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New to Healthcare Conference Compliance Roundtable

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Presenter Bios



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Dhara Satija is the Director of Healthcare Consulting in the Life Sciences Consulting Group of Paul Hastings. Dhara has nearly 15 years of consulting experience serving healthcare and life sciences clients across an array of issues, including projects ranging from strategy and operations to regulatory and corporate compliance, risk management, and investigation and litigation support. In particular, Dhara has led projects related to: development and implementation of compliance programs (i.e., written standards, training, and monitoring/auditing); design and delivery of internal compliance audits, investigations, and corrective action plans; support for provider self-disclosures/voluntary refunds; government-initiated audits; litigation support services; and Corporate Integrity Agreement (CIA) requirements.

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 **Boston Children's Hospital**
Until every child is well

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Tim Hogan is Senior Vice President and Chief Compliance Officer for Boston Children's Hospital. He has previously served in compliance leadership roles at Beth Israel Deaconess Medical Center, Elliot Health System, and Harvard Vanguard Medical Associates / Atrius Health.

Tim recently served as New England regional executive for the Healthcare Financial Management Association and is a past president of the Massachusetts/Rhode Island Chapter. He is also a former chair of the Chapter's Compliance Committee.



Today's Objectives:

During this presentation, we will cover:

1. Overview of Healthcare Compliance and Privacy and why it matters
2. Discuss hot topics / current risk trends in Healthcare Compliance and Privacy
3. Understand the role, responsibilities and benefits of an effective compliance and privacy program

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HIGH-LEVEL
OVERVIEW OF
COMPLIANCE



Polling Question #1

What is the most strictly regulated industry in the United States?

- A. Nuclear Energy
- B. Commercial Aviation
- C. Banking and Investment Firms
- D. Healthcare

Cost of Compliance Quick-Facts

Organizations that maintain a strong compliance program **save about 3 times** the cost administering their compliance program compared to organizations that do not maintain a strong culture of compliance.

- The average cost of **compliance** came in at **\$5.47 million**, while the average cost of **non-compliance** was **\$14.82 million**
- The average cost of **non-compliance** has risen more than **45%** in 10 years
- The cost of **regulatory risk** averages **\$10,000 per employee**
- Since 2008, compliance-related operating costs have **increased 60%**
- Global compliance costs increased \$33 billion from 2019 to 2020, totaling **\$213.9 billion last year**
- Organizations **lose an average of \$5.87 million** in revenue due to a **single** non-compliance event

Key Regulators



The Department of Justice
(DOJ)



Office of the Inspector General
(OIG) of Department of Health
and Human Services (HHS)

**To identify and eliminate fraud, waste and abuse and
to promote efficiency and economy in operations**

Responsible for conducting audits, evaluations, and both criminal and civil investigations for all HHS agencies, including...

- Centers for Medicare and Medicaid Services (CMS)
- Public Health Service Agencies
 - Agency for Healthcare Research and Quality (AHRQ)
 - Centers for Disease Control (CDC)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Services (IHS)
 - National Institutes of Health (NIH)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
- Human Services
 - Administrations for Children & Families, Aging, and Community Living
- Department of Health and Human Services Office for Civil Rights (OCR)

Key Healthcare Regulations

**Anti-Kickback Statute
(AKS)**

**False Claims Act
(FCA)**

Stark Law

**Health Insurance
Portability &
Accountability Act
(HIPAA)**

**Health Information
Technology for Economic
and Clinical Health
(HITECH)**

Medicare and Medicaid

**State and Local Laws
(e.g., false claims,
privacy)**

**Civil Monetary Penalties
Law**

**Exclusion
Provisions**

Regulators Expect Compliance + Closely Scrutinize the Healthcare Industry



>\$2.2B FCA Settlements & Judgments for FY 2022

\$1.9B of settlements involved a whistleblower

>\$1.7B of settlements involved the healthcare industry

351 Settlements & Judgments in FY 2022 (2nd highest ever)

948 FCA actions filed in FY 2022 (highest ever)

54% of recoveries were in non-intervened cases

Polling Question #2

When did many healthcare organizations begin to implement compliance programs?

- A. After Medicare was enacted in 1965
- B. After HHS-OIG was created in 1976
- C. After Health Insurance Accountability and Portability Act was passed in 1996
- D. After Enron accounting fraud occurred in 2001

Compliance = Doing the Right Thing



- Compliance with Laws and Regulations
Does it break the law?



- Compliance with Policies and Procedures
Does it violate an organizational standard?



- Compliance with Ethical Guidelines
Does it make you feel uneasy or nervous

What is a Compliance Program?

A Compliance Program is a **formalized effort to prevent, detect, and respond to business conduct that is inconsistent with federal laws, state laws, and/or an organization's values.**

Role of Compliance

- Provide guidance on the interplay between risk / standards and business strategy / need
- Provide input on business and company initiatives
- Provide information to Management and the Board to enable them to carry out their duties
- Conduct monitoring, auditing, investigations and risk assessments that could help identify areas for enhancements or efficiency



Everyone has an obligation to be aware of and abide by all policies, procedures that are relative to their respective job function.

Expectations for an Effective Compliance Program

The OIG and DOJ provide particular detail on their expectations – OIG’s “seven elements” and DOJ’s “Hallmarks” establish the program elements that must be tailored to a company’s risk profile to establish an effective compliance program

Three Fundamental Questions

1. **Design**
“Is the corporation’s compliance program well-designed?”
2. **Implementation**
“Is the program being applied earnestly and in good faith?”
3. **Practical Effectiveness**
“Does the corporation’s compliance program work in practice?”



OIG Compliance Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

Source: <https://oig.hhs.gov/compliance/compliance-guidance/>

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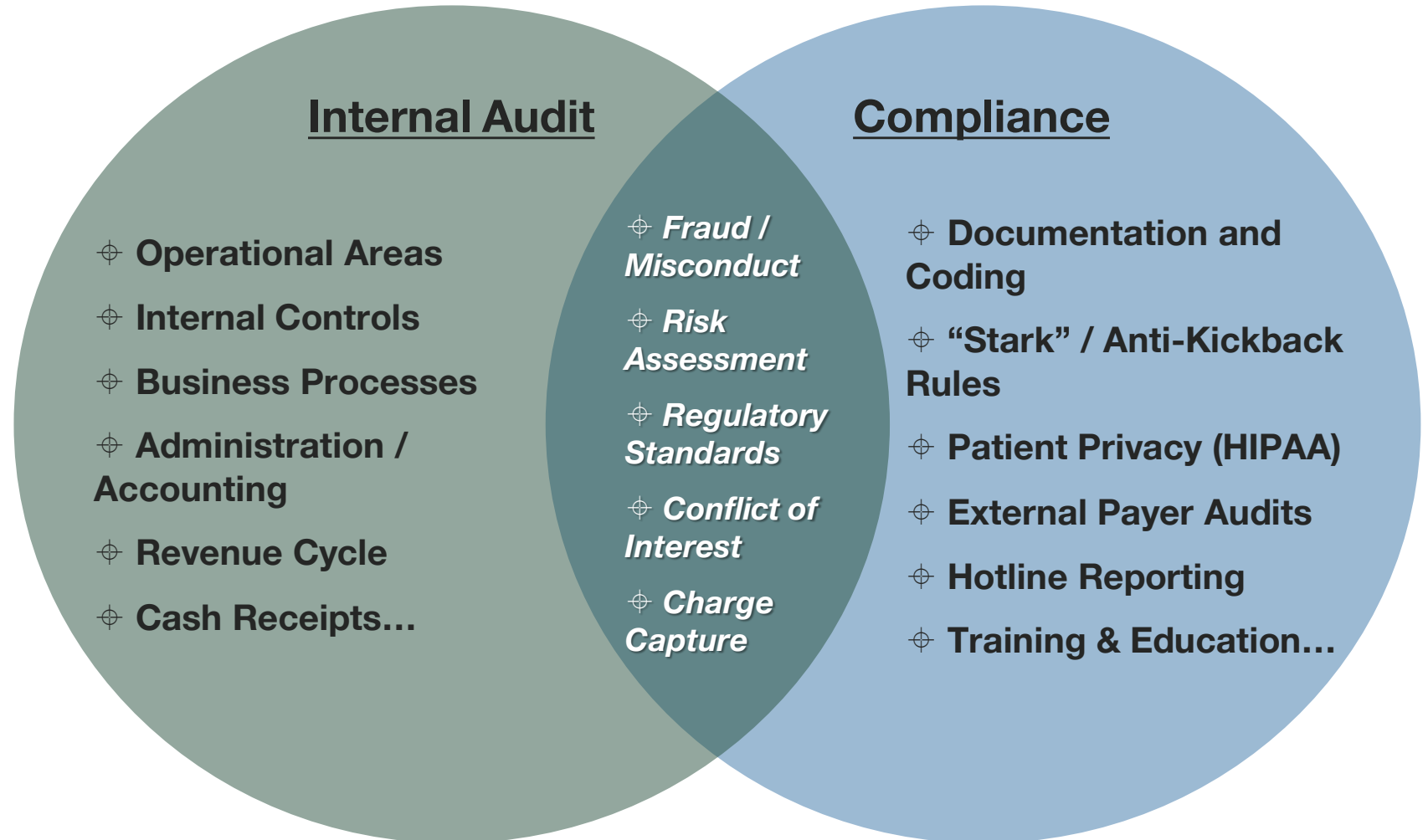
- [Hospitals](#)
 - [Supplemental Guidance](#)
- [Nursing Facilities](#)
 - [Supplemental Guidance](#)
- [Individual and Small Group Physician Practices](#)
- [Home Health Agencies](#)
- [Hospices](#)
- [Clinical Laboratories](#)
- [DME, Prosthetics, Orthotics, and Supplies](#)
- [Ambulance Providers](#)
- [Third-Party Medical Billing Agencies](#)
- [Pharmaceutical Manufacturers](#)
- [Medicare + Choice Organizations](#)
- [Recipients of PHS Research Awards](#)

Benefits of Compliance within an Organization

- ✓ Maintain brand **reputation**, build customer **trust** and increase shareholder **value**
- ✓ Save **time, money, and resources** related to fines, penalties, and settlement costs, in the event of a regulatory inquiry
- ✓ Preserve **business operations**, increase **revenue** and limit disruptions that may result in loss of productivity
- ✓ Raise awareness of actual and perceived compliance **risk areas** to the organization
- ✓ Gain **comfort in pursuing greater risk** in certain areas if adequate control environment is in place
- ✓ Outline **tailored mitigations** to control for known risk areas, providing greater protection against possible regulator inquiries that may disrupt business operations and lead to loss of productivity and revenue

Internal Audit and Compliance

Internal Audit and Compliance can often assist in increasing overall collaboration, efficiency and evolving the capabilities of both teams



Polling Question #3

Is Compliance everyone's responsibility?

- A. Yes
- B. No

Polling Question #4

To which senior leadership role does Compliance report in most healthcare organizations?

- A. Board of Directors
- B. Chief Executive Officer
- C. Chief Financial Officer
- D. Legal Counsel

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HIGH-LEVEL
OVERVIEW OF
PRIVACY



Polling Question #5

Which federal law safeguards your' protected health information?

- A. HIPA
- B. HIPAA
- C. HIPPA
- D. HIPPAA

**Privacy and
Electronic
Security
Health
Insurance
Portability
Accountability
Act of 1996**

Applies to **“Protected Health Information”**

- PHI includes any individually identifiable information relating to provision of health care (including solely demographic or financial information)

Following **breach of unsecured PHI**, notice to:

- U.S. Office for Civil Rights
- Each affected individual
- In addition, notice to prominent media outlet if more than 500 people affected

Notice required **“without unreasonable delay”**

- No later than 60 days of discovery



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COMPLIANCE AND
PRIVACY RISKS /
HOT TOPICS



Traditional and emerging healthcare risks

Coding and Billing Pharmacy **Cybersecurity**
Price Transparency Diversity, Equity and Inclusion
Patient Care and Safety Privacy & Security
False Claims Act Changing Regulatory Landscape **ESG**
Health Equity **Telehealth** **Revenue Cycle Operations**
Third-Party Management **Workplace Safety**
Reputation **Conflict of Interest** Stark Law
Talent Retention and Success Planning **340B**
Behavioral Health **Workforce Culture** **No Surprises Act (NSA)**
Anti-Kickback Statute Clinical Research & Trials
Artificial Intelligence Drug Diversion

Compliance Risk Assessment

The Office of Inspector General (“OIG”) and U.S. Department of Justice’s (“DOJ”) Evaluation of Corporate Compliance Programs (“ECCP”) guide us in assessing the design, implementation and effectiveness of the risk management program and its activities.

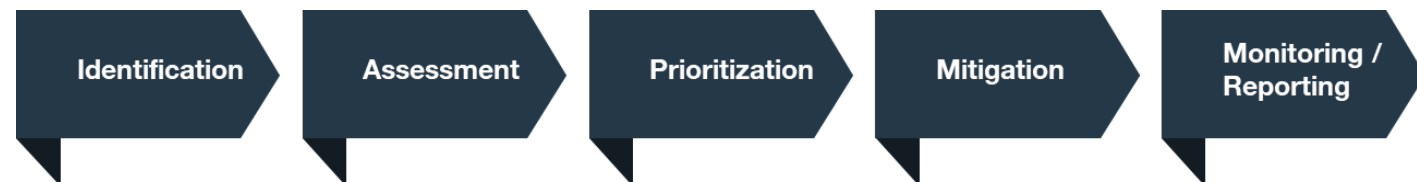
Per OIG Supplemental Compliance Program Guidance for Hospitals:

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? And 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?

Compliance Risk Assessment



Identify, prioritize, and assign accountability for managing existing or potential risks related to legal or policy non-compliance that could lead to fines or penalties, reputational damage, or the inability to operate in key markets



Effective risk assessment is the critical foundation for an effective compliance program tailored to the particular enterprise

Causes of Billing Errors



Rehab. Ass'n of Va., Inc. v. Koslowski, 42 F.3d 1444, 1450 (4th Circuit), cert. denied, 516 US 811, 116 S.Ct. 60, 133 L.Ed.2d 23 (1995) Cited in Briggs v. Comm., 429 Mass. 241, 707 N.E.2d 355 (1999).

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“[T]he statutes and provisions in question, involving the financing of Medicare and Medicaid, and among the most completely impenetrable texts within human experience. Indeed one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.”

Billing and “False Claims”:

- Federal and State law prohibits reimbursement for healthcare services that are not rendered appropriately or documented accurately
- Billing for an inappropriate or inaccurate level of service may be classified as **a false claim** *
- Violations can result in payment refunds, civil fines, imprisonment, and exclusion from government healthcare programs

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OPEN Q&A





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New England Healthcare Internal Auditors (NEHIA) and the Healthcare Financial Management Association (HFMA) MA-RI Chapter are excited to jointly present their annual, highly anticipated 3-day in-person educational conference. The conference attracts healthcare compliance, privacy, internal audit, and finance professionals from throughout the Northeast to learn from experts and peers in the industry. In addition to providing low cost, high quality educational sessions, NEHIA and HFMA MA-RI will connect conference members with each other to create a strong community of healthcare professionals in New England.

Polling Question #6

Are you planning to attend the HFMA-NEHIA November 29th – December 1st, 2023 Compliance & Internal Audit Conference?

- A. Yes, absolutely!
- B. No
- C. May be

Thank You!!!