

# Bartlett Regional Hospital

## Annual Board Compliance Training Agenda

Date: March 2, 2022 Time: 5:30 PM

Zoom Videoconference

Public, staff and Board members wishing to attend virtually may access the meeting via the following link

<https://bartletthospital.zoom.us/j/99557191489>

or call

1-877-853-5247 and enter webinar ID 995 5719 1489

**PUBLIC MEETING – NO PUBLIC COMMENT**

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### Mission Statement

**Bartlett Regional Hospital provides its community with quality, patient-centered care in a sustainable manner.**

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## Compliance Program Assessment Findings and Education

Prepared for Bartlett Regional Hospital

March 2, 2022

Presented by Shannon Sumner, CPA, CHC

Susan Thomas, CIA, CRMA, CHC, CPC

- Introductions and Project Team
- Compliance Program Guidance
- Overview of Fraud and Abuse Laws
- Compliance Program Fundamentals
- The Board's Responsibility for Compliance
- Compliance Program Assessment Executive Summary
- Compliance Risk Assessment Executive Summary
- Questions and Group Discussion
- Resources for the Board





## Executive Compliance Committee Compliance Program Assessment Findings and Education

Prepared for: **Bartlett Regional Hospital**  
March 2, 2022

Presented by:  
**Shannon Sumner, CPA, CHC**  
**Susan Thomas, CIA, CRMA, CHC, CPC**

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## Agenda

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- Introductions and Project Team
- Compliance Program Guidance
- Overview of Fraud and Abuse Laws
- Compliance Program Fundamentals
- The Board's Responsibility for Compliance
- Compliance Program Assessment Executive Summary
- Compliance Risk Assessment Executive Summary
- Questions and Group Discussion
- Resources for the Board

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## Introductions and Project Team



**Shannon Sumner**

(800) 270-9629  
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Shannon manages PYA's Compliance Advisory Services and serves as the Firm's Compliance Officer.

A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

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## Introductions and Project Team



**Susan Thomas**

(800) 270-9629  
stthomas@pyapc.com

Susan has spent nearly three decades working in a variety of managerial and clinical capacities including compliance management, clinical department leadership, provider practice administration, internal audit, quality outcomes, and healthcare advocacy.

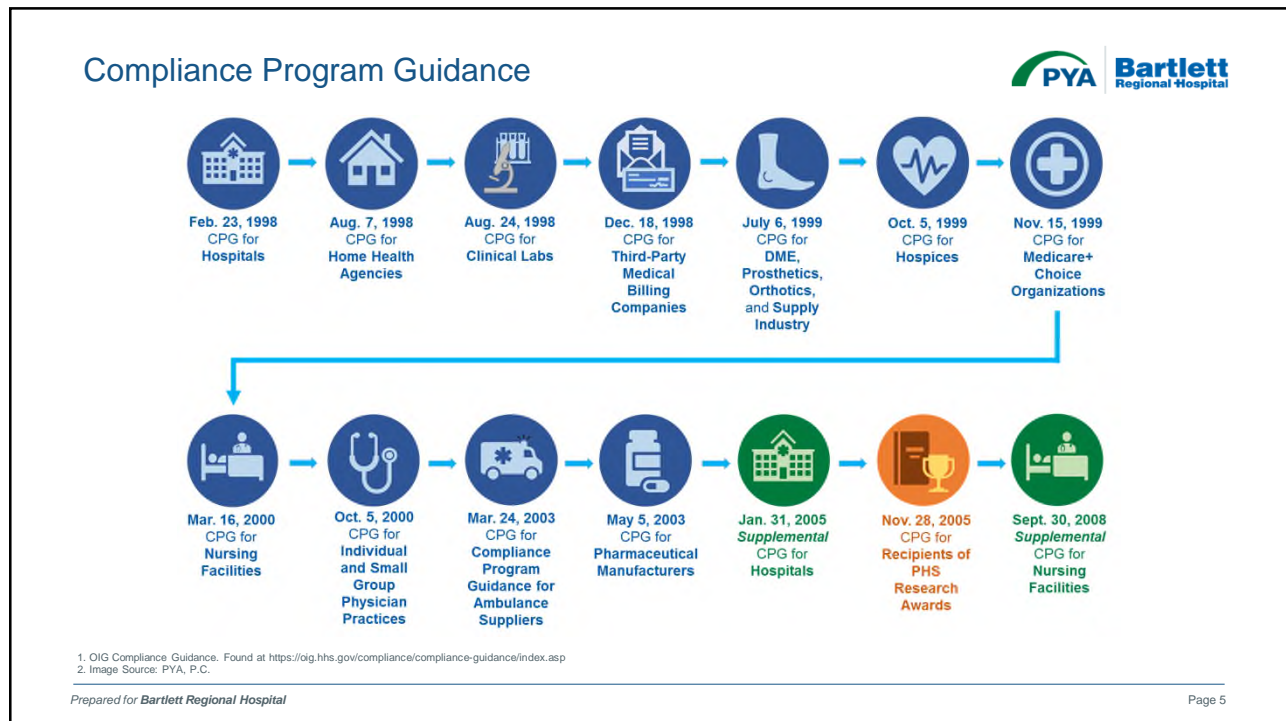
A former corporate compliance officer and clinical department director, she has a demonstrated record of success in program development and expansion as well as the ability to form mutually beneficial relationships.

Susan is a hands-on manager and decisive team leader with highly developed negotiation skills and experience cultivating strategic healthcare business partnerships, recruiting and directing teams, developing performance improvement measures, and creating effective training programs.

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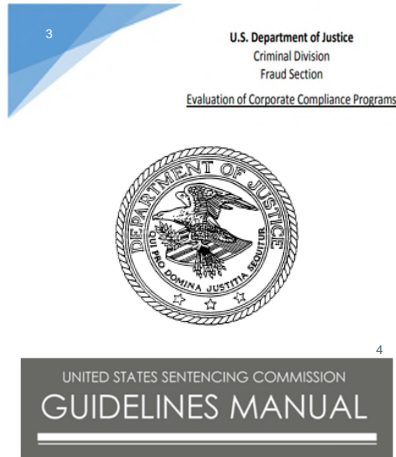
## Compliance Program Guidance

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## Expectations for Compliance Oversight



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



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

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## DOJ Criminal Division Evaluation of Corporate Compliance Programs

- The purpose...
  - "...is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate:
    - (1) form of any resolution or prosecution;
    - (2) monetary penalty, if any; and
    - (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations)."<sup>7</sup>
- Three fundamental questions that the DOJ prosecutors will ask:
  - Is the corporation's compliance program well-designed?
  - Is the corporation's compliance program adequately resourced and empowered to function effectively? (Revised in the 2020 guidance.)
  - Does the corporation's compliance program work in practice?

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

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## Health Care Fraud Is Big Business<sup>8</sup>



- Of the more than \$5.6 billion in settlements and judgments recovered by the DOJ this past fiscal year, \$5 billion relates to matters that involved the health care industry, including:
  - Opioid Abuse
  - Medicare Advantage
  - Unlawful Kickbacks
  - Unnecessary Medical Services
  - Procurement Fraud
  - COVID-19 Related Fraud
- Recoveries in Whistleblower Suits
  - Of the \$5.6 billion in settlements and judgments, over \$1.6 billion arose from lawsuits filed under the *qui tam* provisions of the False Claims Act.
  - During the same period, the government paid out \$237 million to the individuals who exposed fraud and false claims by filing these actions.
- The amounts included in the \$5 billion reflect only federal losses, but in many of these cases the department was instrumental in recovering additional millions of dollars for state Medicaid programs.

<sup>8</sup> <https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year>

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## What do these organizations have in common?



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## Settlements Due to Compliance Violations

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

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

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## Key Themes in Government Settlements<sup>9</sup>

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



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

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## Overview of Fraud and Abuse Laws

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### False Claims Act (FCA)

- What is the FCA?
  - A civil war era law to provide recourse for the sale of defective goods to the U.S.
  - Imposes liability on persons who “knowingly and willfully...make materially false, fictitious or fraudulent statements...in connection with the delivery or payment of health benefits....”<sup>10</sup>
    - Knowledge
      - Actual knowledge
      - Reckless disregard
      - Deliberate indifference
    - Criminal or civil penalties, up to five years imprisonment, and exclusion from participation in federal health care programs
    - **Civil penalties include up to \$23,607 per false claim and up to 3x the amount of damages**
    - Six-year statute of limitations

<sup>10</sup> <https://www.insidethefca.com/doj-releases-2021-fca-civil-monetary-penalties-inflation-adjustment/>

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## FCA

- 2009: Expanded FCA liability for knowingly retaining Medicare or Medicaid overpayments
- Affordable Care Act: 60-Day Repayment Rule:
  - Must report and refund overpayment within 60 days of "identification"
    - "Identification" = quantification
    - FCA definition of "knowledge"
    - Receipt of overpayment can be completely innocent
  - Six-month good faith investigation + 60 days
    - Longer for Stark Law and Anti-Kickback Statute (AKS) issues
  - Six-year look-back period
- Any overpayment retained beyond that point constitutes an "obligation" under the FCA as a reverse false claim.

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## Stark Law

- **In general:** If a physician has a "financial relationship" with a hospital, then that physician is prohibited from making Medicare referrals to the hospital and the hospital is prohibited from billing Medicare, unless an appropriate exception is met.
  - Prohibited Referrals: physician cannot refer
  - Prohibited Billing: hospital cannot bill Medicare, or anyone else
- **Six questions:**
  1. Is there a **Physician**?
  2. Is the Physician making a **Referral**?
  3. Is the Referral for **Designated Health Services (DHS)**?
  4. Are the DHS being furnished by an **Entity**?
  5. Does the Physician (or immediate family member) have a **Financial Relationship** with the Entity?
  6. Are the **DHS payable by Medicare**?
  - If yes to the above, then an exception **MUST** be met.

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## Stark Law Compensation Exceptions



- Rental of office space
- Rental of equipment
- Bona fide employment relationships
- Personal service arrangements
- Physician recruitment
- Assistance to compensate a non-physician practitioner
- Isolated transactions
- Certain arrangements with a hospital
- Group practice arrangements with a hospital
- Payments by a physician (for items and services)
- Charitable donations by a physician
- Non-monetary compensation
- Fair Market Value compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesies
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic prescribing items and services
- Electronic health records items and services
- Certain timeshare arrangements

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## Stark Law Penalties



- Sanctions:
  - Overpayment/refund obligation
  - False Claims Act liability
  - Civil monetary penalties and program exclusion for knowing violations
  - Potential \$15,000 CMP for each service
  - Civil assessment of up to three times the amount claimed
  - Risk of exclusion from Medicare and Medicaid
- **Hospital has burden of proof.**



11. <https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf>

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## Anti-Kickback Statute



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

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## AKS Safe Harbors



- Investment interests
- Space rental
- Equipment rental
- Personal services and management contracts
- Sale of practice
- Referral services
- Discounts
- Employees
- Group purchasing organizations
- Waiver of beneficiary coinsurance and deductible amounts
- Ambulance replenishing
- Federally qualified health centers
- Price reductions offered to health plans
- Practitioner recruitment
- Investments in group practices
- Ambulatory surgical centers
- Referral arrangements for specialty services
- Price reductions offered to eligible managed care organizations
- Price reductions offered by contractors with substantial financial risk to managed care organizations
- Electronic Health Record items and services
- Pharmacy cost-sharing waivers
- Public ambulance cost-sharing waivers
- Relationships between Medicare Advantage Organizations and FQHCs
- Medicare coverage gap discount programs
- Free or subsidized local transportation services

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## AKS Penalties

- Penalties for violation:
  - **Criminal:**
    - Fines up to **\$25,000 per violation**
    - Up to a **5-year prison term** per violation
  - **Civil/Administrative:**
    - False Claims Act liability
    - Civil monetary **penalties** and program **exclusion**
    - Potential **\$50,000 CMP per violation**
    - Civil assessment of **up to three times** amount of kickback



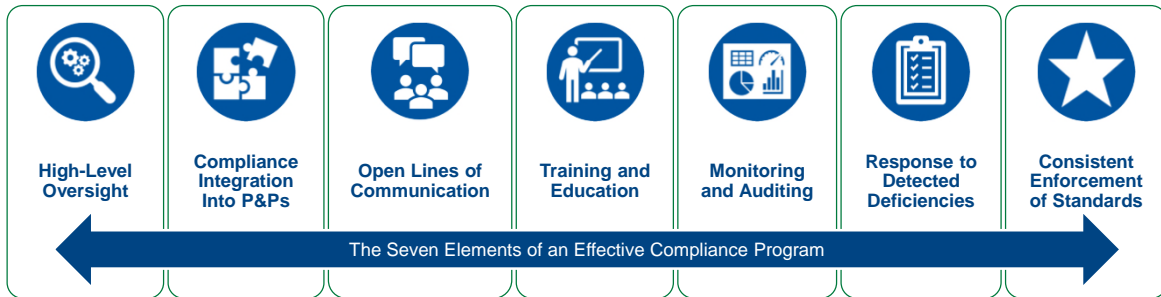
12: <https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSCharHHandou508.pdf>

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## Compliance Program Fundamentals

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## Federal Sentencing Guidelines 7 Elements



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## High-Level Oversight

- A number of significant legal and regulatory compliance failures have dramatically impacted the economic well-being of various healthcare organizations.
- A compliance plan is a formal statement of a healthcare organization's intention to conduct itself ethically with regard to business operations, government regulations, and patient services and care.
- The purpose of a formal compliance plan is twofold:
  - Provides a blueprint for the organization's compliance program and accomplishing the aforementioned goals
  - Encourages employees to report unethical conduct
- Board responsibility:
  - Helps set the scope of the compliance and ethics program
  - Approves key policies and procedures
  - Aligns incentives
  - Requires meaningful, substantive reporting on the organization's compliance and ethics activities

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## High-Level Oversight<sup>13</sup>



- Tone at the Top
  - Department of Justice (DOJ) Expectation:
  - DOJ prosecutors are instructed to evaluate whether “the Directors established an information and reporting system in the organization reasonably designed to provide management and directors with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law”
  - Section 9-28.800 of the U.S. Attorneys' Manual

13. (<https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations#9-28.800>)

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## High-Level Oversight



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

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## Policies and Procedures



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

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## Open Lines of Communication



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

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## Training and Education



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

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## Consistent Enforcement



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

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## Response to Detected Errors

- **Response and Investigations**

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

- **Corrective Action**

- When vulnerabilities or non-conformances are investigated, corrective action must be conducted in response to the potential violations.



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## Auditing and Monitoring

- A system for auditing and monitoring must be implemented to:
  - Measure the effectiveness of the compliance program
  - Ensure compliance with legal, regulatory, internal policy and contractual requirements
  - Identify compliance risks
- Difference between auditing and monitoring:
  - **Monitoring** is performing regular reviews as part of normal operations to confirm ongoing compliance.
  - **Auditing** is formal reviews of compliance with a particular set of standards as base measures.
- Includes periodic risk assessment and work plans to focus on auditing and monitoring activities
- Determines your organization's risks by completing a compliance risk assessment
- Prioritizes the risks to be evaluated and what resources are necessary for mitigation

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## The Board's Responsibility for Compliance

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### DOJ Criminal Division – Evaluation of Compliance Programs

#### 1. Is the corporation's compliance program well designed?

- A. Risk Assessment
- B. Policies and Procedures
- C. Training and Communication
- D. Confidential Reporting Structure and Investigation Process
- E. Third Party Management
- F. Mergers and Acquisitions

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

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2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
  - A. Commitment by senior and middle management
  - B. Autonomy and Resources
  - C. Incentives and Disciplinary Measures
3. Does the corporation's compliance program work in practice?
  - A. Continuous Improvement, Periodic Testing, and Review
  - B. Investigation of Misconduct
  - C. Analysis and Remediation of any Underlying Misconduct

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

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### Board Members Should be Asking...

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



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## The Board's Responsibilities



- Request an evaluation of the effectiveness of the organization's compliance program annually.
- Ensure funds budgeted for compliance program are sufficient and appropriate, considering the organization's high risks.
- Review and approve any modifications to the key policies and procedures that define the compliance program framework.
- Request regular reports from the Compliance Officer regarding compliance program activities.
- Evaluate the performance of the Compliance Officer.

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## The Governance Institute Board Compass Survey Responses



- Regulatory/Compliance Activities
  - Review executive compensation to ensure compliance with regulatory requirements
  - Enforce Conflict of Interest policy to meet IRS definition
  - Ensure the Compliance Plan is properly updated, implemented, and effective
  - Provide oversight of organizational compliance
  - Approve a whistleblower policy
  - Create a separate audit committee or audit and compliance committee

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## Reporting to the Board: Frequency

- **Optimal:** Quarterly
- **Minimum:** Annually



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## Reporting to the Board: Contents

- Board and management compliance and ethics committees
- Compliance program review
- Changes or amendments to written standards
- Standard of conduct certifications
- General and job specific training
- Reportable events and status
- Aggregate overpayments returned to federal programs
- Compliance issues log
- Excluded parties screening process
- Identified excluded parties
- Annual review of program charter
- Notable audit results



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## In Conclusion....

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

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

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

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## Compliance Program Assessment Executive Summary

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## Assessment Approach and Timeline



### Discovery Phase (January 2021)

- Kick-off meeting
- Document review



### Analysis Phase (March 2021)

- Preliminary information analysis
- Remote interviews
  - Over 16 interview sessions with over 30 key personnel



### Validation of Findings Phase (April – May 2021)

- Draft report development
- Client review and feedback



### Deliverables (June 2021)

- Final report submission

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## Compliance Program and Risk Assessment Scope

### • Compliance Program Assessment Scope

- Based upon the seven elements identified in the US Federal Sentencing Guidelines for Organizations and the HHS OIG Compliance Program Guidance
- Key areas of focus: overall compliance infrastructure, senior leadership/Board of Directors support and oversight, auditing and monitoring activities, comparison of program to industry benchmarks and compliance program leading practices

### • Compliance Risk Assessment Scope

- Comprehensive examination of regulatory risk to assist with continued identification and prioritization of risks
- Initial areas of focus: identification of compliance risk, evaluation of methodology for conducting compliance risk assessments, development of compliance work plan, evaluation and prioritization of risk categories, identification of high-risk areas that could potentially expose Bartlett to a significant level of threat or loss and development of correlated prioritized actions plans, assist with evaluation and prioritization of identified risks for inclusion in the compliance work plan

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## Program Assessment Priority Ranking Definitions



**HIGH PRIORITY:** Expected controls that present a *fundamental program priority* that should be evaluated by management as quickly as possible (within one to three months).

**MODERATE PRIORITY:** Presents a *significant program priority* that should be evaluated by management as a priority (within three to six months).

**LOW PRIORITY:** Expected controls where either no issue has been identified, or the issue noted presents a *standard program priority* that should be evaluated by management in the normal course of business (within one year).

- Bartlett's summary priority ranking for each of the Guidance's seven elements, as well as strengths and opportunities for each element:

Compliance Plan Elements	Priority Ranking
1. High-Level Oversight	HIGH
2. Integration of Compliance into Policies and Procedures	LOW
3. Consistent Enforcement of Standards	HIGH
4. Training and Education	MODERATE
5. Open Lines of Communication	MODERATE
6. Response to Detected Deficiencies	LOW
7. Monitoring and Auditing	HIGH

## Compliance Program Strengths



- High-level Oversight and Tone at the Top**
  - Senior leadership support
  - Sense of accountability for compliance among staff
  - Compliance Risk Management Director's (CRMD) experience, leadership skills, credibility, and respect within the organization
  - Engagement of independent assessment of the program and key risks
- Policies and Procedures**
  - Utilization of PolicyTech
  - Actively engaged Policy Review Committee
  - Employees receive the Code of Conduct at hire and can access at any time within PolicyTech
- Open Lines of Communication**
  - Employees feel comfortable reporting concerns to their direct supervisor or to the CRMD
- Auditing and Monitoring**
  - The Revenue Cycle Committee (RCC) and oversight of associated revenue cycle processes and procedures



## Tone at the Top



The success of an effective compliance program is highly dependent upon the support provided by the organization's governance and management (the Tone at the Top). The Tone at the Top is the foundation and begins with the Board's oversight responsibility, followed by the CEO's commendation of the program, support by a senior leadership team, and a CCO that facilitates organization-wide accountability for compliance issues.

- **Observations**

- Executive leadership team and the Board has verbalized their commitment to, and support of, the compliance function.
- Bartlett has experienced significant leadership changes.
- The Bartlett Compliance Director also has responsibilities for risk management.
- The Bartlett Compliance Director is sought after for advice and consultation across the organization.

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## Compliance Program Opportunities



- **High-Level Oversight**

- An internal compliance risk assessment is performed annually.
- The Compliance Department is adequately and appropriately staffed.
- The CCO is a key stakeholder in the strategic initiatives of the organization, including strategic planning and due diligence processes.
- Formalize the use of compliance program benchmarks and measurable goals.

- **Training**

- All employees, vendors, and physicians receive annual compliance training and training completion is tracked.
- Promotion of compliance through activities such as Compliance Awareness Week, compliance fairs/other employee involvement activities occurs.

- **Open Lines of Communication**

- Existence of a hotline which allows for the workforce, patients, and vendors to report concerns and remain anonymous

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## Compliance Program Opportunities



- **Consistent Enforcement**

- Conflict of Interest (COI) auditing and evaluation of Open Payments Database
- In-person exit interviews for all senior leadership and high-risk positions

- **Monitoring and Auditing**

- Compliance work plan reflects the most significant compliance risks identified through an annual risk assessment
- Enhance the compliance function throughout the organization with implementation of departmental compliance work plans

- **Vendor Management**

- Vendor management process inclusive of requirements for vendor training, expectations for compliance, and exclusion screening

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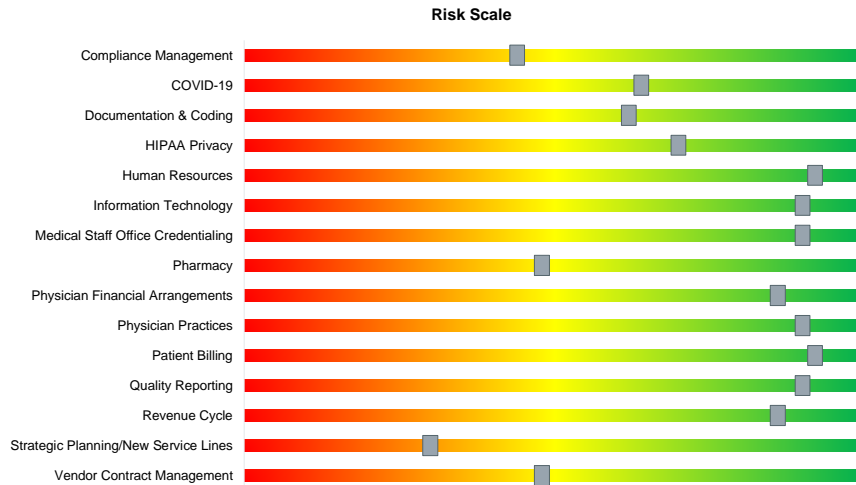


## Compliance Risk Assessment Executive Summary

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## Risk Assessment Summary Findings

- Graded organizational exposure using the same **red, orange, green** risk-ranking system:



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## Compliance Risk Strengths

Risk Area	Internal Controls Communicated to Be in Place to Mitigate Risk
<b>Information Technology</b>	<ul style="list-style-type: none"> <li>A process is in place to assure that all workstations, laptops, and tablets are updated with anti-virus and/or endpoint security and critical security patches per industry standards.</li> <li>The organization completes an annual HIPAA Security Risk Analysis (HSRA) that includes an assessment of data at rest.</li> <li>A plan is in place to manage the enterprise in the event of a cyber-attack and includes the ability to detect attackers, efficiently respond to events, and restore operations.</li> <li>The organization has a well-defined IT project management process.</li> <li>A process is in place to protect biomedical devices from cybersecurity threats, including product procurement security standards, device testing prior to implementation, and regularly scheduled biomedical device functional assessments.</li> </ul>
<b>Physician Financial Arrangements</b>	<ul style="list-style-type: none"> <li>The types of physician arrangements are defined and approved contract templates are in place for each. (e.g., Employment, Independent Contractor, Medical Director, On-Call, etc.)</li> <li>Arrangements for physician services are monitored for compliance with the Stark Law and the AKS.</li> <li>All physician contracts are audited for appropriate execution (terms, signatures, dates/timeframes, etc.), implementation, and reconciliation.</li> <li>The physician compensation arrangement represents fair market value in an arm's-length transaction for the items and services.</li> </ul>
<b>Physician Practices</b>	<ul style="list-style-type: none"> <li>The practice reviews claims and medical records for compliance with applicable coding, billing, and documentation requirements.</li> <li>An appropriate protocol is in place to respond to issues detected during audits.</li> <li>All practice employees receive compliance training and understand that compliance is a condition of employment.</li> </ul>
<b>Revenue Cycle and Patient Billing</b>	<ul style="list-style-type: none"> <li>Denials are managed on a daily basis.</li> <li>Third-party audit requests that result in refunds of overpayments are analyzed for system and human errors, and appropriate action plans are implemented.</li> <li>The organization follows the 'payment window' rules applicable to each payer in combining outpatient services with inpatient claims.</li> <li>Remittance information is appropriately updated and routinely monitored against claims data.</li> </ul>

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## Compliance Risk Considerations



- Certain departments are not actively involved in the compliance program
- Limited compliance program resources
- Required reporting of COVID-19-related expenditures
- Limited assurance of coding accuracy
- Industry risk related to 340B programs
- Compliance implications with strategic initiatives and new service lines
- Informal vendor management processes

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## Prioritized Recommendations for Compliance Risk Mitigation



- Develop and implement departmental compliance work plans to disseminate the compliance function throughout the organization.
- Adequately staff and budget the compliance program.
- Develop methodology to track COVID-19 related costs and resources.
- Undergo an independent audit to ensure coding accuracy.
- Include 340B compliance on the compliance work plan.
- Include assessment of compliance implications in strategic initiatives and new service lines.
- Review the vendor management processes.

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Questions?



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Resources

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## Resources for the Board



### • Essential Compliance Resources for Boards:

- Practical Guidance for Health Care Governing Boards on Compliance Oversight (OIG, AHIA, AHLA and HCCA)
  - <https://oig.hhs.gov/documents/root/162/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>
- Measuring Compliance Program Effectiveness: A Resource Guide (HCCA and OIG)
  - <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>
- DOJ Criminal Division - Fraud Section, Evaluation of Corporate Compliance Programs
  - Initially published in 2017. Updated in 2019 & 2020
  - Three Questions:
    - 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?
  - <https://www.justice.gov/criminal-fraud/page/file/937501/download>

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## Resources for the Board



### • Other Useful Resources for Boards:

- Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (OIG and AHLA)
  - <https://oig.hhs.gov/documents/compliance-guidance/816/040203CorpRespRscceGuide.pdf>
- An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors (OIG and AHLA)
  - [https://oig.hhs.gov/documents/compliance-guidance/815/Tab\\_4E\\_Appendx-Final.pdf](https://oig.hhs.gov/documents/compliance-guidance/815/Tab_4E_Appendx-Final.pdf)
- Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (OIG and AHLA)
  - [https://oig.hhs.gov/documents/compliance-guidance/813/CorporateResponsibilityFinal\\_9-4-07.pdf](https://oig.hhs.gov/documents/compliance-guidance/813/CorporateResponsibilityFinal_9-4-07.pdf)
- A Toolkit for Healthcare Boards (OIG)
  - <https://oig.hhs.gov/documents/compliance-guidance/809/toolkit-handout.pdf>

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## Thank you!

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