



massachusetts-rhode island chapter

# ***New to Healthcare* Law, Compliance, and Regulations**

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# Compliance = Doing the Right Thing

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- 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?***

# Polling Question #1

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

- a) Nuclear Energy
- b) Commercial Aviation
- c) Banking and Investment Firms
- d) Healthcare

# “Compliance” Means...

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- Confidentiality (HIPAA)
- Payments, Discounts, Gifts
- Patient Referrals
- Regulatory Programs
- Federally Funded Programs
- Scientific Integrity
- Computer Use
- Anti-Discrimination
- Billing, Claims, and Medical Record Documentation
- Market Competition
- Purchasing
- Workplace Safety
- Waste Disposal
- Controlled Substances
- Political Contributions
- Fundraising

**...not an exhaustive list!**

# The Medicare Perspective

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“Physicians, medical equipment suppliers, clinical laboratories, beneficiaries, and other healthcare providers are all possible candidates for committing Medicare fraud and abuse.”



# What is the “OIG?”

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- Department of Health and Human Services Office of the Inspector General (HHS-OIG)
- Established by Congress in 1976
  - To identify and **eliminate fraud, waste and abuse**
  - 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

## **Polling Question #2**

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**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

# Eight

## ~~Seven~~ Essential Elements of Compliance

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1. Designation of Compliance Officer and Committee
  2. Code of Conduct and Written Policies and Procedures
  3. Conducting Effective Training and Education
  4. Auditing and Monitoring
  5. Developing Effective Lines of Communication
  6. Enforcing Standards Through Well-Publicized Disciplinary Guidelines
  7. Responding to Detected Offenses and Developing Corrective Action Initiatives
  8. Defining Roles and Responsibilities and Assigning Oversight Responsibility
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United States Sentencing Commission, Guidelines Manual, §8A1.2, comment n.3 (2004)



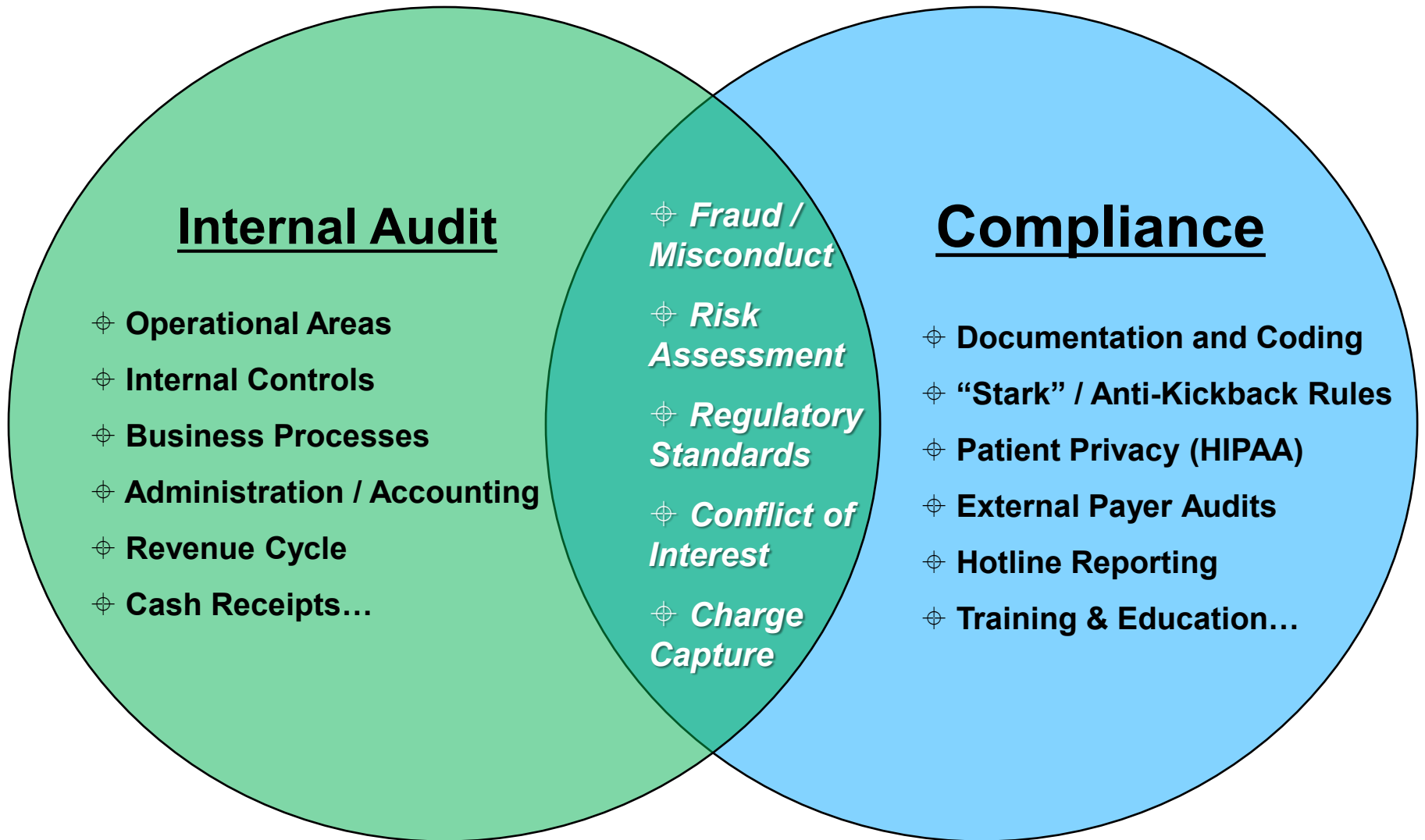
# OIG Compliance Guidance

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- Hospitals
- Nursing Facilities
- 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

# Internal Audit and Compliance

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## **Polling Question #3**

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**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

# Key Compliance Risk Areas

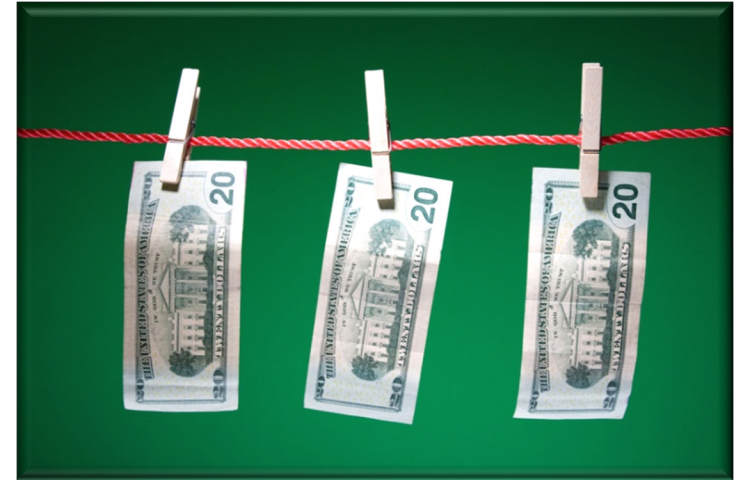
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- 1. False Claims**
- 2. Physician Self-Referral vs. Kickbacks**
- 3. Privacy / Electronic Security**

# Billing and “False Claims”

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- 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



# Polling Question #4

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**Which of the following is an example of a potential false claim?**

- a) Consistently billing for office visits at a high level of service
- b) Routinely copying-and-pasting notes from previous patient encounters
- c) Documenting inaccurate face-to-face time spent with a patient
- d) Ordering tests or procedures that are not medically necessary

# Causes of Billing Errors

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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.**”

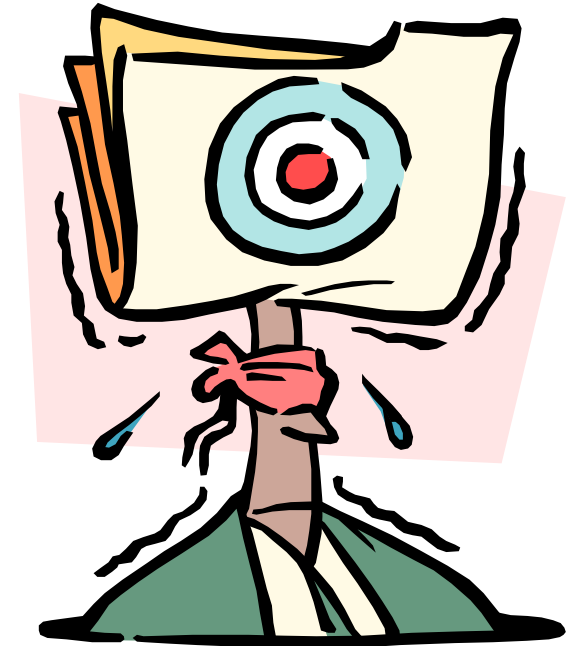


*Rehab. Ass'n of Va., Inc. v. Koslowski*, 42 F.3d 1444, 1450 (4th Circuit), cert. denied, 516 US 811, 116 S.Ct. 60, 133 L.Ed.2d 23 (1995) Cited in *Briggs v. Comm.*, 429 Mass. 241, 707 N.E.2d 355 (1999).

# Identifying Risk: External Data

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- OIG Work Plan
- Recovery Audit Contractors (RAC)  
“Issues Under Review”
- National Government Services (NGS)  
Prepayment Audits for Specific Services
- Centers for Medicare and Medicaid Services (CMS)  
Medicare Quarterly Provider Compliance Newsletter
- Publically Available Data (e.g., MEDPAR)
  - Comprehensive Error Rate Testing (CERT) Reports
  - Medicare Provider Utilization and Payment Data
  - Public Data on Industry-Physician Financial Relationships, i.e., “Open Payments Program” or “The Sunshine Act”
- Proprietary Data (e.g., MGMA, PEPPER)

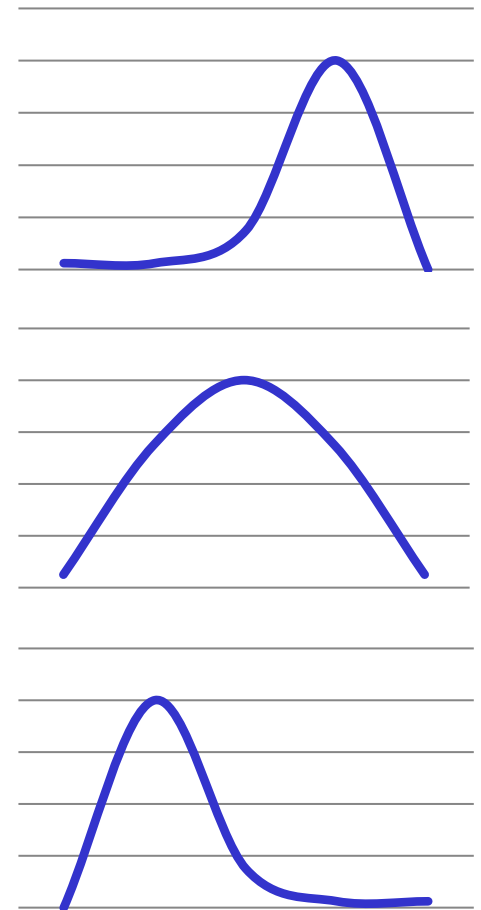




# Identifying Risk: Internal Data

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- Allegations, Complaints, and Questions
- Findings from Previous Audits
- Data Benchmarking
  - Provider by Provider
  - Specialty by Specialty
  - Year by Year



# Polling Question #5

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**The “Stark” prohibition against self-referrals is named after...**

- a) The stark -- i.e., severe -- consequences for any violation
- b) Fortney Stark, former surgeon and US senator
- c) Tony Stark, genius billionaire philanthropist

# Laws Governing Referrals

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## Stark Prohibition on Self-Referrals

- \* A Physician
- \* May Not Make Medicare Referrals
- \* For “Designated Health Services”
- \* If the Physician (or a family member) has a Financial Relationship with the Entity
  - Direct or Indirect
  - Compensation or Ownership

## Anti-Kickback Statute (AKS)

- \* Knowingly and Willfully
- \* Offer, Pay, Solicit, or Receive
- \* Remuneration (i.e., “anything of value”)
  - Directly or Indirectly
  - Overtly or Covertly
  - In-cash or In-kind
- \* To Induce or Reward the Referral of Items or Services Reimbursable by a Federal Health Care Program

# Laws Governing Referrals – Safe Harbors

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- Academic Medical Centers
- Ambulance Replenishing
- Ambulatory Surgery Centers
- Assistance to Compensate a Non-physician Practitioner
- Certain Arrangements With Hospitals
- Charitable Donations by a Physician
- Community-Wide Health Information Systems
- Cooperative Hospital Service Organizations
- Compliance Training
- Discounts
- Electronic Health Records Items and Services
- Electronic Prescribing Items and Services
- Employment Relationships
- EPO and Other Dialysis-Related Drugs
- Eyeglasses and Contact Lens Following Cataract Surgery
- Fair Market Value Compensation
- Federally Qualified Health Centers
- Group Practice Arrangements With a Hospital
- Group Purchasing Organizations
- Investment Interests
  - Publicly-Traded Securities/Large Investment Interest
  - Mutual Funds
  - Invest. Int. Held by Active or Passive Investors
  - Invest. Int. /Joint Ventures in Rural, Underserved Areas
  - Investments in Group Practices
  - Hospital Investment or Ownership
- Implants in an ASC
- Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
- Indirect Compensation Arrangements
- In-Office Ancillary Services
- Intra-Family Rural Referrals
- Isolated Transactions
- Medical Staff Incidental Benefits
- Non-Monetary Compensation
- Obstetrical Malpractice Insurance Subsidies
- Payments by a Physician
- Personal Service Arrangements
- Physician Services
- Physician/Practitioner Recruitment
- Preventive Screening Tests, Immunizations, and Vaccines
- Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered to Health Plans
- Professional Courtesy
- Referral Agreements for Specialty Services
- Referral Services
- Rental of Office Space and Equipment
- Retention Payments in Underserved Areas
- Risk Sharing Agreements
- Sale of Practice
- Services Furnished by an Organization to Enrollees
- Timeshare Arrangements
- Waiver of Coinsurance and Deductibles
- Warranties

# Enforcement Examples

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- A medical laser company agreed to pay **\$126K** to settle allegations of providing physicians an all-expense paid trip to the **Masters Golf Tournament**
- Recent Justice Department complaint alleging that drug company operated multi-million dollar “incentive programs” for doctors who steered patients toward its drugs
  - Payments to doctors for **purported speaker programs** that either did not occur at all or that had few or no attendees
  - Speaker programs held “in circumstances in which it would have been virtually impossible for any presentation to be made” such as **Hooters restaurants or fishing trips off the Florida coast**
- Blood lab bribed a doctor with tickets to see **Justin Bieber, Katy Perry, the Mets, the Knicks and Broadway shows** in exchange for referring his patients' samples to them
  - Physician took \$3,300 a month plus tickets and meals in bribes
  - In exchange, he referred his patients' blood samples to the blood lab
  - The deal generated \$900K in business for the New Jersey-based lab
  - The president of the lab was convicted of bribery and faces 21 years in jail
  - Prosecutors sought \$50M from the physician

# Polling Question #6

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**Which federal law safeguards your' protected health information?**

- a) HIPA
- b) HIPAA
- c) HIPPA
- d) HIPPAA

# Privacy and Electronic Security

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**H** Health  
**I** nsurance  
**P** ortability  
**A** ccountability  
**A** ct of 1996



# HIPAA Breach Notification Regulation

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- 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



# Massachusetts Data Breach Notification Statute

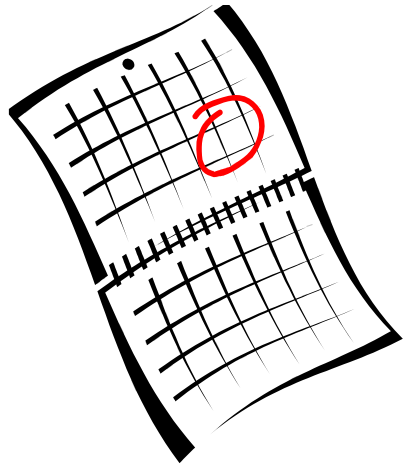
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- Applies to **“Personal Information”**
  - First and last name or first initial and last name in combination with 1 or more of the following:
    - Social Security Number;
    - Driver's License Number or State-Issued ID; or
    - Financial Account, Debit/Credit Card Number (*incl. certain insurance policy numbers*)
- Following **breach of security**, notice to:
  - Mass. Office of Attorney General
  - Mass. Office of Consumer Affairs & Business Regulation
  - Each affected resident of Massachusetts
- Notice required **“as soon as practicable and without unreasonable delay”**

**Save the Date!**

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# **HFMA MA-RI & NEHIA Joint Compliance Conference**



**December 1 - 3, 2021  
Mystic Marriott, Groton CT**

**Info available at:**

**<https://www.ma-ri-hfma.org/events/>**

# Questions?

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