expired, lease continues under the same terms and conditions

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Consequences

If Stark exception is not met:

- Physician can't refer Medicare patient to the entity
- If referral, entity can't bill Medicare
- If entity already billed/collected, must repay
- Administrative penalties of $15,000 per referral
- Claims submitted pursuant to a Stark Law violation = False Claim
  - Whistleblower exposure!

- NOTE: Stark does not penalize the referring physician.

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Stark Self-Referral Disclosure Protocol

- Referred to as SRDP
- Application made to CMS
- Settlement Agreements published by CMS
- May take several years

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Exclusion Authorities *(42 U.S.C. § 1320a-7)*

- OIG has authority to bar individuals and entities from participation in all Federal health care programs
  - Mandatory and permissive exclusions
- List of Excluded Individuals/Entities (LEIE)
  - List of all currently excluded individuals and entities
  - Entities participating in Federal health care programs should check the LEIE
    - before employing/contracting with individuals and entities
    - monthly checks thereafter

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Mandatory Exclusions

- OIG is *required* to exclude individuals and entities convicted of certain criminal offenses, including:
  - Offenses related to the delivery of an item or service under Medicare or a State health care program;
  - Patient abuse or neglect;
  - Felony convictions for other health care-related fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; and
  - Felony convictions related to the unlawful manufacture, distribution, prescription, or dispensing of controlled substances.

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Permissive Exclusions

- OIG has *discretion* to exclude individuals and entities on several grounds, including:
  - Misdemeanor convictions related to health care fraud not involving Medicare or a State health program;
  - Fraud in a program funded by any Federal, State, or local government agency;
  - Misdemeanor convictions relating to the unlawful manufacture, distribution, prescription, or dispensing of controlled substances;
  - Suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity;
  - Provision of unnecessary or substandard services;
  - Submission of false or fraudulent claims to a Federal health care program;
  - Engaging in arrangements that violate the Federal anti-kickback statute;
  - Defaulting on health education loan or scholarship obligations; and
  - Controlling a sanctioned entity as an owner, officer, or managing employee.

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Consequences of Exclusion

- No Federal health care program payment may be made for any items or services furnished:
  - (1) by an excluded person, or
  - (2) at the medical direction or on the prescription of an excluded person
- Civil monetary penalties (CMPs) may be imposed on individuals and entities that arrange or contract with an individual or entity that the person knows or should know is excluded by OIG

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Criminal Health Care Fraud *(18 U.S.C. § 1347)*

- Statute making it a criminal offense to defraud a health care benefits program
- Prohibits knowingly and willfully executing, or attempting to execute, a scheme to either:
  - (1) defraud any health care benefit program; or
  - (2) obtain, by means of false or fraudulent pretenses, representations, or promises, any money or property from any health care benefit program
- Government must prove intent to defraud but need not prove specific intent to violate this statute
- Penalties:
  - Fines of up to $250,000, imprisonment of not more than 10 years, or both.

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CMP – Beneficiary Inducement

(Section 1128A(a)(5) of the Social Security Act, 42 U.S.C. § 1320a-7a(a)(5))

- Any person who offers or transfers
- remuneration
- to any individual eligible for Medicare or Medicaid
- that such person knows or should know
- is likely to influence such individual
- to order or receive from a particular provider
- any item or service for which payment may be made by Medicare or Medicaid.

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Beneficiary Inducement CMP Exceptions

- Exceptions to the definition of "remuneration":
  - Preventive care
    - Allows providers to give patients free items or services to encourage them to engage in preventive care services
  - Financial hardship
    - Allows providers to offer or transfer items or services for free or less than fair market value if:
      - the items or services are not offered as part of any advertisement or solicitation;
      - the items or services are not tied to the provision of other services reimbursed in whole or in part by Medicare or Medicaid;
      - there is a reasonable connection between the items or services and the medical care of the individual; and
      - the person provides the items or services after determining in good faith that the individual is in financial need.
  - AKS safe harbors = Exceptions to "remuneration"
    - Patient engagement tools and supports allows certain providers to give patients items and services up to $500 annually in order to achieve specified identifiable health goals

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CMP – Grant Fraud

- OIG has the authority to impose CMPs for fraudulent/improper conduct related to HHS grants, contracts, and other agreements
- Fraudulent/improper conduct includes:
  - Presenting a false or fraudulent specified claim
  - Making a false statement or omission
  - Making or using a false record
  - Concealing or improperly avoiding an obligation owed to HHS
  - Failing to grant access to OIG for the purpose of audits, investigations, or evaluations.

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CMP – Information Blocking

"Information blocking means a practice that…is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information…"

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Who Must Comply

Providers

Health Information Networks and Health Information Exchanges

Health IT Developers of Certified Health IT

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Actor-Specific Knowledge Standards

Health information technology developer, exchange, or network

- "…knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information."

Health care provider

- "…knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."

42 U.S.C. § 300jj–52(a)(1)

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What is HIPAA?

- A federal law effective since 2004
- Addresses the privacy and security of protected health information (PHI)
- The Health Information Technology for Economic and Clinical Health Act (HITECH)
  - Signed into law February 2010
  - Included significant expansions/changes to HIPAA
  - Most changes went into effect September 23, 2013
- Amended to account for reproductive health information in 2024
  - Most changes went into effect June 25, 2024
  - Texas Federal District Court Invalidates the HIPAA Reproductive Health Rule in June 2025

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HIPAA in a Nutshell

- HIPAA permits **covered entities, business associates** and subcontractors of business associates to use and disclose **protected health information** for their own treatment, payment and health care operations purposes.
- Specific patient **authorization** is required for use/disclosure for other purposes.

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Who Enforces HIPAA?

- The Office for Civil Rights (OCR) within the Department of Health and Human Services (HHS)
- The US Department of Justice (criminal enforcement)

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Who Are Covered Entities Under HIPAA?

Health Plans	Health Care Clearinghouses	Health Care Providers
▪ HMOs ▪ Insurance Companies ▪ Employer-Sponsored Group Health Plans	▪ Billing Companies	▪ Hospitals ▪ Physicians

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Business Associates

- Business Associate is an outside entity that handles PHI and performs services on behalf of a Covered Entity, or provides certain services to a Covered Entity
- A Business Associate agreement is required to specify permitted uses and disclosures of PHI and to require the BA to use appropriate security safeguards.

Common examples of Business Associates:

Management company	Biller	Law firm that receives individually identifiable information about patients	A cloud service provider that stores medical records

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Covered Entities

Requirements:

- **Draft and implement policies and procedures**
- **Assign a HIPAA privacy & security officer**
- **Conduct a HIPAA risk assessment**
- **Conduct HIPAA training**

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What Is Protected Health Information?

- Any individually identifiable information, whether oral or recorded in any form or medium that:
  - relates to the past, present or future physical or mental health or condition of an individual;
  - the provision of health care to an individual; or
  - the past, present or future payment for the provision of health care to an individual.

Examples of PHI:

Insurance claims	DME orders	Recording of phone call with patient in which care was discussed

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What is De-identified Information?

The HIPAA Privacy Rule provides the standard for de-identification of protected health information. Under this standard, health information is **not individually identifiable** if it does not identify an individual and if the covered entity has no reasonable basis to believe it can be used to identify an individual.

The HIPAA Safe Harbor Method provides that information is "de-identified" if all of the following identifiers of the individual or of relatives, employers or household members of the individual are removed:

Names	Telephone/ Fax numbers	Medical record number	Certificate/ license #	URL	Full face photos
Geographic subdivisions smaller than a state (address, zip code)	E-mail addresses	Health plan number	Vehicle identifier/ serial #	IP address	Other unique characteristics
Elements of dates except year (birth date, service date)	SSN	Account number	Device identifier /serial #	Biometric identifiers (finger/voice prints)	As well as any number or code derived from one of the above pieces of information

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HIPAA: Two Important Rules

Privacy Rule

- Governs the use and disclosure of medical records and personal health information of patients, research subjects and others.

Security Rule

- Requires health care providers and health plans to protect PHI that is created, received, used or maintained by a Covered Entity by establishing a national set of security standards.

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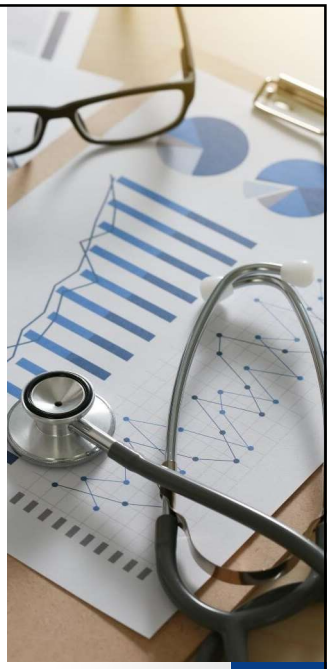
HIPAA Privacy Rule – Use and Disclosure of PHI

- The Privacy Rule governs how a Covered Entity can "use" and "disclose" PHI
- "Use" means accessing or utilizing PHI within the Covered Entity
  - e.g., if an employee looks at a record with PHI simply because the employee is curious, the employee has just "used" the PHI
- "Disclose" means to send PHI outside the Covered Entity
  - e.g., if an employee emails PHI to an outside friend, the employee has just "disclosed" the PHI
    - (both examples are prohibited under HIPAA)
- Only individuals who need access to PHI to perform job functions should have access to PHI



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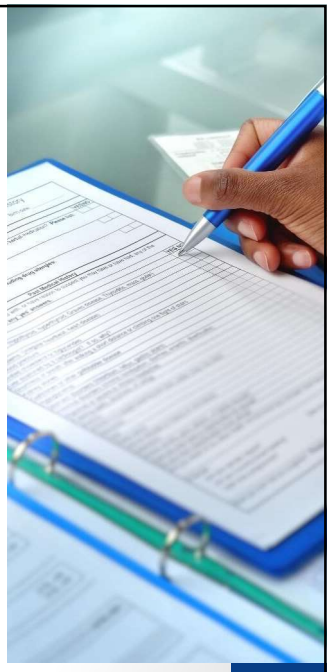
Uses and Disclosures of PHI

Three primary categories of proper uses and disclosures:

- **Treatment:** Provision, coordination or management of health care and related services for individual by one or more health care providers.
- **Payment:** Broadly interpreted and includes: obtain premiums, determine or fulfill responsibilities for benefits coverage, and furnish/obtain reimbursement for Individual's health care.
- **Healthcare Operations:** Quality assessment and improvement activities; competency assurance activities; conducting medical reviews, audits or legal services; business management and administration activities.



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HIPAA Privacy Rule

- Under the Privacy Rule a Covered Entity generally cannot use or disclose PHI without
  - Patient authorization; or
  - A specific regulatory exception
- Uses and disclosures noted in a Notice of Privacy Practices
  - Updates to adhere to 42 CFR Part 2 changes by February 2026
- Run a Part 2 program need to draft a Part 2 patient notice similar to an NPP

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Minimum Necessary Rule

Minimum Necessary Rule:

A Covered Entity must make reasonable efforts to use, disclose and request only the minimum amount of PHI needed to accomplish the intended purpose of the use, disclosure or request

Minimum Necessary Rule does not apply to:

1. Treatment
2. Access Requests
3. Authorization
4. Disclosure to HHS for complaint investigation, compliance review or enforcement
5. Required by Law

In sum, only use and disclose the minimum PHI

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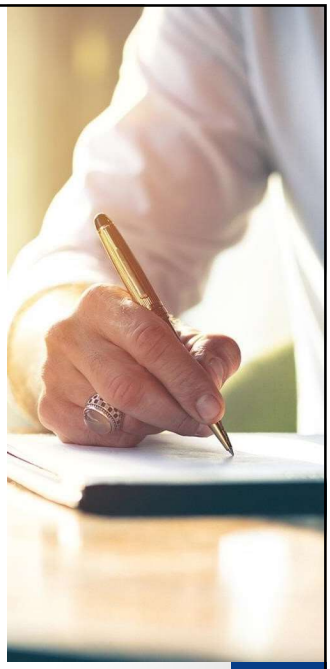
Business Associate Agreement

- HIPAA requires that before a Business Associate receives PHI the Covered Entity and Business Associate must enter into a Business Associate Agreement (BAA)
  - Signed by both parties
  - Include required language
  - Specifies how and for what purpose the Business Associate can use and disclose PHI
- In sum, the Business Associate can only use and disclose PHI to provide services to the Covered Entity, and as required by law



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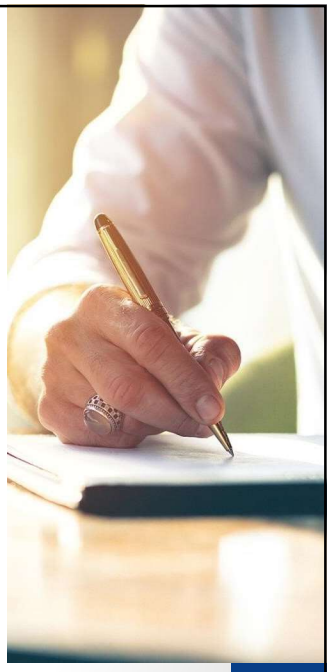
Business Associate Agreement

A BAA also imposes other obligations on the Business Associate:

- Compliance with the Security Rule
- Duty to use appropriate safeguards to protect the PHI
- Requirement to obtain a BAA with any Subcontractors of the Business Associate
- Must keep an accounting of disclosures
- A duty to report an unauthorized use or disclosure of PHI, including a breach
- Upon inquiry or investigation, must make available PHI in Designated Records Sets for inspection and amendment



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HIPAA in the real world: Stanford/Student of Fortune

An individual Googled their name and found it, along with some of their health information, in a database which was used on the homework help website, Student of Fortune, to explain how to turn a table into a graph

STANFORD HOSPITAL & CLINICS
Stanford University Medical Center

STUDENT of FORTUNE
Smart Homework Help

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HIPAA in the real world: Stanford/Student of Fortune

The PHI of 20,000 emergency room patients seen in the Palo Alto, CA hospital made its way from the hospital's BA, Multi-Specialty Collection Services, to the Student of Fortune website

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HIPAA in the real world: Stanford/Student of Fortune

Litigation from breach settles for **$4.1M**

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Individual Rights

- Access to PHI
- Amendment of PHI
- Accounting for Disclosures
- Notices of Privacy Practices

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Right to Access

- Hackensack Meridian Health (NJ SNF) – received a request for access from patient's son April 19
- Request denied April 22, with request for submission of POA or other appropriate documentation confirming authority to receive the requested information
- April 23, SNF received a copy of the son's POA, but did not provide the requested documents
- May 19, son submitted complaint to HHS

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Request for Access

- What should the outcome be?
- HIPAA Privacy Rule requires that a covered entity "must act on a request for access no later than 30 days after receipt of the request" 45 C.F.R. § 164.524(b)(2)

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Request for Access

- SNF acknowledged it failed to provide the requested records to the son, and instead provided them to another facility to which his mother was transferred
- At the time of the request, the son/his mother were in litigation with the SNF over non-payment for care
- SNF said it was struggling with the pandemic
- SNF highlighted that the request was submitted and then the complaint was filed with OCR before the response was even due

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Request for Access

- The requested access was not provided until approximately seven months after the complaint was submitted to OCR
- What was the harm?
- Should there be a penalty?
- Actual outcome: $100K penalty

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HIPAA and State Law

Example: Illinois

- HIPAA doesn't treat sensitive information any differently than basic PHI
- Illinois law requires authorization/court order to disclose sensitive information (e.g., genetic testing, HIV/AIDS, mental health, and sexual assault)

Lesson:

Don't just do HIPAA research online unless you know that your state follows HIPAA. Might need to consider state law.

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Privacy Safeguards

- Avoid conversations involving PHI in public or common areas such as hallways or elevators
- Keep documents containing PHI in locked cabinets or locked rooms when not in use
- During work hours, place written materials in secure areas that are not in view or easily accessed by unauthorized persons
- Do not leave materials containing PHI on desks or counters, in conference rooms, on fax machines/printers, or in public areas
- Do not remove PHI in any form from the designated work site unless authorized to do so by the privacy officer

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Privacy Safeguards

- Only those employees who need access to PHI to perform a job task should access PHI
- Only use/disclose PHI if it is necessary for your job
- Only use/disclose the minimum PHI necessary to complete your job task
- Protect the confidentiality of PHI
- Do not sell PHI
- If you have any doubt whether a use/disclosure is allowed, contact the Privacy Officer
- Dispose of PHI properly – usually by shredding

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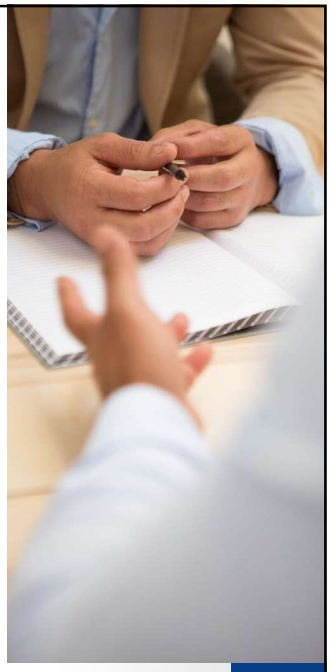
Security Rule in a Nutshell

Requires Covered Entities and Business Associates to maintain reasonable and appropriate **administrative, technical and physical** safeguards for protecting e-PHI

Specifically:

- Ensure the confidentiality, integrity and availability of all e-PHI created, received, maintained or transmitted
- Protect against reasonably anticipated, impermissible uses or disclosures
- Identify and protect against reasonably anticipated threats to security or integrity of the information
- Ensure workforce compliance



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HIPAA Security Rule – Proposed Modifications

- Risk Analysis
- Technology Asset Inventory & Network Map
- Compliance Audits, Penetration Tests & Vulnerability Scans
- Contingency Planning and Incident & Disaster Response
- Security Awareness & Training

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HIPAA Security Rule – Golden Rules

- Your organization must have a Security Officer who is responsible for the organization's compliance with the Security Rule
- Electronic media (discs, hard drives, flash drives, etc.) must be disposed of according to your organization's policies
  - So provide media to the Security Officer for disposal
- Be mindful of all electronic media – for example copy machines that make digital images of PHI
- Follow your organization's policy on emailing PHI
- Follow your organization's policy on accessing PHI through mobile devices
- Follow your organization's policy on mobile devices (e.g., do not leave a laptop in your car!)

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Breach Notification

Breach: "The acquisition, access, use, or disclosure of protected health information in a manner [not permitted by the Privacy Rule] which compromises the security or privacy of the protected health information."

A Covered Entity must notify:

- Individuals whose PHI has been or has reasonably believed to have been involved in a breach.
- Department of Health and Human Services (HHS).
- Prominent media outlets serving the state if the breach affects 500 or more residents of the state.

Also applies to Business Associates:

- BAs must notify CEs of breaches.

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Enforcement – Government Sanctions

Violation Type	Amount Per Violation	Annual Limit
Did not know	$100 - $50,000	$25,000
Reasonable Cause	$1,000 - $50,000	$100,000
Willful neglect - Corrected	$10,000 - $50,000	$250,000
Willful neglect – Not Corrected	$50,000	$1.5M

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Questions

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Compliance Essentials Workshop

Delegation of Authority:
Screening Third Parties and Hiring and Promoting Employees

Kenneth Zeko, Esq., CHC
Founder/President
Zeko LLC

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Agenda

1. Three Lines Refresher
2. U.S. DOJ, Criminal Division, Evaluation of Corporate Compliance Programs (Updated March 2023) – 3rd Party Management
3. Measuring Compliance Program Effectiveness: A Resource Guide - Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Identifying and Assessing 3rd Party risks
5. Understanding Due Diligence Processes
6. Links to Web Pages

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Recent Activity – Rady/Blackbaud

- "Defendant breached its duty owed to Plaintiff and the Class by failing to utilize a vendor with fair, reasonable, or adequate computer systems and data security policies to safeguard Plaintiff's and Class Members' medical information and allowing that Private Information to be released and viewed by unauthorized persons."
- "The unauthorized disclosure of Plaintiff's and the Class Members' Private Information to unauthorized individuals in the Data Breach resulted from the affirmative actions of Defendant who knew or should have known that its vendor had inadequate computer systems and data security practices to safeguard such information."

See: https://www.classaction.org/media/doe-v-rady-childrens-hospital-san-diego.pdf

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Recent Activity – McKinsey Settlement

- The agreement "calls for McKinsey to release tens of thousands of its internal documents detailing its work for OxyContin manufacturer Purdue Pharma, as well as other opioid manufacturers, for public disclosure online. Additionally, McKinsey agreed to adopt a strict document retention plan, continue its investigation into allegations that two of its partners tried to destroy documents in response to investigations of Purdue Pharma, implement a strict ethics code that all partners must certify each year, and stop advising companies on potentially dangerous opioid-based Schedule II and III narcotics."
- The settlement shows how McKinsey allegedly showed Purdue "how to maximize profits from its opioid products, including targeting high-volume opioid prescribers, using specific messaging to get physicians to prescribe more OxyContin to more patients, and circumventing pharmacy restrictions in order to deliver high-dose prescriptions."

See: https://ag.ny.gov/press-release/2021/attorney-general-james-delivers-more-573-million-communities-across-nation-fight

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Three Lines Model

"The Third Line"

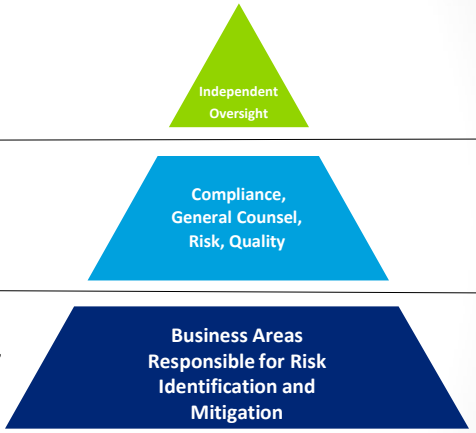
Internal Audit and sometimes Compliance or consultants will provide independent oversight and audits.

"The Second Line"

Compliance, General Counsel, Risk and Quality will provide compliance management, framework and policies to guide the Organization (can also be 1st line departments).

"The First Line"

Management is accountable for identification of risks, internal controls, compliance activities and monitoring in order to be compliant with laws and regulations (can also be Compliance).



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The Federal Sentencing Guidelines Defines Substantial Authority Personnel

- *(C) "Substantial authority personnel" means individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of an organization. The term includes high-level personnel of the organization, individuals who exercise substantial supervisory authority (e.g., a plant manager, a sales manager), and any other individuals who, although not a part of an organization's management, nevertheless exercise substantial discretion when acting within the scope of their authority (e.g., an individual with authority in an organization to negotiate or set price levels or an individual authorized to negotiate or approve significant contracts). Whether an individual falls within this category must be determined on a case-by-case basis.*

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U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (Updated Sept. 2024) ("U.S. DOJ Document")

- "For example, prosecutors should consider whether the company has analyzed and addressed the varying risks presented by, among other factors, the location of its operations, the industry sector, the competitiveness of the market, the regulatory landscape, potential clients and business partners, transactions with foreign governments, payments to foreign officials, use of third parties, gifts, travel, and entertainment expenses, and charitable and political donations."

- "Prosecutors should assess the steps taken by the company to ensure that policies and procedures have been integrated into the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners."

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U.S. DOJ Document - Third-Party Management

- "A well-designed compliance program should apply **risk-based due diligence** to its third-party relationships. Although the need for, and degree of, appropriate due diligence may vary based on the size and nature of the company, transaction, and third party, prosecutors should assess the extent to which the company has an understanding of the qualifications and associations of third-party partners, including the agents, consultants, and distributors that are commonly used to conceal misconduct, such as the payment of bribes to foreign officials in international business transactions."

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U.S. DOJ Document - Third-Party Management

- "Prosecutors should also assess whether the company knows the business rationale for needing the third party in the transaction, and the risks posed by third-party partners, including the third-party partners' reputations and relationships, if any, with foreign officials. **For example, a prosecutor should analyze whether the company has ensured that contract terms with third parties specifically describe the services to be performed, that the third party is actually performing the work, and that its compensation is commensurate with the work being provided in that industry and geographical region**."

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U.S. DOJ Document - Third-Party Management

- "Prosecutors should further assess whether the company engaged in ongoing monitoring of the third-party relationships, be it through updated due diligence, training, audits, and/or annual compliance certifications by the third party. In sum, a company's third-party management practices are a factor that prosecutors should assess to determine whether a compliance program is in fact able to "detect the particular types of misconduct most likely to occur in a particular corporation's line of business."

- "Risk-Based and Integrated Processes – How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company? How has this process been integrated into the relevant procurement and vendor management processes?"

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U.S. DOJ Document - Third-Party Management

- "Appropriate Controls – How does the company ensure there is an appropriate business rationale for the use of third parties? If third parties were involved in the underlying misconduct, what was the business rationale for using those third parties? **What mechanisms exist to ensure that the contract terms specifically describe the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered**?"

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U.S. DOJ Document - Third-Party Management

- "Management of Relationships – How has the company considered and analyzed the compensation and incentive structures for third parties against compliance risks? How does the company monitor its third parties? Does the company have audit rights to analyze the books and accounts of third parties, and has the company exercised those rights in the past? How does the company train its third-party relationship managers about compliance risks and how to manage them? How does the company incentivize compliance and ethical behavior by third parties? Does the company engage in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process?"

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U.S. DOJ Document - Third-Party Management

- "Real Actions and Consequences – Does the company track red flags that are identified from due diligence of third parties and how those red flags are addressed? Does the company keep track of third parties that do not pass the company's due diligence or that are terminated, and does the company take steps to ensure that those third parties are not hired or re-hired at a later date? If third parties were involved in the misconduct at issue in the investigation, were red flags identified from the due diligence or after hiring the third party, and how were they resolved? Has a similar third party been suspended, terminated, or audited as a result of compliance issues?"

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U.S. DOJ Document – Third Party Management Summary

- Who are you contracting with and who are they contracting with?
- Are you doing risk based due diligence
- Do you know your business rational for doing business with the 3rd party?
- Are you performing ongoing monitoring?
- Can you evidence appropriate controls?
- Can you evidence ongoing management of the 3rd party relationships?
- Are there real actions and consequences when you identify risks?

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Measuring Compliance Program Effectiveness: A Resource Guide ("Resource Guide")

- Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - "3.1 The individual(s) responsible for exclusion screening has clear accountability for the screening function.
    - Audit the job description, training material, orientation material, and annual performance evaluation of the individual(s) responsible for exclusion screening to ensure this responsibility is clearly articulated and performance is measured.
    - Annually review/discuss the exclusion screening process individually with each person responsible for sanction check screening; review the document retention processes to ensure documentation of the screening function, response to findings, and corrective actions are adequately maintained."

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Resource Guide - Screening

- Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - "3.2 Potential conflicts of interest are disclosed.

    Audit the conflict- of- interest disclosures for completeness and the extent to which those who complete the disclosure information.
  - 3.3 The organization conducts effective education on Conflict of Interest (COI).
    - Review training materials and interview staff to determine the effectiveness of the education.
    - Audit completed attestations or disclosures to ensure individuals are disclosing conflicts according to education provided."

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Resource Guide - Screening

- Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - "3.24 Vendors and other 3rd parties are interviewed at the termination of the engagement and asked about their awareness of the compliance program and any concerns, risks, violations, or failures of the compliance program."

    "Review organization's vendor termination/off-boarding process such as interviews, surveys, and/or questionnaires to ensure compliance program questions are incorporated into the process and interviews/results are reviewed and evaluated."
  - "3.33 Vendors and other 3rd parties adequately satisfy compliance obligations.

    Conduct audit of vendors and other 3rd parties to ensure they have documented evidence of required compliance training, orientation to the organization's Standards of Conduct, orientation to applicable compliance policies and procedures."

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Resource Guide - Screening

- Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - "3.34 The organization has established a process to ensure vendor and other third party agreements are managed consistent with the terms of the agreement."

    Conduct a document review and interviews to ensure there is communication between lawyers who develop the agreements and facility level personnel managing the engagement to make sure it is implemented and being managed according to the terms of the agreement." *(Hint: think of medical directorship agreements)*
  - "3.35 The organization requires vendors and other third parties to certify screening has been completed as required by the agreement.

    Audit to determine that vendors respond to request for certification. Review process to determine that actions taken for failure to respond or provide required certifications are consistent with the agreement. Ensure that response to certification is reviewed by an appropriate individual and communicated to facility operations. Audit to ensure that renewal decisions consider compliance with certification requirements." *(Hint: again, think of medical directors)*

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Resource Guide - Screening

- Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - "3.38 Vendors and other 3rd parties are adequately screened for exclusion."
    - Audit vendor records and cross check to ensure the vendor is adequately screened, in accordance with agreement and/or entity requirements.
    - Develop checklist of criteria for vendor compliance review and audit against that list for vendor screening requirements.
    - Survey peer organizations to ensure the organization's vendor and 3rd party screening process is consistent with industry practice."

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Resource Guide - Screening

Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents

- "3.39 The organization has an effective process to review third party vendors.

  Audit and conduct a document review to ensure:

  - Third party contracts allow for organization to review vendor files for compliance with screening requirements.
  - The organization has requested the third party's policy and procedure related to vendor screening of employees.
  - The organization conducts reviews of third-party contracts.
  - The organization has established a policy on how often screenings are required to be done by the third party.
  - The organization has established a policy requiring third parties to produce proof that they are checking their employees.
  - The organization has established a policy establishing which databases third parties are checking, especially regarding practitioners, including geographic specifics (state databases).
  - The organization has established a process for independent evaluation of what screening the vendor is supplying."

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Resource Guide - Screening

Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents

- "3.40 The organization has requirements, via policy or contractual terms, for screening of first-tier, downstream and related entities (contractors).

  Audit to verify evidence that contractors are being screened pursuant to contractual requirements."

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Resource Guide - Screening

- "3.9 All employees are screened prior to hire.

  Audit human resource files to ensure documentation supports that newly hired employees were screened prior to their first day worked."

- "3.10 Screening considers other names/alias and States used by a prospective employee.

  Review applications for each type of screening (criminal, OIG, SAM, State, SSN, etc.) and audit to determine if screening was completed against other names/states used by the prospective employee."

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- 3.11 The organization has defined which employees, vendors, medical staff, and others will undergo criminal, financial and/or other background checks prior to hire.
  - Perform assessment/audit to ensure the organization had identified which individuals receive criminal, financial, Social Security trace, drug screening, or other background checks.
  - Audit to ensure such background checks are being performed and reviewed prior to employment.
- 3.12 The organization has defined criteria for review of criminal, financial, and/or other background checks and hiring decision are made based on this established criteria.

  Perform assessment/audit to ensure the organization has established criteria to evaluate the acceptability of a candidate based on findings of criminal, financial, or other background check(s) used by the organization.

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Resource Guide - Screening

- "3.13 Employees are provided education regarding the organization's screening process.

  Interview employees and conduct documentation reviews to confirm that employees understand the importance of not letting licenses expire and the effect of exclusion."
- "3.14 The organization ensures that applicants for employment understand disclosure requirements.

  Review employment applications to ensure disclosure is made to prospective employees, including exclusion and background screening requirements, and these screenings are completed."

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Resource Guide - Screening

- "3.15 The organization has established a policy regarding the frequency of screening.
  - Perform a document review to ensure the frequency of screening is being done in accordance with policy.
  - Audit the screening process to ensure screening is being completed according to policy."
- "3.16 The organization has established sufficient controls in the hiring process and vendor engagement process to prevent the organization from hiring an ineligible individual or entity.
  - Audit, perform document review, interviews staff and vendors, and conduct datamining to determine if sufficient controls are in place to prevent the organization from hiring an "ineligible" individual or entity.
  - Use data-mining to compare lists of new employees with due diligence lists.
  - Ensure the vendor master file is updated with vendors that have been screened."

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Resource Guide - Screening

- "3.17 The organization has established a screening program that is consistent with all laws and regulations.

  Conduct a legal review and analysis of screening process to ensure it is being administered in a manner consistent with federal and state laws."
- "3.18 The organization has established a process to screen employees and other relevant individuals at least monthly.

  Audit screening process to ensure screening of employees and other relevant individuals is being conducted at least monthly and according to policy."

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Resource Guide - Screening

- "3.19 The organization has established a policy and procedure which defines the screening requirements for employees, vendors, medical staff and others. The policies include description of the databases that individuals will be screened against and the frequency of screening.
  - Conduct a document review to verify the policy and procedure has been established, is complete, and audit to ensure screening is being conducted consistent with policy.
  - Perform assessment/audit to ensure organization has identified which lists to check and how often each is checked and the screenings are being checked per policy.
  - Perform assessment/audit to ensure all relevant types of individuals and entities (employees, temps, vendors, etc.) are being screened per policy."

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- "3.20 The organization has a process to determine when additional screening may be necessary based on findings from compliance investigations. (Relevant event (situational) screening (R.E.S.))
  - Conduct a review of compliance investigation files to determine if consideration for additional screening is warranted and review the results of additional screening completed as part of the investigation process (situational) when applicable."
- "3.21 The organization has a policy and procedure which articulates the process for screening, investigation of potential "hits," actions taken in response to a positive finding, tracking exclusions, and communication to appropriate stakeholders.
  - Conduct documentation review and audit to ensure screening is being completed according to policy requirements and that all process elements related to investigation, resolution, tracking, and communication are being managed according to policy requirements."

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HHS-OIG General Compliance Program Guidance

- "All organizations should have a policy and procedure on the screening of employees, contractors, and other individuals and entities that furnish items and services for or on behalf of the organization against the LEIE and any applicable State Medicaid program exclusion lists. The policy should clearly identify which individual(s) in the organization are responsible for conducting the screening, the process for performing the screening and verifying any potential matches, and the steps that should be taken in the event an entity learns that an individual or entity that has been excluded by the OIG or a State Medicaid program."
- "Entities may choose to rely on screening conducted by a contractor (e.g., staffing agency, physician group, or third-party billing or coding company), but OIG recommends that entities validate that the contractor is conducting such screening on behalf of the provider (e.g., by requesting and maintaining screening documentation from the contractor). The entity remains responsible for any overpayment or CMP liability that may result from employing or contracting with an excluded individual or entity in a manner that violates the exclusions authorities."

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Identifying Third-Party Arrangements

- Are you using a 3rd party billing company? If so, how do they bill; do they code; do their coders/billers bill or code from the entire record; who vets their billers/coders? Do you conduct claims reviews after they've coded and billed.
- Are you outsourcing revenue cycle (do you use revenue cycle consultants)? Do you have transparency into what revenue cycle consultants or outsourced provider are recommending.? See McKinsey & Company Settlement: https://ag.ny.gov/press-release/2021/attorney-general-james-delivers-more-573-million-communities-across-nation-fight
- Do you use on-call physicians, do you outsource ER physicians, medical directorships, sales reps, etc.?

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What Risks do Your Arrangements With Third Parties Pose?

- The more crucial or vital the 3rd party is to your organization, the more vetting you should do.
- Can you document your vendor onboarding processes? Do you require vendors to review your code of conduct? Do you require vendors to certify that they reviewed and understand your code of conduct? Are they required to take your Compliance training? Do you monitor/audit to what extent they are?
- Make sure your contracts have audit clauses.
- Can you document your employee onboarding process? Do you conduct background checks, OIG, GSA, SAM checks.
- Do the entities even exist?
- Do your employees, Board Members have relationships with your vendors (Conflicts of Interest)?
- Have the vendors teammates been whistleblowers or party to a settlement?

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Understanding Due Diligence Processes

- Is the Compliance Department involved in Strategy discussions?
- Is Compliance at the "table" when new services are being implemented?
- What types of diligence activities are done?
  - Financial
  - Compliance Program Assessment
  - Coding Compliance
  - Legal
- Who performs the diligence? What's the Compliance Department's role (creating internal centers of excellence)?
- Have diligence venders been vetted?
- What is done with diligence results?
- Are new risks incorporated into your organization's risk assessment process?

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Risk Based Approach to Due Diligence

The organization should conduct a mini-risk assessment for each acquisition or merger.

- What type of merger or acquisition is being proposed?
- What's the reason for the merger or acquisition?
- How will revenue be generated?
- What's the risks associated with the new revenue?
- Does the new venture pose different regulatory risks?
- Do you have internal subject matter experts to mitigate those risks, once the deal goes live?
- Where do the new risks rank on the organization's existing risk profile?

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Web Pages

Federal Sentencing Guidelines, Chapter 8

https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8

DOJ Evaluation of Corporate Compliance Programs (Updated Sept. 2024)

https://www.justice.gov/criminal-fraud/page/file/937501/download

Measuring Compliance Program Effectiveness: A Resource Guide

https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf

General Compliance Program Guidance

https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf

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Questions?

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Contact Information

Ken Zeko, Esq., CHC

Founder/President

Zeko LLC

Kenneth.zeko@gmail.com

214-458-3457

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36

Compliance Essentials Workshop

Communication and Training

Tomi Hagan, MSN, RN, CHC, CHPC

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Objectives

- Learn how communications from management can be used to promote the Compliance Program.
- Differentiate between general and focused, risk-specific training.
- Analyze various methods of training.
- Link training to risk assessments.
- Identify approaches to measure the results of training.

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GCPG Element 4: Effective Lines of Communication with the Compliance Officer and Disclosure Programs

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- How to contact compliance
  - Multiple independent reporting paths
- Encourage questions
  - Create ideas for new FAQs
  - Evaluate the effectiveness of training and compliance messaging
  - Determine whether policy or process changes may be needed
  - Identify potential compliance risks
- Confidentiality and nonretaliation
  - Whistleblower protection
- Disclosure log
  - Communicate to Compliance Committee, CEO, Board

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Communications from Management

- Organizational leaders support the Compliance Program by:
  - Communicating key compliance messaging
  - Including adherence to the Compliance Program in performance appraisals and job descriptions
  - Incorporating compliance into meetings

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Communications from Management

- Formal messaging
  - Letter from CEO in Code of Conduct
  - Memos and newsletters
  - Compliance as standing line-item agenda for leadership and staff meetings
- Informal messaging
  - Staff discussions
  - Leading by example
  - Casual conversations

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Leadership Training

- Sets clear expectations for leadership's role in the Compliance Program
- May have higher level overview initially, with more in-depth training to follow

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Leadership Responsibility

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- Be familiar with the Code of Conduct
- Promote an ethical workplace
- Non-retaliation
  - Overt vs. subtle
- Compliance program awareness
- Identification of departmental compliance education and training needs
- Recognition of potential compliance issues
- Prompt reporting of actual or potential compliance issues
- Assist with investigations

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GCPG Element 3: Training and Education

- Annual training plan
  - Topics
  - Target audience
  - Address concerns identified in audits and investigations
  - Reviewed by Compliance Committee
- All board members, officers, employees, contractors, and medical staff should receive training at least annually on the compliance program and potential compliance risks
- Targeted training
  - Billing, coding, documentation, medical necessity, beneficiary inducements, gifts, interactions with physicians and other sources or recipients of referrals of Federal health care program business, and sales and marketing practices
- Materials accessible to all members of designated audience

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General Compliance Training

- Why?
  - Lay the foundation for a culture of compliance
  - Meet regulatory requirements
  - Element of an effective compliance program
  - Provide clear guidance

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General Compliance Training

- Who?
  - Employees
  - Medical Staff
  - Volunteers
  - Students
  - Contactors
  - Board

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GCPG Element 3: Training and Education

- Specific Topics:
  - Identity and role of the compliance officer
  - Role of the Compliance Committee
  - Importance of open communication with the compliance officer
  - Various ways individuals can raise compliance questions and concerns with the compliance officer
  - Nonretaliation for disclosing or raising compliance concerns
  - Means through which the entity enforces its written policies and procedures equitably and impartially

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General Compliance Training

- What?
  - Compliance Program Basics
    - Elements of an effective compliance program
    - Code of Conduct
    - Compliance Program policies and procedures
    - Process for reporting compliance concerns
    - Non-retaliation policy

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General Compliance Training

- What?
  - Overview of Compliance Risk Areas
    - False Claims Act
    - Stark/Anti-Kickback
    - Beneficiary Inducement
    - Exclusions/Sanctions
    - HIPAA Privacy
    - HIPAA Security

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General Compliance Training

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- When?
  - New Hire
  - Annual
  - Remediation
  - New or changing regulations
  - New or revised policies and procedures
  - Process improvements

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Methods of Training

- Most effective varies with audience
- Most efficient may not be most effective
- Consider multiple methods to reach different types of learners
  - Auditory
  - Visual
  - Kinetic
- Post-training evaluations should include questions regarding effectiveness of method

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Polling Question

- What method of training do you use most often?
  - Case Studies
  - Computer Based Learning
  - Discussion Groups
  - Email Blast
  - Live Presentation
  - Paper/Packets
  - Other

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Paper/Packets

- Often most efficient method for:
  - Medical Staff
  - Vendors
  - Volunteers
  - Students
- More effective if supplemented with live presentations or other methods
- May include tests and evaluations
- Include certification of understanding and agreement to adhere to the Code of Conduct and Compliance Program

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Computer Based Learning

- Efficient
- Tracking available
- Sophisticated systems available
  - Reminders to audience
  - Reminders to management
- Ability to purchase ready-made modules
- Ability to create home-grown modules
- Ability to include pre and/or post testing

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Computer Based Learning Considerations

- Tailor the training to your organization
- Ensure that employee language, literacy, and disability needs are being met
- Provide adequate time to complete the training
- Use video, cartoons, or other enhancements to provide more effective training

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Email Blast


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- Efficient
- Easy to track
- All staff may not have access or check frequently
- May be ignored
  - "Blast fatigue"
- Harder to evaluate effectiveness

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Live Training

- Opportunity to put a face to the compliance program
- Ability to have dialogue
  - Try to anticipate questions that may be asked and prepare for answers
  - Consider soliciting specific questions ahead
- Scheduling may be difficult
  - Be sensitive to department budgets
- Consider high-frequency, targeted approach for risk-based training
  - 10-15 minutes on department meeting agenda vs. longer in-service
  - May supplement with computer-based learning, handouts, etc...

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Discussion Groups

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- Promotes learning from one another
- Small groups vs. larger groups
  - Small groups may facilitate more open conversation
  - Larger groups may have more experiences to draw from

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Case Studies

- Effective in making difficult compliance concepts more "real"
- Choose examples that relate to the audience
  - EMTALA for ED/OB
  - False Claims for Revenue Cycle
  - Identity theft for Patient Access

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GCPG Element 3: Training and Education

- Training not limited to annual formal training requirements
  - Developing and updating FAQs on the entity's electronic communication site or on posters in employee common areas
  - Having a standing compliance item on the agenda for regularly scheduled meetings
  - Writing a regular column in the entity's newsletter
  - Posting video clips
  - Participating in the annual sales meeting
  - Occasionally dropping in on an informal morning huddle
  - Walking the floors
- Normalize compliance as integral part of the culture
  - Compliance Committee and leaders deliver compliance training in meetings

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Polling Question

- What method of training do you think is most effective?
  - Case Studies
  - Computer Based Learning
  - Discussion Groups
  - Email Blast
  - Live Presentation
  - Paper/Packets
  - Other

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External Resources

- Webinars
  - Helpful for risk-based training
  - Free webinars often available for new regulations
  - Be cautious of marketing vs. education
- Conferences
  - National
  - Regional
  - Virtual
- Books

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External Resources

- Professional Organizations (Compliance)
  - Listservs
  - Social media groups
  - Newsletters
    - Report on Medicare Compliance
    - Report on Patient Privacy
- Professional Organizations (Other)
  - Specialty-specific professional organizations also provide valuable compliance guidance to their members
  - Encourage leaders, providers, and staff to share any compliance related information they receive

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Governmental Resources

- Straight to the source
- Several types of training available to the public
- Watch enforcement actions to identify potential training needs

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Governmental Resources

- OIG
  - OIG HEAT Provider Compliance Training
    - Video and Audio Podcasts
    - Presentation Materials
  - Physician Education Training Materials
  - CME available
  - Email Updates
  - Medicare Compliance Reviews

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Governmental Resources

- CMS
  - Listservs
  - Medicare Learning Network (MLN)
    - Provider Compliance Tips
    - Provider Compliance MLN Matters® Articles
    - Medicare Quarterly Provider Compliance Newsletter
    - Comprehensive Error Rate Testing (CERT) Outreach and Education Task Forces
    - Medicare Parts C and D Compliance and Fraud, Waste, and Abuse (FWA) Trainings
  - Comprehensive Error Rate Testing (CERT) Outreach and Education Task Forces
  - MAC listservs

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Governmental Resources

- Office for Civil Rights
  - Listservs
  - HIPAA Training Materials
- Office of the National Coordinator for Health Information Technology (ONC)
  - Health IT Privacy and Security Resources
  - Games, videos, papers

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Length of Training

- Per OIG Compliance Program Guidance for Hospitals (February 23, 1998), "Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities."
  - Corporate Integrity Agreements (CIA) generally required one to three hours for basic training
  - More is required for high-risk fields such as billing and coding
- More recent CIA require submission of a written training plan that includes length, schedule, and format
- Shorter, more frequent may be more effective
- Consider impact of methodology on length
- Not defined in GCGP

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Linking Training to Risk Assessments

- Assess and evaluate risks
- Use results to:
  - Prioritize compliance work to optimize resource utilization
  - Identify role-based, specialized compliance training needs
  - Mitigate identified risks through education and training
- Dynamic process
  - New risks may evolve over the course of a year

Likelihood severity occurs	Potential Severity Rating: Minor	Moderate	Significant	Catastrophic
Very Likely	Moderate	High	Extreme	Extreme
Likely	Low	Moderate	High	Extreme
Unlikely	Very Low	Low	Moderate	High
Rare	Very Low	Very Low	Low	Moderate

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Planning Process

- Use the annual Risk Assessment to prioritize compliance education and training
  - Identify area of high compliance risk
  - Identify all stakeholders/influencers
    - Leaders
    - High-risk positions
- Consider topics that may not be the highest risk for your organization, but still warrant training
  - HIPAA
  - EMTALA
  - Conflict of Interest

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Planning Process

- Develop an education and training plan
  - By department and/or role
  - Include:
    - Topic
    - Audience
    - Method
    - Schedule
  - Consult with leaders regarding other compliance-related training that could be captured on the plan

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Planning Process

- Documentation of Plan
  - Software
  - Spreadsheet
- Availability of Plan
  - Intranet
  - SharePoint

Date	Topic	Method	Audience
1/14/2019	General Compliance Training	Live Presentation, PowerPoint	Medical Staff
4/29/2019	General Compliance Training	Live Presentation	Diagnostic Imaging
6/10/2019	Patients Over Paperwork	Live Presentation, PowerPoint	Family Medicine Providers Family Medicine and Family Medicine Mercy Staff
6/11/2019	Non-Retaliation	Live Presentation	Directors Meeting

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Execute Education & Training Plan

- Collaborate
  - Education/Staff Development department
    - Consistent tracking of education and training provided
    - Management of computer-based learning systems
  - Managers/Directors
    - Reporting process for compliance-related departmental training
    - Identification of additional training needs

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Execute Education & Training Plan

- Review
  - Periodic review of progress to plan
  - Re-prioritization as necessary based on:
    - Reported issues
    - Needs identified by management
    - Enforcement actions
  - Identification and mitigation of any barriers to plan execution

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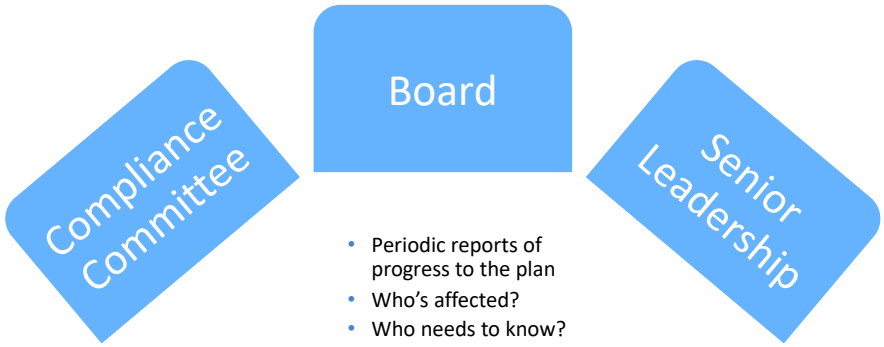
Execute Education & Training Plan



- Periodic reports of progress to the plan
- Who's affected?
- Who needs to know?

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Measuring the Results of Training

- Evaluate all training on an annual basis to ensure that the content is appropriate and sufficient
  - Up to date with regulatory changes
  - Accurately reflects current organizational processes
  - Addresses organizational risk
- Implement processes to solicit feedback
- Implement objective methods to evaluate effectiveness of training

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Testing

- Objective method to evaluate effectiveness of training
  - Pre-test
  - Post-test
  - Knowledge survey – 6 months after training
- Pass rate
  - Remediation for scores that do not meet
- Literacy
  - Write the questions at a level readable by the audience
  - Avoid “trick questions”

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Evaluations

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- Subjective assessment of training
- Audience feedback regarding:
  - Topic
  - Content
  - Method
  - Delivery

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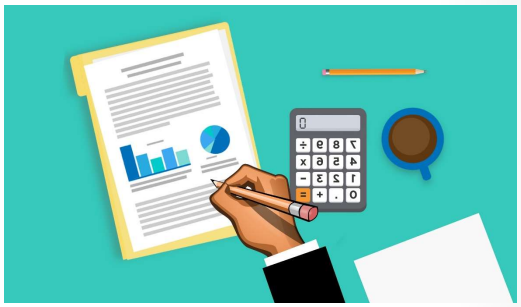
Results

- Compliance issue trends
- Compliance program awareness
- Audits and reviews
- Employee engagement



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Documentation

- Maintain documentation of training provided according to retention schedule
  - Attendance logs
  - Training materials
  - Tests/evaluations
- Documentation may be maintained via:
  - Paper
  - Electronic learning management system (LMS)
  - Electronic compliance program management system

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Enforcement

- Compliance training as a condition of employment
- Sanctions for failure to attend required training
  - Disciplinary actions
- Consistency in enforcement actions
- §8B2.1(6) The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

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Incentivizing Compliance

- Incentives for:
  - Adhering to the Compliance Program
  - Completing compliance training
  - Reporting compliance concerns
- Incentives may be in the form of:
  - Money/compensation
  - Tangible items
  - Kudos

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Resources

- OIG Compliance Guidance
- Federal Sentencing Guidelines Chapter Eight
- Measuring Compliance Program Effectiveness: A Resource Guide, March 27, 2017 HCCA-OIG
- OIG HEAT Provider Compliance Training
- OIG Physician Education Training Materials
- CMS Provider Compliance
- OCR HIPAA Training Materials
- ONC Health IT Privacy and Security Resources for Providers

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Questions?

Contact info:
thagan@greatriverhealth.org

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Sample Report Template

Providence St.Joseph Health

Investigative Report

Case No.: XXXX

Date Received:

Reporter(s):

[If known, include position and contact information]

Subject(s):

[If known, include position and contact information]

Investigator(s):

Executive Summary:

Alleged violation(s):

List out one-by-one:

[Identify the policy that is alleged to be violated. For example, if a privacy violation is alleged, cite the system or regional policy that applies. If the Code of Conduct is allegedly violated, state the principle in the Code of Conduct.]

Witness List

Name	Position	Date(s) Interviewed	Interview Method
(Reporter)			(In-person, telephonic)
(Subject)			
(Witness)			
(Witness)			

Chronology

Date	Event

Confidential

1

Providence St.Joseph Health

Investigation

Summary of statements [Attach complete statements separately]:

- Reporter's statements
- Subject's statements
- Witness statements

Evidence received:

[List out (i.e., emails, documents, other reports) and attach separately)]

Forms/Documents completed by investigator:

[List out and attach separately]

Analysis

Apply facts and summarize findings for each allegation using preponderance of the evidence standard:

First Allegation: Substantiated/Unsubstantiated

Second Allegation: Substantiated/Unsubstantiated

Describe any mitigating (i.e., self-reporting, cooperation with the investigation, etc.) and/or aggravating factors (i.e., pattern of misconduct, criminal behavior, concealment/destruction of evidence) affecting the level of a violation.

Conclusion:

Recommendations/Actions Taken:

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2

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Compliance Essentials Workshop

Auditing, Monitoring and Reporting Systems

Traci Rooks, JD CHC

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Road Map for this Training

- Topics we will discuss in this training:
  - Understanding the essential aspects of auditing and monitoring
  - Developing the compliance auditing and monitoring plan
  - Techniques and approaches to auditing and monitoring

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Understanding the essential aspects of auditing and monitoring

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Essential Aspects of Auditing & Monitoring

- Why do you need to audit and monitor activities in your organization?
  - If someone were to ask you if your organization were "in compliance," how would you answer that question?
  - How do you truly know that your organization is complying with applicable legal and regulatory requirements?
  - The only way to concretely answer this question is through auditing and monitoring.

"An ongoing evaluation process is critical to a successful compliance program." – *Compliance Program Guidance for Hospitals, Federal Register, Vol. 63. No. 35, Feb 23, 1998, p. 8996.*

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Essential Aspects of Auditing & Monitoring

- What is the difference between ***auditing*** and ***monitoring***?
  - **Auditing** is a pre-defined scope and is a one-time event, a snapshot in time, or a lookback at static history
  - **Monitoring** is the use of a consistent tool to evaluate ongoing performance that can be tracked over time and measured for improvement, variance and trending

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Developing the compliance auditing and monitoring plan

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The Compliance Auditing & Monitoring Plan

- Your Compliance Risk Assessment – It all starts here!
  - Your auditing and monitoring plan should be based on your routine compliance risk assessment.
  - There are a million things you could be auditing and monitoring and you can't do them all; how do you know where to spend your limited resources?
  - At its core, the risk assessment is a sophisticated prioritization tool to help you focus your time, effort and resources to the topics that matter most.

"Measuring Compliance Program Effectiveness: A Resource Guide," March 27, 2017, Element 5: Monitoring, Auditing and Internal Reporting Systems, Monitoring and Auditing Work Plans, 5.37-5.48.

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The Compliance Auditing & Monitoring Plan

- Your Compliance Risk Assessment – It all starts here!
  - Your risk assessment should consider the following:
    - A sound understanding of the make-up of the organization
      - Consider also off-site departments, partnerships, joint ventures, etc.
    - Compliance risks "inherent" to the organization
    - Actual compliance risk trends in the organization
    - Controls in place to mitigate risk
      - The stronger the controls, the lower the risk
    - Past auditing and monitoring activities
    - Government enforcement activities/publications
    - Multidisciplinary feedback from other functions of the organization (e.g., Legal, risk management, revenue cycle, IT, HR)
    - Coordination with other enterprise-level risk assessments (e.g., internal audit, strategic committees)
    - Review the COSO publication on compliance risk management

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Foundational Principles

POLLING QUESTION

How would you describe your compliance risk assessment process?

A. **The Compliance Department conducts the compliance risk assessment multiple times throughout the year.**
B. **The Compliance Department conducts the compliance risk assessment once a year (annually).**
C. **The Compliance Department conducts the compliance risk assessment less than once a year (e.g., bi-annually)**
D. **Our compliance risk assessment process is combined with an Enterprise Risk Management (ERM) program risk assessment.**
E. **We have not done a compliance risk assessment in the past.**

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The Compliance Auditing & Monitoring Plan

- What should your annual auditing and monitoring plan consist of?
  - High-risk compliance topics
    - Billing/coding topics
    - Privacy-related processes
    - Physician relations topics
  - Government focus areas (consider the OIG Work Plan)
    - OIG Work Plan topics
    - Recent enforcement activity (CIAs, settlements, etc.)
    - Recent new regulatory requirements
  - Substantive vs. Structural auditing
    - Substantive: Regulatory topics that create compliance risk to your organization
    - Structural: Auditing or monitoring of features of your Compliance Program for ongoing effectiveness

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The Compliance Auditing & Monitoring Plan

- What types of auditing and monitoring might you conduct?
  - Formal audits
    - With formal audit scope and report (deep dive)
  - High level reviews
    - Overviews at a high level to assess compliance (skim the surface)
  - Gap analyses
    - Comparing what we should be doing with what we are doing and finding the "gaps"
  - Checklist audits
    - For example, list the compliance requirements and check the box
  - Readiness reviews
    - Assessing your preparation for upcoming regulatory requirements
  - Spot checks/"test of one"
    - Minimal samples of transactional processes

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The Compliance Auditing & Monitoring Plan

- Who will conduct your audits or perform your monitoring?
  - Compliance department staff?
  - Internal audit staff?
  - External auditors?
  - Departmental management?
- A word on independence
  - Topics of particularly high risk or suspected of potential fraud should be conducted by individuals who are "independent" of the processes being audited in order to avoid conflicts and to ensure the integrity of audit results.
- Also, a word on original source documentation
  - You may need to rely on others to obtain information or data during an audit. Be mindful of how this information is obtained and if it can be modified before getting into your hands. It's often better if you can obtain the data yourself from the source "unaltered."

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The Compliance Auditing & Monitoring Plan

- Every Work Plan is different
- Should be based on the risks identified in your organization
- Consider your organization's make-up, strengths, weaknesses, opportunities
- You will need to consider the available resources for compliance auditing and monitoring in your organization (internal and external)
- Your resulting auditing and monitoring work plan should be defensible based on your risk assessment
  - You should have a ready response to explain why certain topics are *on* your work plan as well as why other things were left *off*.

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Foundational Principles

POLLING QUESTION

How would you rate your compliance auditing and monitoring plan?

A. Our compliance auditing and monitoring plan would be considered best practice.
B. We have a functioning auditing and monitoring plan that works well.
C. Our auditing and monitoring plan is good but could use some work.
D. Compliance auditing and monitoring is done, but not as a formalized plan.
E. We don't do compliance auditing and monitoring.

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Techniques and approaches to auditing and monitoring

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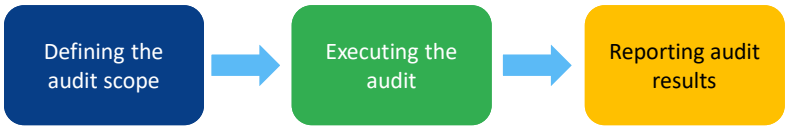
Conducting Audits

- An audit is a formal means of evaluating the effectiveness or adequacy of a process or event.
- An audit is generally broken down into three main steps:



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The Audit Scope

- A pre-defined description of how you're going to conduct the audit.
- Defined boundaries of what the audit will (or won't) include.
- Probably the most important part of your audit – take your time to do it right
- In theory, the scope doesn't change as the fieldwork is conducted
- Determine the time period the audit will encompass
  - Is this audit concurrent or a look-back audit? How far back will you look when evaluating reviewable attributes?
- What will you be auditing? What are your audit "attributes"?
  - Services? Activities? Processes? Transaction? Claims? Records? Controls?

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The Audit Scope

- What are internal controls?
  - A "control" is an established function to ensure that a process is working effectively and as designed. Controls might include such things as:
    - Policies and procedures
    - Organizational charts
    - Job descriptions
    - Education and training
    - Employee competencies and performance standards
    - Management reports and supervisory reviews
    - Segregation of duties
    - Checklists, forms, auditing, monitoring, exception/variance reports
    - IT controls, physical controls, etc.

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The Audit Scope

- Audits are usually more time-consuming than high-level reviews, checklists, spot checks or individual monitoring activities.
- Given the time and resources consumed in an audit, choosing which areas to audit shouldn't be taken lightly.
- What you decide to include in your audit is just as important as what you decide *not* to include in your audit.
- The audit scope allows you to tailor the exercise to your available resources.
- Stay true to your audit scope, even if you find other concerns during the audit. Put other identified issues on a list and address them separately. Avoid "scope creep" (expanding the audit parameters during the audit). If you say you're going to audit the accuracy of assigning billing code XYZ, the final audit report should not state that billing code ABC was done incorrectly (unless it's directly related to the billing of XYZ).

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The Audit Scope

- You will likely not have the resources to audit every instance of a particular process (e.g., auditing all Modifier 59 codes used at your network of 100 physician offices), nor is it wise.
- Using "sampling" techniques can allow you to evaluate ongoing, systemic processes with a degree of confidence without needing to audit an entire universe of transactions.
- How many samples should you select for it to be a statistically valid representation of the universe?
  - Most statisticians say 30 is the sweet spot for statistical validity.
  - You may choose to do more or less than this based on the nature of the subject being audited.
- There are a lot of considerations when it comes to sampling for purposes of extrapolating an overpayment which we won't cover in this session.

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The Audit Scope

- Sampling Techniques
  - How will you select your sample?
    - Sampling techniques
      - **Random**
        - RAT-STATS
        - Random number generator
      - When might you use random sampling?
        - If you anticipate the need to extrapolate your results, random sampling allows extrapolation with any degree of accuracy
        - More representative of the entire universe of transactions

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The Audit Scope

- Sampling Techniques
  - How will you select your sample?
    - Sampling techniques
      - **Judgmental**
        - *n*th selection
        - Extremes (high/low)
        - Cherry-picking (unusual samples)
        - Hybrid approach
        - Test of one
      - When might you use judgmental sampling?
        - Allows you to focus attention on specific samples you know may be at risk
        - May be useful in smaller samples or spot checking
        - *Cannot* be used for extrapolation with any degree of reliability.

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The Audit Scope

- Alternate Samples
  - When selecting your sample size, it can often be helpful to select some "alternate samples" in case any of the original samples are not usable or viable.
  - A rule of thumb of 10% of your sample size is often a good number of alternates to choose from.
  - For example, if you conduct a probe audit and sample 30 claims, selecting 3 additional claims (i.e., 10% of 30) as alternates can maintain the integrity of the original sample selection and save time by not having to go through a sampling selection again in case any of the original samples turns out to be unauditable.
  - Why might a sample be unauditable?
    - A medical record may not be available at the time of the audit (if the patient is currently under active care).
    - When reviewing appropriateness of payment, if payment has not yet been received.
    - If the original sample universe contained an error.
  - Use of alternate samples will likely be rare, but it can be helpful to incorporate them into your normal process for sample selection.

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The Audit Scope

- "Probe" Audits
  - Probe audits can be a very effective and helpful approach to conducting audits, especially in areas that haven't been audited before.
  - A probe audit is a minimally scoped audit that gives you sufficient confirmation that no further action need be taken without needing to conduct a "deep dive" audit. In short, it helps answer the question – "Do we have a problem that warrants further review?"
  - The sample size would typically consist of **30** randomly selected samples if the audit is based on a transactional process (e.g., claims, coding, billing) in order to achieve a minimum degree of statistical confidence.
  - If the results of the audit falls under your designated threshold for margin of error, no further work would need to be done. If the results are higher than your established error rate threshold, additional auditing may be necessary.

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The Audit Scope

- In which areas will you audit?
  - Consider the departmental or geographic divisions
  - Will you include all areas or only a few? Will you combine them all together or only audit a few? Or will you audit all of them separately?
- Conduct some data analysis before you embark on this or you may find yourself re-doing your auditing or starting over half-way through!
- This decision also speaks directly to the efficiency of your process. You will want to scope your audit correctly up front to avoid having to re-do the audit numerous times with multiple configurations.

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The Audit Scope

- Consider this example:
  - You would like to conduct a probe audit at 6 podiatrist offices assessing potential inappropriate billing of routine footcare for Medicare fee-for-service patients.
  - How would you approach auditing these offices?
    - Put all claims into a single bucket and draw your sample from that? **Blue**
    - Create a universe for each office and sample from each office? **Orange**
    - How would your decision change if the offices were managed by two different regional directors? **Green**

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The Audit Scope

- Partnering with Stakeholders
  - Work with key stakeholders when creating the audit scope.
  - They will likely know the process you're about to audit and can offer advice on setting up an appropriately scoped audit.
- Entrance Meetings
  - Consider holding an entrance meeting for the audit with the affected stakeholders to walk through the audit scope.
  - This might include management level personnel who are responsible for the department, area, function or location you're auditing.
  - Offers a good means of communicating the working relationship with your auditees and setting expectations for timing, what will be looked at, how the audit will be conducted, etc.
  - This step can help pave the way for a successful audit.

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The Audit Scope

- When might you put an audit under Legal privilege?
  - If you think, in advance, the topic will result in non-compliance or you have reason to believe it's not in compliance (based on anecdotal/empirical information, a Compliance Hotline call, an anonymous report).
- Consult with Legal to see if it should be placed under legal privilege before starting the audit.
- Legal will then need to "direct" the work of the audit going forward so make sure you're following their lead and advice, or the privilege may be inadvertently waived.
- Mark all documents appropriately according to Legal counsel's advice (e.g., "attorney client privilege").
- Be cautious not to put ***all*** compliance audits under legal privilege. Overuse of the privilege may create risk itself.

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Executing the Audit

- Approaches to your audit
  - Review of documents
    - claims or medical records
    - policies and procedures
    - contracts, payments
    - routine or ad hoc reports, trend reports, operational/finance reports
    - reports from outside entities (e.g., Quality Improvement Organizations (QIOs), Recovery Audit Contractors (RAC), Program for Evaluating Payment Patterns Electronic Reports (PEPPER), Office for Civil Rights notices).
  - Direct observation of a process, on-site visits
  - Interviews with personnel involved in processes
  - Questionnaires, surveys
  - Testing

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Executing the Audit

- What if you get half-way through your audit and find some major compliance concerns?
  - If your audit isn't already placed under legal privilege, embed in your routine process the ability to stop the audit and seek Legal advice before proceeding

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Executing the Audit

- How will you characterize findings in your audit?
  - Subjective
    - Adequacy of written policies and/or procedures
    - Compliance with procedures
    - Observation of non-compliance, but not quantifiable
  - Objective
    - Existence (or lack thereof) of documentation of a process (e.g., 5 of 10 records didn't have sufficient documentation)
    - Number of times a process was performed correctly based on observation (e.g., 4 of 10 observations were not performed correctly)
    - Number of claims with errors (e.g., 2 of 10 claims contained errors)
    - Net reimbursement error rate (NRER)

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Executing the Audit

- Calculating the Net Reimbursement Error Rate
  - When auditing claims, a key metric/calculation that you'll need to make is the net reimbursement error rate (NRER).
  - The net reimbursement error rate accounts for all overpayments and underpayments identified in the audit which is then computed against the total amount. One example is as follows:

$$1 - \frac{\text{(Total amount paid) + (Total amount underpaid) - (Total amount overpaid)}}{\text{(Total amount paid)}}$$

Example:

$$1 - \frac{(\$25{,}500) + (\$1{,}250) - (\$7{,}250)}{(\$25{,}500)} = .235 = +23.5\%\ \text{NRER}$$

A "+" number is an overpayment, a "-" number is an underpayment.

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Executing the Audit

- What is a reasonable threshold for a net reimbursement error rate?
  - This is largely a decision that each organization must make based on their own risk tolerance levels.
  - Government enforcement agencies and other sources vary widely in their assessment of a range of acceptable net reimbursement error rates that might warrant further review and possible extrapolation for refund.
  - Many industry standard NRER thresholds range from 5-20%. Sometimes exceptions can be made if a particular audit runs higher than the established threshold based on the topic, the nature of the audited attributes, the volume of the service, etc., but these would likely be *exceptions*.
  - It's a good idea to establish a policy that dictates your reimbursement error rate thresholds to maintain a consistent standard. Legal counsel can assist in making this determination and deciding on any ranges open for discussion.

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Executing the Audit

- Be aware of audit bias tendencies:
  - **Revenue integrity audits** tend to focus on ensuring full payment for a claim as opposed to looking for potential overpayments.
  - **Compliance audits** tend to focus on overpayments as opposed to looking for potential lost revenue opportunities.
  - A true and balanced audit should assess for both underpayments *and* overpayments equally (i.e., the **right** payment) based on appropriate coding, billing and documentation guidelines. This is how the government expects coding and billing auditing to be conducted.
  - Coding and billing audits should only be conducted by subject-matter experts who are trained in this area. If you are a compliance professional without appropriate coding certifications, consider enlisting the assistance of an independent, trained expert to conduct or assist with the audit.

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Reporting Audit Results

- Describes the results of the audit
- Contents of your report might include:
  - Review the original audit scope
  - Documents approach to the audit
  - List any observations/findings made in the audit
    - Observations can be balanced, meaning you can outline both areas being performed well and areas for improvement
  - Make recommendations for action to address opportunities for improvement identified in the audit
  - Consider risk ranking your findings to give context for severity of risk (e.g., numerical weighting, color-coding, categorical, etc.)
    - This is very helpful for those who may not be subject-matter experts to know which findings they should be focusing on.

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Reporting Audit Results

- The Exit/Closing Meeting
  - Bring all the appropriate stakeholders together to review audit findings
  - Be open to negotiation in case findings aren't accurate or if they aren't characterized correctly.
  - Consider marking the report "Draft" at this stage.

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Reporting Audit Results

- Request and obtain Management Action Plans (MAPs) from key "process owners"
  - Format and content of MAPs
    - Audit finding
    - Audit recommendation (made by the auditors)
    - Management's stated action plan
      - What to do if different than the auditors' recommendations?
    - Person responsible for completing the MAP
      - Be cautious of multiple owners for a single action or just a department name. Strive to assign only one responsible person who has authority and will be accountable
    - When the MAP will be completed
      - How long should it take to complete MAPs?
      - Due dates should be commensurate with the scope, complexity and risk of the audit observation. Most should be completed within 30-90 days.
      - Be cautious of extended completion dates.

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Reporting Audit Results

- Ongoing reporting to appropriate leaders/stakeholders
  - MAPs should be routinely reported in your key touch base meetings (Compliance Committee, Board Audit & Compliance Committee) until they are completed.
  - Management Action Plans will need to be tracked and followed-up on over time, so the MAP format provides a convenient tracking mechanism.
    - Consider having a MAP tracking tool that can be added to your standing agenda in these meetings for follow-up and to ensure corrective action was taken.
    - All completed audits can be used to track MAPs collectively.

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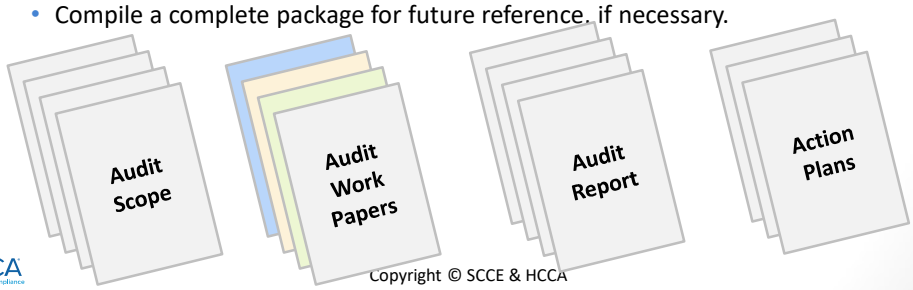
Documenting Audit Results

- Your final audit report package should include:
  - The original audit scope
  - The detailed audit work papers
    - Worksheets, checklists, surveys, interview notes, underlying polices, reference materials, etc.
  - The audit report
  - Results of management action plans, if any.
  - Compile a complete package for future reference, if necessary.



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Identified Compliance Concerns

- Addressing Identified Compliance Concerns
  - What do you do when compliance concerns arise in an audit?
    - Document in the audit report
    - Remember to consider ACP
    - Open a new investigative or resolution case in your compliance matters database
    - Report appropriately to management commensurate to the nature of the finding and risk imposed

> "Compliance reports created by…ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the [organization]'s senior management and the compliance committee." *Compliance Program Guidance, Vol. 63, No. 35, February 23, 1998.*

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Re-Auditing

- Should I re-audit past audited topics?
  - Yes, depending on the scope, nature and risk of the topic it can help to ensure that corrective action has taken hold effectively.
  - Remember, re-auditing takes resources and may divert resources away from new audits in other areas.
  - However, it may be advisable for certain high-risk matters.

> Organizational "management can take whatever steps are necessary to correct past problems and prevent them from reoccurring. In certain cases, subsequent reviews or studies would be advisable to ensure that the recommended corrective actions have been implemented successfully." " *Compliance Program Guidance, Vol. 63, No. 35, February 23, 1998.*

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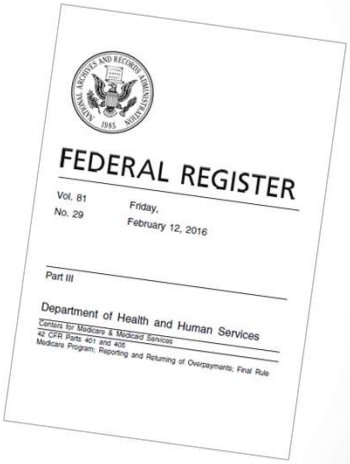
Identification of Overpayment

- What if you identify overpayments to the government in an audit?
  - Identified overpayments should be returned within 60 days from the date such overpayments were identified.
  - Don't wait for a more comprehensive audit to be completed before re-payments of individual audit findings are made.
  - See the CMS overpayment Final Rule Feb 2016 for more information.


FEDERAL REGISTER

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Friday,
February 12, 2016

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401 and 405

Medicare Program; Reporting and Returning of Overpayments; Final Rule

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Foundational Principles

POLLING QUESTION

How would you rate your compliance auditing process?

A. **Our compliance audits could be considered best practice.**
B. **We have a functioning compliance audit process that works well.**
C. **Our compliance audits could be more formalized.**
D. **Our compliance audits are not very robust or frequent.**
E. **We don't do compliance audits.**

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Conducting Monitoring Activities

- Monitoring is the use of a consistent tool to evaluate ongoing performance that can be tracked over time and measured for improvement, variance and trending.
  - Consistent measuring tool evaluates the same factors, metrics, attributes each time it is used
  - Routinely monitored over time generally using a consistent interval (e.g., weekly, monthly, quarterly). Intervals may also be event driven (e.g., each time an event occurs).
  - Allows for effective tracking and trending of performance to confirm ongoing compliance or flag variances that may indicate noncompliance, adverse outcomes or need for follow-up.
  - *Automate your monitoring activities where possible to save time and effort*.

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Ongoing Monitoring

- What should you monitor?
  - Key compliance risks that are reflected in an ongoing, systematic manner
  - Examples:
    - E&M coding
    - Certain high-risk medical billing codes
    - Procedures or practices such as
      - Privacy compliance walkthroughs
      - EMTALA compliance walkthroughs
      - Signage requirements
    - Appropriateness of access to patient information
    - Physician payments for Stark compliance

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Ongoing Monitoring

- How frequently should you monitor activities?
  - It depends on the nature of the activity being monitored
    - It could be annually, monthly, weekly, even daily depending on the risk and the tools with which you must monitor
    - Automation is preferred especially for monitoring activities that are evaluated frequently (especially daily, weekly)
    - Event-driven monitoring would occur as often as the event occurs.

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Ongoing Monitoring

- What tools might you use for monitoring compliance risk?
  - Control charts
    - Upper and lower control limits (UCL/LCL) to identify when you may be out of bounds on a certain activity
  - Volume charts
    - Something as simple as a volume chart can show if a certain metric is increasing or decreasing in an unusual or unexpected pattern that might allow you to further analyze
  - Non-existent/unlikely reporting
    - Automate reports that trigger when highly unlikely or unusual activity occurs

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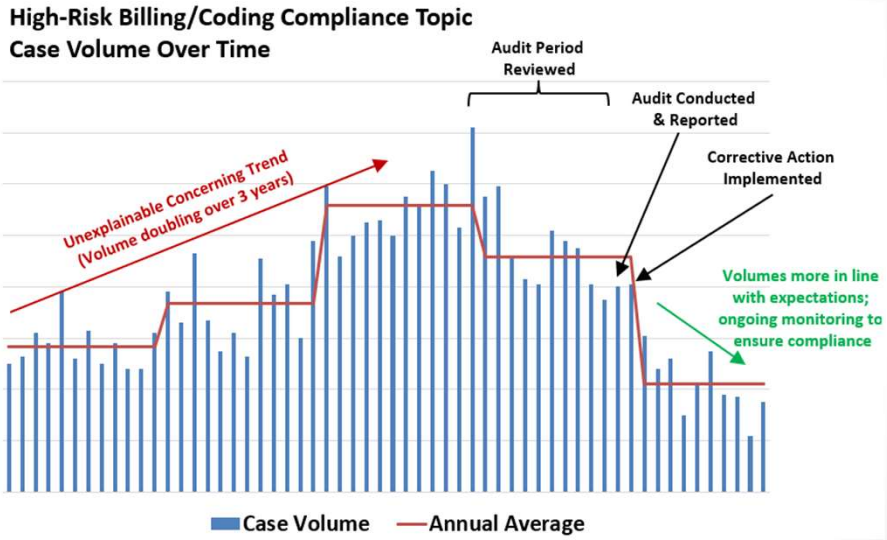
Ongoing Monitoring



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Ongoing Monitoring

- An example of a highly unlikely code
- Kwashiorkor is a high-risk coding topic for the OIG for numerous years.
  - Kwashiorkor is a severe form of malnutrition associated with a deficiency in dietary protein with fewer than 200k cases across the U.S. This condition is usually found in underdeveloped, sub-tropical countries where food scarcity is common. This condition is more commonly found in children in Africa.
- How many Medicare beneficiaries would fit this description?
- The OIG has found numerous situations where physicians have inappropriately diagnosed kwashiorkor for Medicare beneficiaries. *Kwashiorkor results in a much higher payment to providers than claims without this code*.
- Run a routine report identifying situations where this code was used and have them reviewed and refunded, as necessary.
- Coding systems may have controls that flag assignment of certain codes for review before they are billed. Consider implementing this function, but also continue running surveillance reports to confirm.

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Ongoing Monitoring

- What are some Compliance Program structural monitoring examples?
  - Consider the 7 elements of an effective compliance program.
  - Examples of monitoring your Compliance Program effectiveness
    - Completion of annual compliance training by staff (track against annual due date and % completion over time)
    - Aging reports on open compliance investigations (particularly compliance hotline cases)
    - Compliance matters statistics (i.e., increases or decreases in certain metrics)
    - Performance/outcome on monitoring programs (e.g., privacy walkthroughs, EMTALA walkthroughs, physician payment monitoring performance, coding/billing audit accuracy)
    - Attendance % at compliance committee meetings
  - These metrics could be put in a compliance dashboard to measure effectiveness of the program which could then be reported to appropriate compliance committees or Board committees.

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Using Compliance Reporting Systems

- How can you use your existing compliance matters reporting systems to track and trend performance in your organization?
- Consider various metrics that may be helpful in monitoring your program performance:
  - Number of reported compliance matters (direct vs. compliance hotline)
  - Compliance matters by type of concern (topical or by subject matter)
  - Compliance matters by location (e.g., department, division, location, region, operating unit, leader, etc.)
  - Reported matters by source
  - By risk ranking (e.g., high, moderate, low, numerical systems)
  - % anonymous compliance hotline reports
  - Productivity reports (e.g., open vs. closed, days to close, days over 60 days old, cases open at end of each time period)
  - Breakdown by actions taken to resolve matters
  - How reporters heard about the compliance hotline service
  - Number of privacy breaches reportable to the OCR
  - Reporting rates by location (compared against an industry benchmark)

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Using Compliance Reporting Systems

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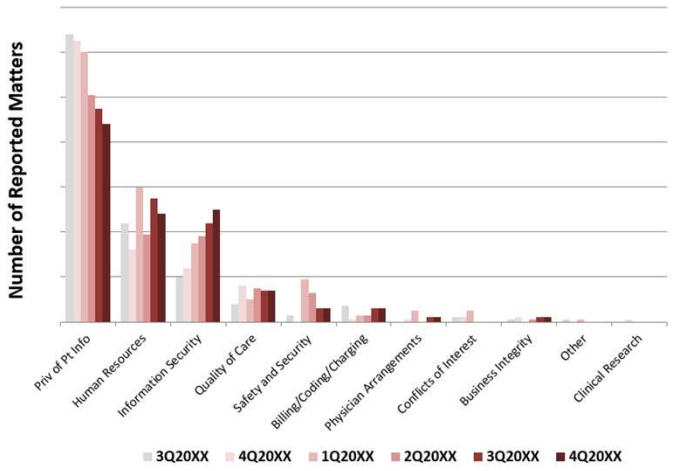
Using Compliance Reporting Systems

Investigated Compliance Matters by Type of Concern
Your Healthcare Organization



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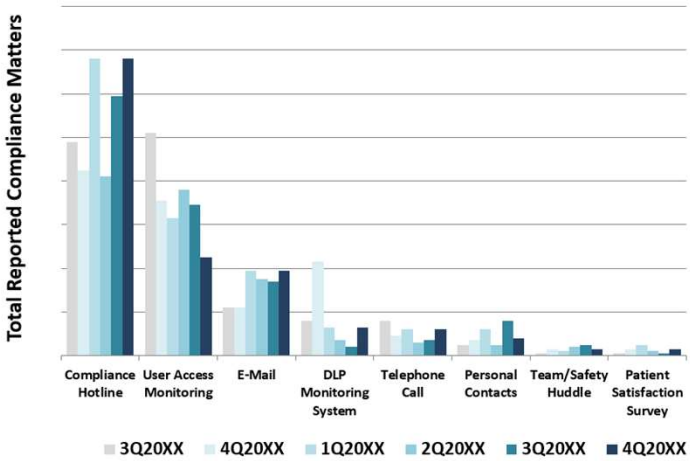
Using Compliance Reporting Systems

Reported Compliance Matters by Source
Your Healthcare System



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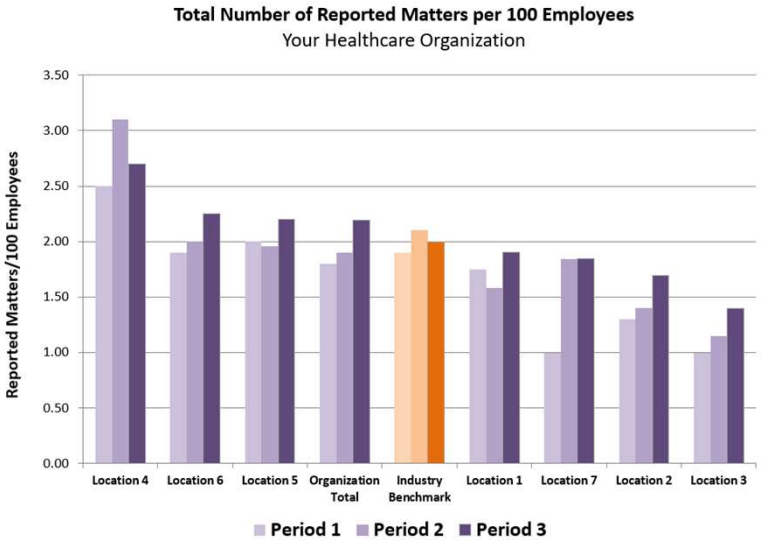

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Using Compliance Reporting Systems

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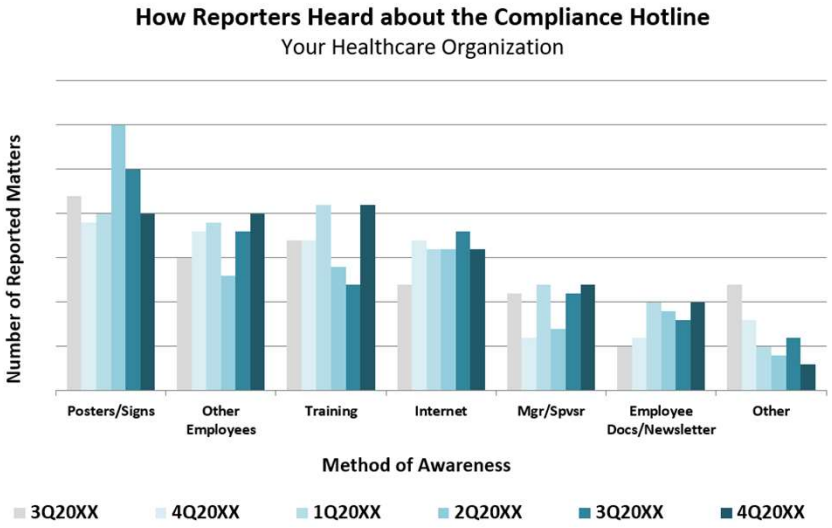

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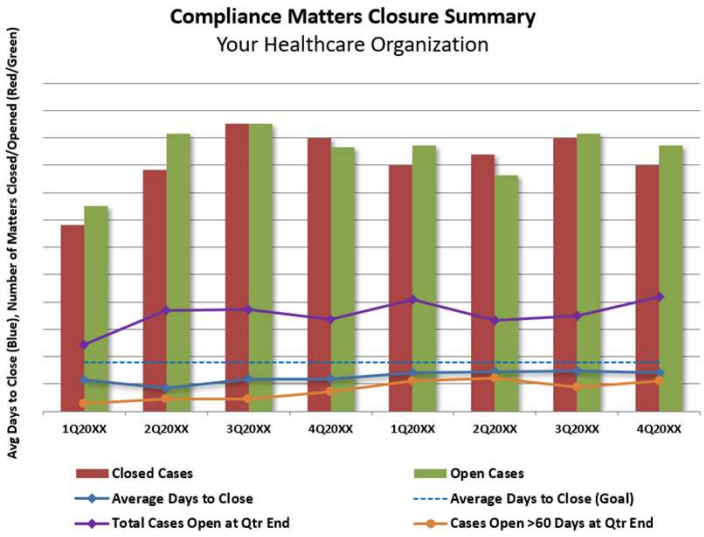
Using Compliance Reporting Systems



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Road Map for this Training

- Topics we discussed in this training:
  - Understanding the essential aspects of auditing and monitoring
  - Developing the compliance auditing and monitoring plan
  - Techniques and approaches to auditing and monitoring
    - Conducting audits
    - The audit scope
    - Executing the audit
    - Reporting audit results
    - Conducting monitoring activities
    - Using compliance reporting systems

59

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Foundational Principles

POLLING QUESTION

What area do you want to improve on *most* based on what was discussed in today's learning session?

A. Improving our compliance auditing and monitoring work plan.
B. Improving our compliance audit process.
C. Improving our compliance monitoring process.
D. Improve in all areas discussed!

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Questions and Comments

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Compliance Essentials Workshop

Compliance Investigations

Traci Rooks, JD CHC

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What is a compliance investigation?

- Compliance investigations are the main mechanism for safeguarding that your organization has completely and appropriately reviewed/investigated all allegations of non-compliant conduct.
  - To be successful and effective, it is essential that employees do not fear retaliation.
  - Can be used to identify the root causes of an issue, and to provide assurances that ongoing harm is halted promptly.
  - Can confirm that established guidelines are in place to enable individuals to conduct investigations and to properly document and maintain investigation findings

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Relevant compliance-related policies in your organization

- Code of Conduct
- Conflict of Interest
- Privacy
- Fraud, Waste, and Abuse
- Environment, Health, and Safety

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How investigations are initiated

- Complaints/Reports
  - Patients
  - Consumers
  - Employees
    - Current and former
  - Government agencies
- Methods
  - Reporting Hotline
  - Walk-ins
  - Email
  - Telephone

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Failure to properly investigate

- Would doing nothing create risk?
  - Potential harm to patients, employees, and organization.
  - Potential for financial penalties and sanctions.
  - Lost opportunity to learn.
- Organizations will be asked to account for their decisions, and should be able to do so with confidence that a fair and proper investigation had been conducted.
- Investigations can potentially lead to litigation.
  - Quality investigations can provide a successful defense and lower defense and settlement costs.
  - Even if no litigation, important from compliance perspective.

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Establishing Standards

- Prompt
- Objective and impartial
- Complete and well-documented
- Trained investigators
- Having an investigative plan
- Things to note:
  - Attorney/Client privilege
  - Confidentiality
  - Non-retaliation
  - Need to know basis

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Being an investigator

- Have the required and necessary training.
- Be an objective, independent fact-finder.
- Can conduct a full, fair and independent investigation.
- Can gather evidence and make determination whether relevant.
- Able to determine whether any policy or law was violated based upon the preponderance of the evidence.

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Unconscious Bias

- We all have unconscious biases.
- Also called “implicit” and “hidden” biases.
  - Hidden biases can take the form of assumptions we make about people, or actions we take without recognizing reasons behind them.
- How can this affect our investigations?

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Developing an Investigation Plan

- Why develop an investigation plan?
  - Allows you to define the scope of the investigation, ascertain what evidence is needed; identify the initial list of potential witnesses to assure that interviews are scheduled timely, and start leveraging the resources needed.
- Written Plan (Map it out)
  - List the specific allegations.
  - Identify all relevant policies, procedures, and regulations.
  - Prepare an evidence list (evidence to obtain).
  - Prepare an interview list and determine the order of interviews.
  - Develop of a timeline of the alleged events.
  - Formulate questions to ask witnesses, which may change depending on the type of witness.
  - Expected completion date.

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Conducting the investigation

- Gathering evidence
  - What kind of evidence can you get?
  - What kinds of evidence are best?
  - What do you do with a lack of evidence?
- Conducting interviews
  - Preparation and consistency
  - Credibility determinations
- Building rapport
  - Important during and after an investigation
- Identifying/monitoring trends and risks

10

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Standard of Reasonableness

- An investigation should be completed in a manner that a reasonable person would expect.
- Balance the potential benefits with the amount of resources and time available.
- The investigation should cover all the necessary bases.
  - Evidence, witnesses and documents must be included if they are important and relevant.
  - The severity of the offense, the range of potential remedies, the impact on the workplace, and confidentiality interests all affect how far the investigation should go.

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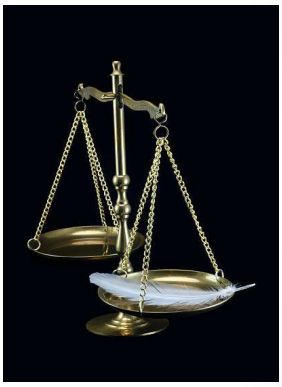
Standard of evidence

- Level of proof needed for an investigation to make a determination.
  - "Preponderance of the evidence"
    - "More likely than not" or more than 50.0%
    - Where does the feather drop on the scale?
  - What does this mean when an investigator conducts an investigation?
- NOT "clear and convincing evidence" standard
- NOT "beyond a reasonable doubt"
  - This is used in criminal matters



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Contacting a person for an interview

- Start with an email, and not a telephone call.
  - Begin email with general “good morning” or “good afternoon” if unsure how the person would want to be identified.
  - Be very general in the email, and do not provide the nature of the allegations.
- If person responds for more information before agreeing to an interview, state that all their questions will be answered at the interview and provide a general overview of process.
  - Why would you not provide them with this information?

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Conducting Interviews

- Before the interview starts
  - Build rapport
    - Why?
  - Explain role as investigator
    - Objective fact-finder
  - Explain nature of investigation
  - Not decision-maker
  - Discuss confidentiality
  - Discuss zero-tolerance for retaliation

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When conducting interviews

- Don't let the person you're interviewing set the tone of the interview.
  - Talking over you.
  - Trying to convince you of something.
- Keep the interview moving.
  - Don't let them say too much or go beyond the question being asked.
- Stay calm and assertive.
- Have evidence/facts at the ready.
  - Use them often.
- Ask them for evidence to support their statements.
  - Having the "receipts."

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Asking questions

- Questions could change based on the person being interviewed.
  - Reporter, subject, witness (character, informational, similarly-situated, subject matter expert).
- Go into the "who, what, when, where, why, and how."
  - Opened-ended
  - Develop a timeline
  - Ask for clarification
- Do not ask "accusatory" questions.
  - "When did you look at the patient's records" v. "Why did you look at the patient's records without authorization?"
- What not to do:
  - Do not say "I'm sorry this happened to you."
  - Do not share opinions, especially political opinions.
  - Do not agree.

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Good questions to ask during an interview

- Do you know why we are speaking today?
- Do you know why these allegations were made?
- What would the person say in response to your allegations?
- Is there anything else I should know?
- How would you like this matter resolved?

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Taking Notes

- There is no correct way to take notes as every investigation is different.
- If the investigator takes handwritten notes during the interview, the notes should be subsequently typed up.
- Highlight areas to come back to or follow back up on later.
  - Getting names or documents.
- Stay consistent in your methods.
- Do not tape record.

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Investigation Report

- Is an investigation report necessary?
- What should be included?
  - Executive Summary
  - Relevant policies
  - Witness list
  - Investigation findings
  - Analysis
  - Conclusion and Recommendations

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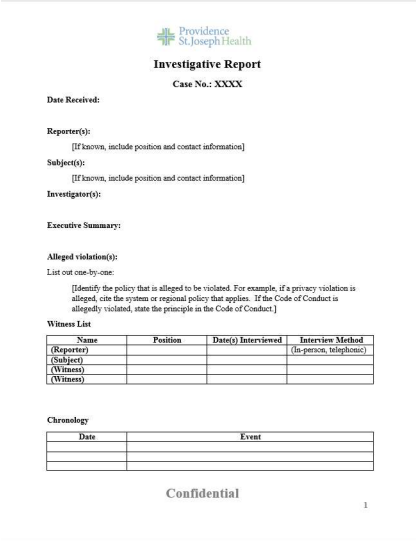
Sample Report Template



Providence St.Joseph Health

Investigative Report

Case No.: XXXX

Date Received:

Reporter(s):

[If known, include position and contact information]

Subject(s):

[If known, include position and contact information]

Investigator(s):

Executive Summary:

Alleged violation(s):

List out one-by-one:

[Identify the policy that is alleged to be violated. For example, if a privacy violation is alleged, cite the system or regional policy that applies. If the Code of Conduct is allegedly violated, state the principle in the Code of Conduct.]

Witness List

Name	Position	Date(s) Interviewed	Interview Method
(Reporter)			(In-person, telephonic)
(Subject)			
(Witness)			
(Witness)			

Chronology

Date	Event

Confidential

1

Providence St.Joseph Health

Investigation

Summary of statements [Attach complete statements separately]:

- Reporter's statements
- Subject's statements
- Witness statements

Evidence received:

[List out (i.e., emails, documents, other reports) and attach separately)]

Forms/Documents completed by investigator:

[List out and attach separately]

Analysis

Apply facts and summarize findings for each allegation using preponderance of the evidence standard:

First Allegation: Substantiated/Unsubstantiated

Second Allegation: Substantiated/Unsubstantiated

Describe any mitigating (i.e., self-reporting, cooperation with the investigation, etc.) and/or aggravating factors (i.e., pattern of misconduct, criminal behavior, concealment/destruction of evidence) affecting the level of a violation.

Conclusion:

Recommendations/Actions Taken:

Confidential

2

20

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Why are investigation reports needed?

- Can help you in preparing a response to wrongdoing.
- Used to identify risk and create action plans.
- Can help prepare a root cause analysis.
- Demonstrates commitment to taking allegations seriously.
- Demonstrates commitment to your polices and procedures.
- Helps leadership, management and human resources in making their decisions.
- Helps in potential future litigation against your organization.
- Can satisfy legal obligations.

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Final Thoughts

- There is no way to conduct the perfect investigation.
- The disclosure of all the relevant facts and findings in an investigation can be provided to leadership and allow them to make fully-informed decisions in reducing risk and minimizing potential harm to your organization.
- Having an effective investigations program will help enable you to remain a trusted and valued partner.
- The appropriate intake of reports helps to proactively spot significant issues of concern and potentially reduces any further risk to an organization.

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Questions?

Thank you!

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Compliance Essentials Workshop

Response to Wrongdoing

Traci Rooks, JD CHC

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Seven Elements of a Compliance Program Review

1. Standards and Procedures
2. Compliance Oversight
3. Due Care in Delegating Authority
4. Communication, Training and Awareness
5. Monitoring, Auditing, and Reporting
6. Enforcement, Incentives and Discipline
7. Response and prevention

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Four Parts in the Response to Wrongdoing

- **Part One:** After the investigation
- **Part Two:** Planning and developing the response
- **Part Three:** Facilitate/assist management in implementing the recommendations
- **Part Four:** Ongoing monitoring to ensure follow up

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Upon Completion of an Investigation

- Draft and prepare an investigation report.
  - Know your audience and the need to keep findings confidential.
  - Can be used as an important resource for carrying out a comprehensive examination of your organization's policies and processes.
  - Provides a framework for communicating with partners that may require actions/response for compliance matters.
  - Can easily be used as a handoff tool to partners and key stakeholders.

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Investigation Report

- What should be included in your investigation report:
  - Executive Summary
    - Most important section of the report
  - Relevant policies or lack/absence of polices
    - Make sure they are current
  - Witness list
  - Investigation findings
    - Witness statements
    - Evidence
  - Analysis
  - Conclusion and Recommendations

5

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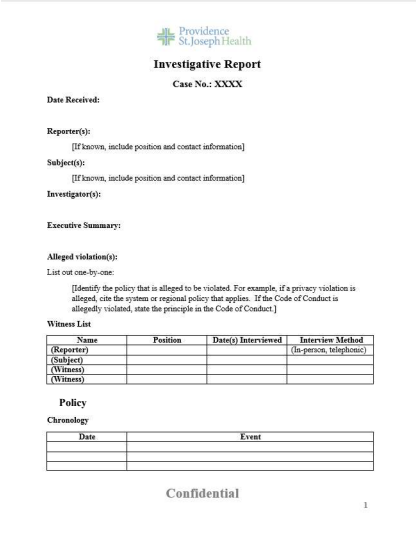
Sample Report Template



Providence St.Joseph Health

Investigative Report

Case No.: XXXX

Date Received:

Reporter(s):

[If known, include position and contact information]

Subject(s):

[If known, include position and contact information]

Investigator(s):

Executive Summary:

Alleged violation(s):

List out one-by-one:

[Identify the policy that is alleged to be violated. For example, if a privacy violation is alleged, cite the system or regional policy that applies. If the Code of Conduct is allegedly violated, state the principle in the Code of Conduct.]

Witness List

Name	Position	Date(s) Interviewed	Interview Method
(Reporter)			(In-person, telephonic)
(Subject)			
(Witness)			
(Witness)			

Policy

Chronology

Date	Event

Confidential

1

Providence St.Joseph Health

Investigation

Summary of statements [Attach complete statements separately]:

- Reporter's statements
- Subject's statements
- Witness statements

Evidence received:

[List out (i.e., emails, documents, other reports) and attach separately)]

Forms/Documents completed by investigator:

[List out and attach separately]

Analysis

Apply facts and summarize findings for each allegation using preponderance of the evidence standard:

First Allegation: Substantiated/Unsubstantiated

Second Allegation: Substantiated/Unsubstantiated

Describe any mitigating (i.e., self-reporting, cooperation with the investigation, etc.) and/or aggravating factors (i.e., pattern of misconduct, criminal behavior, concealment/destruction of evidence) affecting the level of a violation.

Conclusion:

Recommendations/Actions Taken:

Confidential

2

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Administrative Details

- Logo or letterhead
- Case Report Number
- Date Received
- Name of Reporter
- Name of Subject(s)
- Name of investigator
- Shows respect to entity
- Indexing system
- Vs. Date of allegation
- May be anonymous

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Executive Summary Template

On [date] a report was made to the compliance department that [subject] had violated the [policy]. The report was reviewed by management and subsequently assigned to [insert investigator name] on [date] for investigation.

On December 20, 2019, an anonymous report was made to the compliance department alleging that Dr. Smith had violated the Conflict-of-Interest Policy. The report was triaged by the Southern California regional compliance team and sent for review to the Director of Investigations. After review by the Director of Investigations, the case was subsequently assigned to Investigator Traci Rooks on January 15, 2020, for investigation.

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Executive Summary Template Contd.

Based on my investigation, which included [evidence descriptions] I find by a preponderance of the evidence that it was more likely than not that [subject] violated [policy] by failing to [insert policy language].

Based on my investigation, which included interviews, review of Command Council meeting materials and emails, I find by a preponderance of the evidence that it was more likely than not that Dr. Smith violated the Conflict-of-Interest policy by failing to disclose an actual, perceived or potential conflict of interest on his Conflict-of-Interest Disclosure Form as soon as reasonably possible. However, I also find that it was more likely than not that Dr. Smith did not use his position with the hospital to hire ABC Vendor inappropriately and in violation of the Conflict-of-Interest Policy.

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Allegations and Policy

- The Conflict-of-Interest Policy (COI Policy) states the following:
  - Required Disclosures: Affected and interested persons are required to disclose potential conflict of interest situations on their annual disclosure form and on a situational basis for any situation during the calendar year. The following items are a non-exhaustive list that must be reported:
    - Certain outside roles or commitments: A situation in which they serve in a professional activity capacity for any company seeks to do business with the hospital, competes or may compete with the hospital.
    - *Alleged violations:*
      1. *Dr. Smith failed to disclose an actual, perceived or potential conflict of interest to his COI Form as soon as reasonably possible in violation of the COI Policy.*
      2. *Dr. Smith used his position with hospital to promote the hiring of a vendor, ABC vendor, in violation of the COI Policy.*

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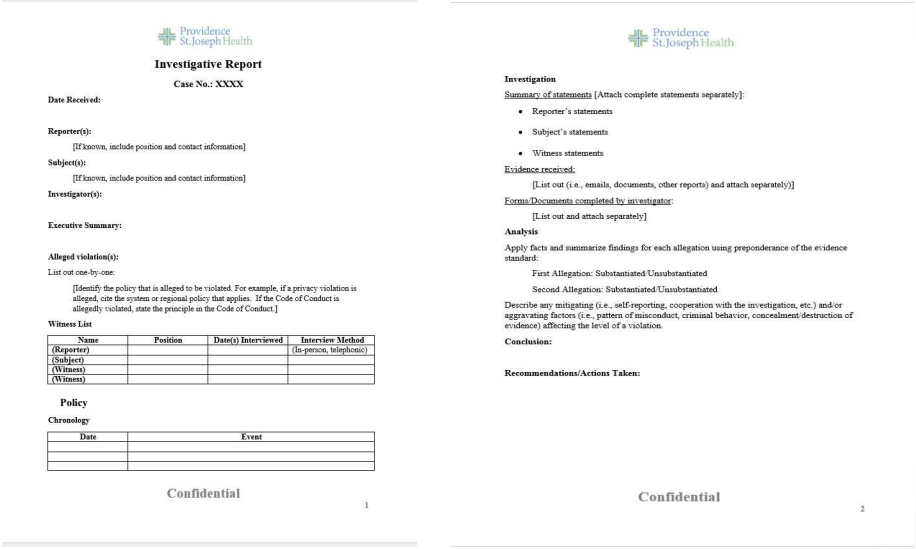
Sample Report Template



Providence St. Joseph Health

Investigative Report

Case No.: XXXX

Date Received:

Reporter(s):

[If known, include position and contact information]

Subject(s):

[If known, include position and contact information]

Investigator(s):

Executive Summary:

Alleged violation(s):

List out one-by-one:

[Identify the policy that is alleged to be violated. For example, if a privacy violation is alleged, cite the system or regional policy that applies. If the Code of Conduct is allegedly violated, state the principle in the Code of Conduct.]

Witness List

Name	Position	Date(s) Interviewed	Interview Method
(Reporter)			(in-person, telephonic)
(Subject)			
(Witness)			
(Witness)			

Policy

Chronology

Date	Event

Confidential

1

Providence St. Joseph Health

Investigation

Summary of statements [Attach complete statements separately]:

- Reporter's statements
- Subject's statements
- Witness statements

Evidence received:

[List out (i.e., emails, documents, other reports) and attach separately)]

Forms/Documents completed by investigator:

[List out and attach separately]

Analysis

Apply facts and summarize findings for each allegation using preponderance of the evidence standard:

First Allegation: Substantiated/Unsubstantiated

Second Allegation: Substantiated/Unsubstantiated

Describe any mitigating (i.e., self-reporting, cooperation with the investigation, etc.) and/or aggravating factors (i.e., pattern of misconduct, criminal behavior, concealment/destruction of evidence) affecting the level of a violation.

Conclusion:

Recommendations/Actions Taken:

Confidential

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Analysis

- Apply the facts you uncovered during your investigation to the allegation.
  - ***First Allegation***
  - *Dr. Smith failed to disclose an actual, perceived or potential conflict of interest to his COI Form as soon as reasonably possible in violation of the COI Policy. By Dr. Smith's title of physician, he qualified as an Affected Person under the COI Policy, and therefore I find that he was an Affected Person. As a consequence, I find that Dr. Smith was required to disclose his potential COI situation on his annual COI Form. Here, Dr. Smith acknowledged that he was paid for consulting services that he provided to ABC Vendor from 2013-2019. Per the COI Policy, a consultant was a certain outside role or commitment that was required to be disclosed on an annual basis on his COI Form. Further, Dr. Smith acknowledged that he did not disclose his consulting work he provided for ABC Vendor in 2014 and 2018.*
  - *In addition to the annual compliance education that instructed employees to disclose actual, perceived, or potential conflicts of interest (Attachment D). Therefore, I find that Dr. Smith was aware of his responsibility to disclose his relationship with ABC Vendor on his COI Form on an annual basis, yet it was not disclosed.*
  - ***Second Allegation***
  - *In this case, it was alleged that Dr. Smith used his position with hospital to promote the hiring of a vendor, ABC vendor, in violation of the COI Policy. According to Dr. Smith, he did not know the clientele of ABC Vendor and specifically did not know that the hospital was a client of ABC Vendor. Dr. Smith stated that the hiring of ABC Vendor had nothing to do with him, but that the arrangement was reviewed by outside counsel and signed off on by management. Witness A and Witness B confirmed Dr. Smith's statements. Review of Command Council meeting materials revealed that outside counsel did review the contract to hire ABC Vendor. Based on the above, I find by a preponderance of the evidence that Dr. Smith did not use his position with the hospital to have the hospital hire ABC Vendor inappropriately.*

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SBAR Template

SBAR: [Topic for investigation]	
Situation A statement that describes the problem or opportunity	
Background Additional information or references that help explain the context of the situation	
Assessment Analysis and considerations of options	
Recommendation Action requested	
Key Stakeholders *Leaders engaged in decision-making*	

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Part Two: Planning the Response

- Assist management in developing Draft recommendations, which can include:
  - Disciplinary action(s)
  - Changes to policy or processes
  - Further investigation into other matters learned during the investigation
  - Review, develop, and/or recommend education and trainings.
  - *May* be included in your investigation report
- Draft corrective action plan to address findings.
- Determine whether a root cause analysis or a compliance risk assessment should be conducted.

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Appropriate Disciplinary Mechanisms

- Employees must comply with law and policies.
- Compliance Department does not make the final decision or apply discipline.
- Should be well-documented and reflect the severity of non-compliance.
- Enforced consistently system-wide.

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Compliance-related Root Cause Analysis

- When would a compliance-related root cause analysis be needed?
  - Understand that a Root Cause Analysis is used in many disciplines.
- Conducting the root cause analysis.
  - Determine who will be conducting it.
  - May have to talk with people who are not part of the investigation.
  - Continually ask the "who, what, when, where, why" questions until you uncover the root problem(s).
    - Emphasis on the "why" questions.
- Common root problems:
  - Policies and procedures, human error, employee capabilities, documentation issues, technological issues, lack of accountability, fraud/waste/abuse.

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Compliance Risk Assessment

- What is a compliance risk assessment?
  - A proactive review to identify and prioritize existing or potential threats to your organization resulting in non-compliance with regulatory requirements.
- Why would a compliance risk assessment be needed?
  - Can help learn about work culture.
  - Can help with risk identification.
  - Can help risk ranking and risk prioritization.
  - Reduce non-compliance.
  - Decrease potential fines and penalties.
  - Help identify where resources are needed.
  - Help with strategic planning.

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Drafting a Corrective Action Plan

- Facilitate and assist management in identifying the following in developing their correction action plan:
  - The objective of the plan of action.
    - To address what issue(s) of non-compliance?
  - The tasks that are needed to complete the actions.
    - For example, to review relevant policies and current employee compliance trainings.
  - The parties/functions responsible to complete the tasks.
  - The resources needed to complete the tasks.
  - Expected completion dates.
    - Should include proposed quarterly/regular check-in dates.

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Communicating your Findings and Response

- Identify who needs to know and how your communication will be disseminated and its frequency.
  - Your relationships with these partners should already be established before your investigation.
    - Regularly scheduled check-ins.
  - Your compliance team
  - Human resources, legal, leadership, quality, risk management, physical safety, supply chain
- Having effective conversations to address the impact of the findings in your investigation will help instill trust and confidence in the investigation and response process.
  - Discuss how you drafted your recommendations to assist their plan of action

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Part Three:
Facilitate/assist management in implementing the recommendations

- Effective implementation of the recommendations is important to prevent further incidents and to mitigate future risk.
- Is there a formal process in place to implement recommendations?
  - Identify who has ownership to each recommendation.

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Part Four:

Ongoing monitoring to ensure follow up

- Need to make sure that management's action plan is monitored and tracked.
  - Management may choose to not follow our recommendations, but issue will still need to be corrected.
- Continued review on the plan of action.
  - Are expected completion dates being met?
- Regular post-investigation check-ins.
  - How often should you do this?

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Challenges in Implementing the Recommendations

- What challenges are to be expected with management implementing the recommendations and resolving issues?
  - Budget issues
  - Unexpected events
  - Technological issues
  - Workplace culture
- How can you overcome these challenges?

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When is Your Work Done?

- Compliance work is never done.
- Elements related to the response needs to be continuously evaluated and adaptable.
- Importance of having an effective investigations program.

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Questions?

Thank you!

Traci Rooks
Commercial Compliance Consultant
Providence Health Plan
Email: traci.rooks2@providence.org

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Topic

Date: 10/10/2023 Form completed by:

SBAR: [Restate Topic]	
Situation *a statement that describes the problem or opportunity*	
Background *additional information or references that help explain the context of the situation*	
Assessment *analysis and considerations of options*	
Recommendation *action requested*	
Key Stakeholders *leaders engaged in decision-making*	

Topic

Date: 10/10/2023 Form completed by:

Attendees

☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐

Meeting Minutes

Topic	Decision/Action Needed	Notes

Compliance Essentials Workshop

Enforcement and Incentives

Sarah Couture, RN, CHC, CHRC, CHPC

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What is it?
Enforcement and Incentives Overview

- The Department of Justice Evaluation of Corporate Compliance Programs (https://www.justice.gov/criminal-fraud/page/file/937501/download) :
  - A hallmark of an effective compliance program is the establishment of incentives for compliance and disincentives for non-compliance.
    - An opportunity to portray a clear message that misconduct is not tolerated.

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What is it?
Enforcement and Incentives Overview

- Similarly… the U.S. Federal Sentencing Guidelines (https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2018/GLMFull.pdf) :
  - (A) appropriate **incentives** to perform in accordance with the compliance and ethics program; and (B) appropriate **disciplinary measures** (enforcement) for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

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What is it?
Enforcement and Incentives Overview

- The development and maintenance of meaningful accountability is crucial.
- An organization creates a culture that promotes compliance through both:
  - The enforcement of disciplinary standards, and
  - The motivation for employees to adopt compliant business practices.
- Enforcement and discipline are not sufficient together to address compliance infractions.
  - Incentives are necessary to promote an effective compliance program.

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What is it?
Enforcement and Incentives Overview

- Compliance program effectiveness is directly linked to its ability to affect the conduct of individuals….one at a time.
- When compliance failures occur, there must be a process for enforcement and discipline to hold those that engage in unlawful/unethical actions accountable (*the stick*).
  - i.e. An organization must define their standards (and communicate their standards) in order to be able to enforce these standards (discipline).

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What is it?
Enforcement and Incentives Overview

- There must also be incentives to promote a culture of ethics and compliance…and not inadvertently encourage non-compliant behavior (*the carrot*).
  - Provides a consistent message of what is expected of individuals and what is rewarded.
  - "Catch those doing something right" rather than just "catch those doing something wrong."

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Enforcement and Incentives Session Outline

- Enforcement and Discipline:
  - What is it?
  - Why is it important?
  - Best practices
  - Challenges
- Incentives:
  - What is it?
  - Why is it important?
  - Best practices
  - Challenges

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ENFORCEMENT AND DISCIPLINE

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What It Is – Enforcement and Discipline

- An effective compliance program will utilize discipline AND enforcement.
- Enforcement should hold parties and individuals responsible for their actions by using disciplinary measures to guide organizational conduct.
- Enforcement and discipline should be used to ensure that employees take their compliance responsibilities seriously.

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Why it Matters: Enforcement and Discipline

- Adequate discipline for an offense is a necessary component of enforcement.
- Holding those accountable that violate the compliance program standards illustrates the organization's commitment to compliance.

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Why it Matters: Enforcement and Discipline

- DOJ's Evaluation of Corporate Compliance Programs looks to pervasiveness of wrong-doing, history of similar conduct, and remedial action:
  - Did management create a corporate culture in which criminal conduct is either discouraged or tacitly encouraged?
  - Did organization fail to heed to prior warnings of misconduct?
  - Have wrongdoers at all levels of organization been disciplined?
  - Is there an awareness among employees that criminal conduct (non-compliance) is not tolerated?

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Why it Matters: Enforcement and Discipline

- US Federal Sentencing Guidelines:
  - Organizational tolerance or involvement of improper behavior increases organizational punishment.
  - Failure to enforce the compliance program and failure to discipline may amount to tolerance of criminal activity.

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Best Practices: Enforcement and Discipline

Disciplinary Policy

- Must develop a Disciplinary Standards Policy:
  - Include guidance regarding disciplinary action for all stakeholders that have failed to comply with standards of conduct, Policies and Procedures, federal and state laws, or have otherwise engaged in conduct adversely affecting the organization.
  - Should include clear expectations, including discipline for failing to report or identify wrongdoing.

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Best Practices: Enforcement and Discipline

Enforcement Process Outlined in Policy

- A written compliance program policy documenting the process for enforcing compliance standards and discipline.
- Including recoupment of compensation gained from misconduct attributable directly or indirectly to an individual.

Degrees of Discipline

- A written policy, often an HR Policy, should outline the degrees of discipline to be imposed for varying degrees of violations.

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Best Practices: Enforcement and Discipline

Deferring, Reducing, or Recoupment of Compensation

- Compensation system should include mechanisms to tie compensation to the organization's values, ethics, and compliant conduct. Document in policy and procedure.
- Contracts with employees, executives, and independent contractors should include claw-back provisions for when non-compliance or wrongdoing is identified.
- Existence alone is not enough. Actual enforcement of these provisions when applicable shows the organization values compliance.

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Best Practices: Enforcement and Discipline

Discipline Considerations

- Disciplinary consequences should be based on severity of wrongdoing and be applied consistently. Discipline should contemplate:
  - Oral warnings
  - Suspension
  - Privilege revocation
  - Financial penalties
  - Termination

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Best Practices: Enforcement and Discipline

Duty to Report

- All stakeholders should be reminded they have a duty to report non-compliance or violations.
  - Discipline may be applicable for failure to detect or report violations.

Duty to Detect

- Managers should be held accountable for failing to detect foreseeable noncompliance.
  - Discipline may be appropriate when a failure to detect issues is due to negligence (or turning a blind eye).

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Best Practices: Enforcement and Discipline

Communication of Discipline Standards

- Disciplinary standards and policies should be publicized across the organization.
  - Within compliance education and training material.
    - Using redacted, specific examples of disciplinary actions.
  - Commitment that disciplinary standards are applied equally, regardless of position or status.

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Best Practices: Enforcement and Discipline

Make the Most of Compliance Violations

- Specific aspects from DOJ Evaluation of Corporate Compliance Programs:
  - Remedial actions are opportunities to turn compliance violations into learning and awareness.
  - They show that personnel, operational, and organizational changes have been made to establish an awareness that criminal conduct will not be tolerated.

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Best Practices: Enforcement and Discipline

Oversight Activities

- Oversight of discipline and enforcement must occur as well.
  - Document ALL disciplinary and enforcement actions.
    - An opportunity to demonstrate fair and consistent application of discipline.
  - An oversight committee should regularly review discipline to promote consistency and fairness.
    - Further demonstrates a commitment to compliance.

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Best Practices: Enforcement and Discipline

Ensuring Consistent Discipline Across the Organization

- Discipline should be case-specific but driven by common principles.
- All levels of employees, regardless of role, should be subject to the same discipline for commission of similar offenses.
- Corporate officers, managers, and employees ALL RECEIVE SIMILAR disciplinary action for similar offenses.
- Consistent application and enforcement to have the required deterrent effect.
- Oversight demonstrates that discipline is proportionate and administered appropriately.
- Compliance should consider auditing disciplinary actions.

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Best Practices: Enforcement and Discipline

Monitoring and Tracking

- Effectiveness and consistency of disciplinary measures.
- Monitor staff and organization-wide perception of discipline consistency using questions within an annual survey.
- Allows measurement and tracking of trends over time.
- Analyzing data across departments, locations, or compared to competitors is important.

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Best Practices: Enforcement and Discipline

Discipline and Human Resources

- Transparency also plays a key role.
  - If an executive is disciplined for a compliance violation, the actual reasons for discipline should be communicated, if possible.
  - Transparency aides with consistency and promotes compliance.
- This requires the compliance program to partner and work with HR.
- Inclusion of compliance objectives in job descriptions provides open, clear expectations.

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Best Practices: Enforcement and Discipline

Considerations for Vendors

- Keep vendors and other third-parties in mind as well.
- Create a proactive process for avoiding ones with poor track records.
  - Should include screening process for OIG exclusion and process/policy on how to handle positive hits.
- Ensure vendors and third-parties receive copies of all relevant policies, procedures, and code of conduct.
- Similar to staff discipline standards, discipline or enforcement standards must exist for vendors.

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Challenges – Enforcement and Discipline

- Any inconsistent policies or standards of discipline should be amended.
- Discipline standards applied inconsistently can be a major concern.
  - Highly productive physicians treated more favorably.
  - Lower-level hospital staff receiving harsher treatment.

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Challenges – Enforcement and Discipline

- Lack of awareness as to what offenses warrant specific levels of discipline.
- Poorly communicated or publicized guidelines and standards.
  - Requires a clear communication strategy.

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Challenges – Enforcement and Discipline

- Compliance program lacking adequate authority or resources.
  - The compliance program must have the appropriate authority and resources to ensure enforcement and discipline is carried out properly.
  - Additional time and resources are required to work with HR in particular discipline cases, as well as to provide monitoring of consistency and any oversight reporting.

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Challenges – Enforcement and Discipline

- Compliance officers not providing input and focus on discipline.
  - Discipline may be handled solely by HR, instead of in collaboration with compliance.
- Transparency and coordination with HR is required.
  - Includes follow-up on violations and discipline.

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Challenges – Enforcement and Discipline

- Consistency:
  - Especially difficult across large organizations and multi-facility systems.
  - Ensure policies and procedures are consistent across system.
  - Oversight from compliance program and committees will help.

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INCENTIVES

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What It is - Incentives

- Federal Sentencing Guidelines:
  - Promoting an organization's Compliance and Ethics Program through incentives drives individuals and the organization to perform and act in accordance with the Compliance and Ethics Program objectives.

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What It is - Incentives

- DOJ Evaluation of Corporate Compliance Programs:
  - Incentives, in addition to enforcement and discipline, are hallmarks of an effective compliance program.
  - Expectation that organizations use compliance as a means of career advancement and a significant metric for bonuses.
- OIG General Compliance Program Guidance (https://oig.hhs.gov/compliance/general-compliance-program-guidance/):
  - As a part of the OIG's minimum standards, it expects adherence to compliance programs to be an aspect when evaluating management and employees.

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What It is - Incentives

- The Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (https://www.ussc.gov/sites/default/files/pdf/training/organizational-guidelines/advgrprpt/AG_FINAL.pdf) emphasizes these concepts, stating:
  - "Culture of Compliance can be promoted where organizational actors are judged by, and rewarded for, their positive compliance performance."

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What It is - Incentives

- Promotions, rewards and bonuses based on participation in the compliance program and/or compliance performance (i.e., working on compliance program or initiatives, championing compliance, demonstrating ethical leadership) that promote a culture of compliance.
  - Complement disciplinary measures.
  - Demonstrate management's commitment to compliance.
  - Demonstrate organization's commitment to regulators AND employees.
  - Those who get promotions and salary increases/bonuses signal what management values most.
  - Reinforces value-based behaviors.

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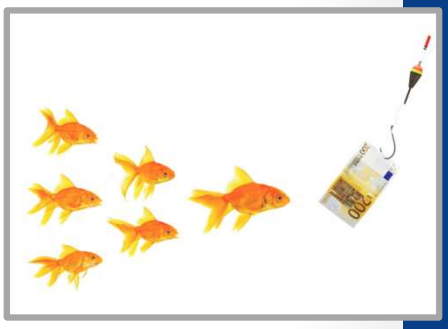
Why it Matters – Incentives

- Enforcement and Discipline assumes that employees will naturally do the right thing.
  - Implies discipline is sufficient to address all compliance infractions.
  - *Effectiveness* requires more than just discipline.
  - Compliance programs need to incentivize positive behavior.



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Why it Matters – Incentives

- Through the development of incentives, management and leadership can:
  - Demonstrate their commitment to compliance and ethics;
  - Fulfill their fiduciary obligation to ensure that the organization has an effective Compliance and Ethics Program; and
  - Reduce risk of illegal or unethical conduct.

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Why it Matters – Incentives

- An incentive system boosts an organization's culture of compliance in multiple ways:
  - Indicates to regulators the organization is serious about promoting compliance;
  - Creates a practical effect on individuals within the organization; and
  - Shows the message comes from the top down, that management values compliance and ethics.

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Best Practices – Incentives

<u>Compliance Opportunities – Engaging Operations</u>

- Employees or managers working on compliance a means of career advancement.
  - Meeting compliance related metrics or goals.
  - Activities that reduce compliance risk.
  - Mentoring others in compliant performance of job duties.
- Opportunities for serving as a 'compliance champion.'

<u>Policy and Procedure</u>

- Document the approach to compliance incentives in policy.
  - Compliance expectations.
  - Job descriptions and performance evaluations.
  - Bonuses and promotions.
  - Recoupment tied to non-compliance.

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Best Practices – Incentives

Performance Evaluations

- Organizations should require the promotion of and adherence to the compliance program as an element of all Performance Evaluations.
- How will be the rating or value be assigned, and how important is this element in the individual's overall evaluation?
  - Simple "Check the box" method?
  - Compliance/ethics rating – could be linked to bonus amount.

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Best Practices – Incentives

Performance Evaluations – General Staff and Employees

- Serves as another reminder to employees the significance of compliance & ethics and that it is everyone's responsibility.
- Measures and standards:
  - Adherence to the Code of Conduct.
  - General aspects of the compliance program.
  - Attends and completes training and evaluation.

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Best Practices – Incentives

Performance Evaluations – Managers and Supervisors

- Measures and Standards:
  - Ensures subordinates complete training.
  - Specific job-related duties and measurements tied to related risk areas.
  - General promotion of compliance and the compliance program.
  - Willingness to raise compliance matters and whether they encourage their employees to do so.
  - Whether they met specific annual compliance objectives.
  - Involvement in remediation and CAP completion.

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Best Practices – Incentives

Performance Evaluations – Senior Leadership

- Measures and Standards:
  - Active promotion of compliance programs with words and actions.
  - Rigorous example of compliance; helps set tone at the top.
  - Compliance integration into leadership style.
  - Compliance integration regarding business decisions.
  - Hold management and supervisors accountable for compliant operations.

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Best Practices – Incentives

Bonuses

- Compliance as significant metric for management bonuses.
- Highlight the importance of the compliance component.
- Can be contingent on a minimum threshold of compliance, based on performance evaluations.
- Hold back bonuses until compliance education, training, CAP completion, and/or attestations are complete.
- Establish compliance goals tied to bonus amounts.
- Reduction or claw-back of bonuses when non-compliant or unethical behavior is identified.

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Best Practices – Incentives

Promotions

- Individuals who are known to have engaged in misconduct or illegal activities should be excluded from promotions.
- Consider promotions contingent on minimum threshold compliance score on performance evaluations, such as:
  - Completion of training, reporting when appropriate, and no compliance infractions.
- Allow CCO input on promotions of key positions.

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Best Practices – Incentives

Other Rewards and Recognition

- Promote compliance through small rewards.
- Build praise for ethical behavior into day-to-day operations.
- Publicize recipients of rewards and recognition to harness power of peer pressure and competition.
- Consider incentivizing reporting of compliance issues.

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Best Practices – Incentives

Partner with Human Resources

- Incentives start with commitment from the top.
- Requires planning, communication, and multi-disciplinary involvement.
- Obvious need for collaboration since HR would be primarily responsible for administering performance reviews, promotions, and bonuses.
- Requires transparency with Compliance and HR.

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Challenges – Incentives

- It's common for developing compliance programs (and even established compliance programs) to lack well-developed incentive programs.
- Weak compliance incentives may signal a lack of commitment.
  - If compliance incentives are inferior compared to others (i.e., revenues or productivity), it may project that compliance is less valued.
- Lacking documentation – policy, procedure, tracking, implementation of incentive program.

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Challenges – Incentives

- Incentives may impact pay or advancement disproportionate to other factors.
- Employees may learn to "game" the system.
- Creating realistic goals and rewards may take time and effort, and they may need to be adjusted over time.
- Use periodic internal audits to ensure that incentives are appropriate and are incentivizing the right things.

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Challenges – Incentives

- Objections to Incentives:
  - Leaders often believe that employees will naturally do the right thing.
  - Not believing compliance is important or provides value to the organization – See March 2023 updates to DOJ Guidance.
  - People believe it to be impossible to evaluate an employee's ethics or virtues.
    - Incentives are meant to evaluate and recognize employee's actions on the job, not their internal ethics.
    - Not evaluating what employees believe, but rather how they promote the culture of compliance and encourage an ethical environment.

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CONCLUSION AND FINAL THOUGHTS

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Role of the Compliance Officer and Program

- Assists organization in development of standards for discipline and enforcement, and incentives.
- Develops and administers communication plan.
- Coordinates with functional areas of organization responsible for administering discipline and incentives.
- Maintains records of discipline for compliance and periodically audits for fair and consistent discipline.

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Role of Management

- Assists CCO in communicating standards for enforcement and discipline throughout organization.
- Ensures that Policies and Procedures and controlling documents include Compliance links and considerations so that organization will be permitted to take appropriate disciplinary action when necessary.
- Responsible for enforcement and discipline of employees in the manager's accountable areas.

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Role of the Board

- Provides oversight of compliance activities including fair and consistent discipline and meaningful incentives.
- Periodically reviews enforcement and discipline data to ensure that compliance standards are being followed.

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THANK YOU!

QUESTIONS?

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Compliance Essentials Workshop

HCCA Compliance Essentials: Program Improvement

Sarah Couture, RN, CHC, CHRC, CHPC

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WHAT IS COMPLIANCE PROGRAM IMPROVEMENT?

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3 Keys to Compliance Program Improvement

Impact of Effectiveness

Continuous Improvement

Program Assessment

3

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3 Keys to Compliance Program Improvement

Impact of Effectiveness

- More likely to prevent and detect fraud, waste, and abuse
- Better alignment of compliance program with the organization's risk profile

Continuous Improvement

Program Assessment

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3 Keys to Compliance Program Improvement

Impact of Effectiveness

Continuous Improvement

Program Assessment

- Be intentional along the way
- Incorporate lessons learned into the program
- Regulators expect programs to evolve over time

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3 Keys to Compliance Program Improvement

Impact of Effectiveness

Continuous Improvement

Program Assessment

- **Self-assessment**
  - Continuous review should be built into the program
  - Assessments should be regular and documented
- **Outside-assessment**
  - Avoid becoming culturally blind
  - Look to outside compliance experts

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WHY IS COMPLIANCE PROGRAM IMPROVEMENT IMPORTANT?

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Why is Compliance Program Improvement Important?

It just makes sense…

- Identify Existing Barriers
- Discover Improvement Opportunities
- Increase The Program's Overall Effectiveness

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Why is Compliance Program Improvement Important?

Encouraged by regulatory bodies…

- OIG GCPG: Should periodically assess the program's effectiveness
- FSG: Can decrease culpability score
- DOJ: Continuous improvement, periodic testing, and review

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Why is Compliance Program Improvement Important?

Financial benefits…

- Cost reduction through increased efficiency
- Decreased risk of penalties
- Protects reimbursement
- Can help avoid Corporate Integrity Agreements (CIAs)

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Why is Compliance Program Improvement Important?

Other organizational benefits…

- Promotes quality care
- Protects the organization's brand and reputation
- Increases staff awareness and understanding of compliance
- Keeps C-Suite and board engaged

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METHODS AND TOOLS FOR COMPLIANCE PROGRAM IMPROVEMENT

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Methods and Tools: *Guidance Documents*

- "Effective" – was the standard according to the Federal Sentencing Guidelines, but had not been defined
- OIG Measuring Compliance Program Effectiveness: A Resource Guide (https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf)
  - 2017
- DOJ Evaluation of Corporate Compliance Programs (https://www.justice.gov/criminal-fraud/page/file/937501/download)
- 2017, 2019, 2020, 2023
- OIG General Compliance Program Guidance (https://oig.hhs.gov/compliance/general-compliance-program-guidance/)
  - 2023

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Methods and Tools: *Benchmarks*

- Not as many public options as we'd like!
- HCCA for staffing, budget, and compensation
- AAMC for academic medical center compliance benchmarks
- Various vendors provide benchmarks: reporting/hotline, compliance culture and knowledge survey, and high-level compliance.
  - Some free; some with purchased services
- Consider developing your own benchmarks.

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Methods and Tools:
Benchmarks Example

HCCA - Healthcare Industry Compliance Staffing and Budget Benchmarking and Guidance Survey

BY REVENUE OF ORGANIZATION AS A WHOLE

	ANNUAL COMPLIANCE BUDGET				
	Less than $100,000	$100,000 to $249,999	$250,000 to $499,999	$500,000 to $999,999	$1 million or more
Less than $5 million	67%	13%	8%	2%	10%
$5 million to less than $15 million	63%	18%	10%	5%	4%
$15 million to less than $30 million	65%	18%	10%	4%	3%
$30 million to less than $50 million	51%	18%	15%	8%	8%
$50 million to less than $100 million	32%	33%	17%	8%	10%
$100 million to less than $500 million	29%	19%	21%	14%	17%
$500 million to less than $1 billion	17%	15%	14%	17%	37%
$1 billion to less than $3 billion	10%	1%	6%	10%	73%
$3 billion or more	12%	3%	5%	14%	67%

HCCA - Healthcare Industry Compliance Staffing and Budget Benchmarking and Guidance Survey: https://www.hcca-info.org/sites/hcca-info.org/files/2020-03/hcca-2020-benchmarking-guidance-survey.pdf

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Methods and Tools:
Dashboards

- Can help understand and tell the compliance story.
- Provide snapshots of relevant activity with supporting data.
- What compliance data will help tell the narrative?
- Dashboards should evolve as the program evolves.

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Methods and Tools:
Compliance Rounding

- Develop a plan for visiting as many operational areas as you can throughout the year.
- Introduce yourself and the compliance program; take candy or trinkets; build rapport.
- Pay attention to the environment and culture within departments.
- Consider a checklist/survey to help evaluate impact of compliance program, and benchmark and trend results (more on next slide).

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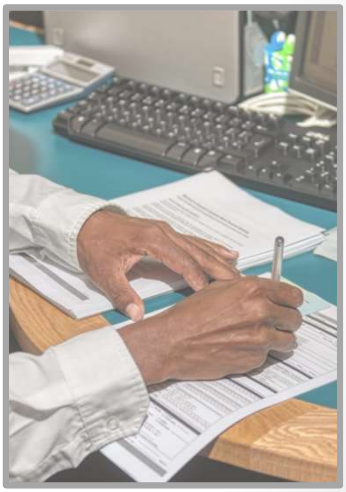
Methods and Tools:
Employee Surveys

Formal- Survey

- May be included in employee engagement survey
- Specific questions regarding compliance knowledge and culture

Informal- Rounding

- Accessibility and knowledge
- Perceptions
- Potential checklist/survey



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Methods and Tools:
Audits

- Audit topics
- Historical results of internal and external audits
- Audits to see if specific program elements are effective

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Methods and Tools:
Data Analysis

- Identify the right data and know how to analyze it.
- Leveraging data will let you do more work with fewer resources.
- Regulators utilize data!!!
- Identify personnel dedicated to data collection and analytics.

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CONCEPTS IN COMPLIANCE PROGRAM IMPROVEMENT

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Concepts in Compliance Program Improvement

Integrating Data

- Audits
- Trends
- Analytics
- Reporting

Integrating Compliance

- Executive commitment
- Management implementation
- Three lines

Resource Management

- Staffing
- Budgeting
- Compliance prioritization by board

Leveraging Partners

- Subject Matter Experts (SMEs)
- Risk Management
- Legal
- Internal Audit

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Concepts in Compliance Program Improvement

Element Maturity

- How mature is each of the 7 elements?
- Consider rating scale

Documentation

- Documented program and review
- If you didn't document it, you didn't do it

Fabric of Program

- Culture of continuous improvement
- In normal course of operations

Outside Expertise

- Outside consultant
- Fresh eyes

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Concepts in Compliance Program Improvement
Internal Audit

Distinctions: Compliance and Internal Audit

	COMPLIANCE		INTERNAL AUDIT
Type of Risk	Regulatory risk	Vs.	Other/all risk (IT, financial, operations, etc.)
Audit Purpose	Compliance with regulatory expectations	Vs.	Assessing internal controls and operations
General Audit Style	More informal	Vs.	More formal

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Concepts in Compliance Program Improvement
Internal Audit

Similarities Between Compliance and Internal Audit

- Independent of operations
- Objective viewpoints
- Assessment of risks and controls
- Independently report to CEO and board
- Full access to the organization's files and records
- Do not generate revenue
- Prioritization based on risk level

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Concepts in Compliance Program Improvement
Internal Audit

Collaborating with Internal Audit

- Coordinate using respective expertise
- Define areas of distinction and collaboration
- Risk assessment
- Ongoing communication
- Auditing collaboration
- Play to each other's strengths- produce a better output
- Perspectives on data

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Concepts in Compliance Program Improvement
Seven Elements

Evaluating Compliance Program Effectiveness: Element by Element

DOJ Evaluation of Corporate Compliance Programs

1. Implementing written policies and procedures
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized discipline and incentive guidelines
7. Responding promptly to detected problems and undertaking corrective action

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Concepts in Compliance Program Improvement
Is the Program Designed for Effectiveness?

Risk Assessment

- Well-designed, documented, and ongoing
- Compliance program tailored to your organization's risks
- Compliance activity prioritized by risk
- Evolving based on lessons learned

Policies and Code

- Accessibility and applicability
- Incorporated into operations
- Appropriate for known risks

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Concepts in Compliance Program Improvement
Is the Program Designed for Effectiveness?

Training & Communication

- Plan: Who, what, why, attestation
- Practical, applicable to significant risk areas, and to those in high-risk roles
- Inclusion of real scenarios in training
- Evaluation of training effectiveness

Reporting

- Well-publicized hotline
- Employee awareness of how to report and what to report
- Process for triaging reports
- Documented follow up/CAP
- Analyze trends in reports and investigations

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Concepts in Compliance Program Improvement
Is the Program Designed for Effectiveness?

Investigations

- Qualified personnel to conduct the investigation
- Focused investigative plan and scope
- Appropriate process and documentation

Third Parties

- Effective vendor management plan
- Compliance at the table
- New vendor review and due diligence
- Evaluation of business need
- Contract and compensation review
- Inclusion of third-party risk in compliance risk assessment

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Concepts in Compliance Program Improvement
Is the Program Designed for Effectiveness?

Mergers & Acquisitions

- Pre-M&A due diligence process
- Identify existing red flags, and follow up
- Compliance involvement in M&A and integration

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Concepts in Compliance Program Improvement
Is the Program Implemented and Empowered?

Program Autonomy

- Access and reporting to CEO and board
- Compliance seating and stature within the organization
- Compliance inclusion in key strategic and business decisions
- Organizational response to compliance concerns
- Sufficient access to data

Resources

- Sufficiency of resources to facilitate compliance efforts
- Qualifications and experience of the Compliance Team
- Obvious investment in compliance staff

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Concepts in Compliance Program Improvement
Is the Program Implemented and Empowered?

Incentives and Discipline

- Collaboration with HR regarding incentives and discipline
- Compensation structure tied to compliance in writing and in practice
- Clearly communicated compliance expectations
- Fair and consistent application of discipline
- Integrated compliance incentives
- Career advancement and bonuses tied to compliance metrics

Engagement

- Employees informed about compliance and convinced of organization's commitment to compliance
- "Tone at the top" and board engagement in compliance
- Senior and middle management actively committed to/involved in the compliance program

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Concepts in Compliance Program Improvement

Does the Compliance Program work?

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Concepts in Compliance Program Improvement
Does the Program Work?

Your Compliance Program should…

- Evolve over time
- Evaluate program effectiveness
- Use root cause analysis
- Ensure corrective action plan implementation
- Audit high risk areas and ensure problems are fixed
- Test and analyze controls
- Evaluate culture of compliance and staff perceptions
- Ensure leadership and employees held accountable with timely disciplinary response

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Key Takeaways

- **A Compliance Program can never rest**
  - Be proactive and intentional
  - Make self-assessments a priority
  - Open dialogue with leadership
- **Focus on not just effectiveness, but also efficiency**
  - Get comfortable working with limited resources
  - Find ways to do more with less
- **Make a plan for compliance program improvement**
  - Consider all available guidance, tools, and methods available
  - Collaborate with compliance staff, compliance committee/operations partners, and ensure board awareness
  - Develop SOPs, checklist, and rating plan

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Key Takeaways

- **Ongoing self-assessment**
  - Create a mindset of continuous improvement
  - Have well documented self-assessments at least annually
- **Intermittent use of outside experts**
  - Try to avoid becoming culturally blind
  - Get an outside perspective on your program every 2-3 years
- **Build continuous improvement into the fabric and culture of the compliance program**

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THANK YOU!
QUESTIONS?

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SCCE and HCCA Compliance & Essentials Workshop

What's Next for Me and My Program

Adam Turteltaub
Chief Engagement & Strategy Officer

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Key Topics for This Session

- Obstacles and keys to success for a compliance & ethics program
- The role of ethics in a compliance & ethics program
- Considerations in planning for a successful career in compliance & ethics

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Keys to Success for a Compliance & Ethics Program

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There are Many Benefits of Having an Effective C&E Program

- Compliance with laws and regulations, leading to avoidance of fines, penalties, and other ramifications of noncompliance
- Reduction in fines and penalties when instances of noncompliance occur, if the program demonstrates an intent and good faith effort to avoid violations
- Respect from the business community
  - Improved organizational reputation
- Promotes a positive and ethical workplace/culture for employees
- Meet expectations of other stakeholders
- Creates a proactive and risk-aware environment – avoid problems before they happen
- Gives management a new set of controls for the business

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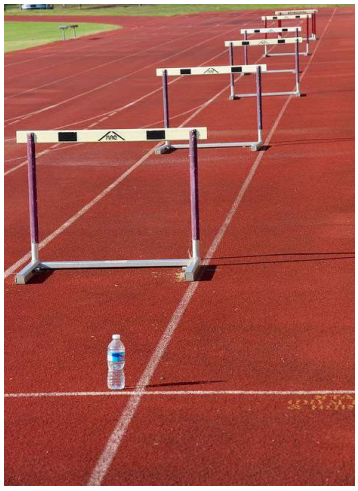
But, There are Ongoing Challenges

- Resistance by some
  - Management doesn't think it's necessary; Views it as a cost center
  - Employees think it's all words and no deeds
  - Belief that company and people are so good that nothing will happen
- People hesitant to come forward and report wrongdoing



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Ongoing Challenges

- Constantly changing laws and regulations
- Not about rules but about corporate culture
  - Also challenge of different cultures across a company, especially when multinational
- Lack of history of enforcement in many countries
- Turf battles
- Belief that all problems will stop, and, if they don't, compliance doesn't work
- Inconsistent enforcement can lead management to "take the chance" the organization will never be investigated

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Changing Scope of C&E Programs

- The history of C&E programs began with bribery and corruption
- Now, C&E programs may address:
  - Antitrust
  - Contracts and agreements
  - False Claims Act
  - Tax compliance
  - Employment laws
  - Environmental
  - Conflicts of interest
  - Product/patient/student safety
  - Privacy
  - Economic sanctions
  - Many other laws and regulations

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Keys to Success

- Securing buy in from the board and direct line to it
- Strong tone at the top
- Ensuring that tone cascades to the middle
- Open lines of communication and acting on it so employees see response
- Consistent discipline
- Willingness to own problems and not hide them

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Keys to Success

- Understanding how the business works and designing a program that is integrated in it and not bolted on
- Learning best practices and applying them
- Strong but independent relationship with other departments: legal, HR, risk
- Approaching compliance as a way to help the business not as a hindrance

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Keys to success

- Take a drip, drip, drip approach.
  - Can't just do once and move on.
  - Need to be communicating constantly: Job descriptions, training, email and other reminders, messages within leadership emails, and on and on

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Bottom Line

- Stronger internal controls
- Avoids cost and reputational harm from violations
- Helps make your business a part of global supply chains if you are a smaller company, and helps bigger companies ensure its suppliers can be trusted
  - Reducing risk to customers
  - Demonstrating commitment to proper behavior
  - Building an ecosystem of how to do business right

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The Role of Ethics

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U.S. Federal Sentencing Guidelines

To have an effective compliance and ethics program, an organization shall—

(1) exercise due diligence to prevent and detect criminal conduct; and

(2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

- Note: 2004 Amendments to the guidelines added the above consideration of ethics
- It's not a question of ethics or compliance. You need both.

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What is "Culture"?

- "the set of shared attitudes, values, goals, and practices that characterizes an institution or organization"
  - Source: Merriam-Webster
- Let's break this down:
  - Attitude – a mental position, feeling or emotion regarding a fact or state
  - Value – something (such as a principle or quality) intrinsically valuable or desirable
  - Goal – the end towards which effort is directed
  - Practice – the usual way of doing something

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Characteristics of Corporate Culture

- Culture is:
  - Shared
  - Pervasive
  - Enduring
  - Implicit
    - Source: The Leader's Guide to Corporate Culture, by Boris Groysberg, Jeremiah Lee, Jesse Price, and J. Yo-Jud Cheng, *Harvard Business Review*, January-February 2018

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Corporate Culture

- Six signs of a poor corporate culture:
  1. Inadequate investment in people
  2. Lack of accountability
  3. Lack of diversity, equity, and inclusion
  4. Poor behavior at the top
  5. High-pressure environments
  6. Unclear ethical standards
     - Source: 6 Signs Your Corporate Culture Is a Liability, by Sarah Clayton, *Harvard Business Review*, December 5, 2019
- Plus one more for compliance: Fear of being able to speak up

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Ethics

- Two relevant definitions from Merriam-Webster:
  - a set of moral principles : a theory or system of moral values
  - the principles of conduct governing an individual or a group
- Individual ethics is not the same as organizational ethics
- But the line can become blurred, esp:
  - Politics
  - Social causes
- Another concept to consider is “situation ethics”:
  - a system of ethics by which acts are judged within their contexts instead of by categorical principles

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Applications to C&E Programs

- Focus on attitudes relating to compliance with laws and regulations
- Important considerations
  - Strive for clarity in policies (Code of Conduct, etc)
  - Effective and ongoing training
  - Focus on communications and transparency
    - E.g. Results of investigations
  - Create an environment where people can feel safe and speaking up
  - Encourage management to value those with the courage to do so
    - Perhaps the most difficult part of all

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Building Your Career as a Compliance & Ethics Professional

- Certification
- Networking
- Additional or specialized training
- Developing a career plan

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Why Get Certified?

- Credibility
  - Peers in the profession
  - Co-workers
  - Supervisors and senior management
  - Regulators and enforcement officials
- Shows that you did more than sit through a class; Rather, that you have mastered a body of knowledge
- Salary surveys show that professionals with certification average higher compensation than those without
- Puts you on par with other professions: HR, fraud, internal audit

CHPC CERTIFIED IN HEALTHCARE PRIVACY COMPLIANCE

CCEP CERTIFIED COMPLIANCE & ETHICS PROFESSIONAL

CHC CERTIFIED IN HEALTHCARE COMPLIANCE

CCEP-I CERTIFIED COMPLIANCE & ETHICS PROFESSIONAL-INTERNATIONAL

CHRC CERTIFIED IN HEALTHCARE RESEARCH COMPLIANCE

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Qualifications and Steps for Taking an Exam

- At least one year in a full-time compliance position or 1,500 hours of direct compliance job duties earned in the two years preceding your application date
- Your job duties directly relate to the tasks reflected in the "Detailed Content Outline"
- Earn 20 CCB approved Continuing Education Units (CEUs) within the 12-month period preceding the date of the examination (at least 10 of the CEUs must be from live events, not recordings, on-demand, etc)
  - These do NOT need to be from SCCE or HCCA
- Complete and submit the application
- Schedule and take the examination
  - At a testing center or
  - Online (available beginning in February 2021)
- See the CCEP and all other handbooks at:
  - https://www.corporatecompliance.org/candidate-handbooks

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Where Next?

- By passing the exam and getting certified, you demonstrate a mastery of some of the most valuable concepts and their application to C&E programs
- But, does certification guarantee success?
  - Of course not
- Other keys to a successful career in compliance and ethics:
  - Communication
  - Relationship-building
  - Persuasion
  - Negotiation
  - Collaboration
  - Networking
  - Business skills
  - Commitment to continued learning

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Continuing Education

- Specific laws and regulations, for example
  - HIPAA, Stark, Anti-Kickback
  - FCPA, UK Bribery Act
- Deeper dives into specific elements of C&E programs, for example
  - Investigations
  - Risk assessments
- Complimentary skills, for example
  - Supervising and developing a staff
  - Budgeting, understanding financial reports
  - Negotiation
- Treat the need for 40 CEUs every two years to maintain certification not as a requirement but an opportunity to stay current or to grow and add new skills

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Connect Online

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25

Questions ?

adam.turteltaub@corporatecompliance.org

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26