



Internal Audit, Risk, Business & Technology Consulting

INTRODUCTIONS



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LEARNING OBJECTIVES




1. Define the DHHS Office of Inspector General's 7 elements of an effective compliance program
2. Evaluate program maturity based on leading practices from the financial services industry
3. Explain why auditing a compliance program for effectiveness is critical in today's environment

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OIG'S COMPLIANCE PROGRAM GUIDANCE



1. U.S. Sentencing Guidelines (effective November 1, 1991)
 - i. Sentencing of corporations and other business entities convicted of federal criminal offenses
 - ii. Sentencing credit for effective compliance programs
 - iii. Set the foundation for the 7 elements
2. Various segments of the health care industry

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OIG GUIDANCE EXAMPLES



1. OIG Guidance for Hospitals – 1998
2. OIG Guidance for Individuals and Small Physician Groups – 2000
3. OIG Guidance for Pharmaceutical – 2003
4. Supplemental OIG Guidance for Hospitals – 2005
 - i. Risk Areas
 - ii. Risk Assessment
 - iii. Annual Compliance Program Effectiveness Review

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THE 7 ELEMENTS



“The Seven Elements of a compliance program are important individually but are most effective on an interdependent basis.”

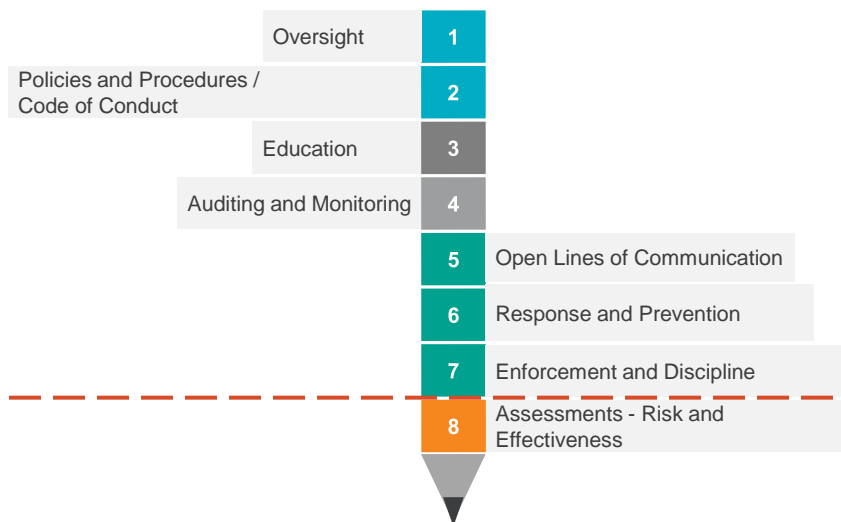
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THE 7 ELEMENTS



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1. OVERSIGHT

Without authority and resources, can compliance be effective?

A strong compliance program begins with tone and top. The actions and messages from leadership – both spoken and unspoken – inevitably shape an institution's compliance culture.

1. Board
2. Qualified Compliance Officer (level and reporting structure)
3. Compliance Department
4. Compliance Committee / Other Committees
5. Periodic evaluation of the sufficiency of resources in relation to the overall size and complexity of the company



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AUDIT CONSIDERATIONS – OVERSIGHT

1. Qualified Chief Compliance Officer (CCO)
2. Does the CCO have direct access to the governing body, CEO, all senior management?
3. Does the CCO have independent authority to retain outside legal counsel?
4. How often and what information/reports goes to the Board?
5. Is the CCO viewed by peers as a trusted member of the team?
6. Do employees know who the CCO is?



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2. POLICIES AND PROCEDURES

1. Outlines Compliance Program responsibilities and sets standards for certain activities
2. Approved by leadership, applicable committees, and Board
3. Formal policy framework established, including standard formats, approval, and active policy management (including version control)
4. Periodically reviewed and revised to meet regulatory, business, and operational changes
5. Readily accessible to employees

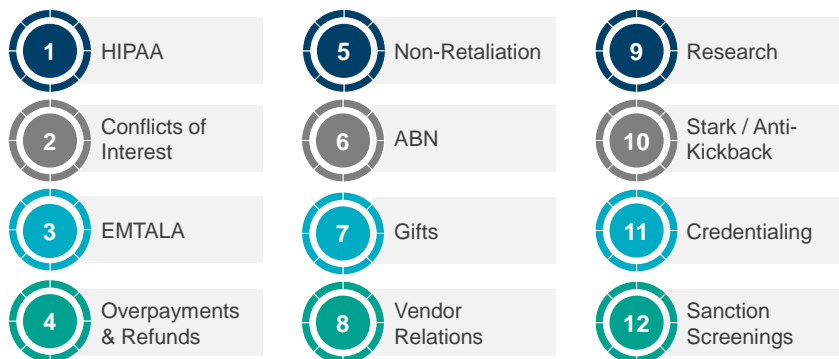


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KEY POLICIES – REGULATORY & RISK



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CODE OF CONDUCT

1. Spirit, tone, culture, and ethical attitude
2. Requirements and expectations
3. Helps define:
 - i. Acceptable conduct
 - ii. Process for proper decision-making
 - iii. What to do if someone has a question
 - iv. Who to tell if the someone suspects misconduct
4. Provided to new individuals and annually - attestation
5. Readily accessible
6. Reviewed annually for changes



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AUDIT CONSIDERATIONS – POLICIES AND PROCEDURES

1. Are policies and procedures, including the Code of Conduct, easily accessible?
2. Are policies and procedures re-evaluated on a regular basis?
3. Are policies and procedures monitored for their implementation and compliance?
4. Do all personnel sign that they have read and agree to abide by the Code of Conduct?
5. Can staff articulate the intent of the Code of Conduct?



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3. EDUCATION

1. Content is specific to roles and responsibilities, including the Board
2. Senior leadership endorsed/approved
3. Required (new hires, annually, and as needed)
4. Test understanding and obtain attestation
5. Focus training on key risk areas, new requirements, hotline reports, audit, and investigation results



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AUDIT CONSIDERATIONS – EDUCATION

1. Is content evaluated on an annual basis to ensure it is relevant and sufficient?
2. Are individuals tested on their comprehension of the training?
3. Has the governing body been provided with training?
4. Is who completed the required training documented?
5. Are there sanctions for failing to complete training?



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4. AUDITING AND MONITORING

Designed to evaluate and improve the effectiveness of processes and related controls.

1. Conducted by individuals independent of the process being audited
2. Compliance Audit Work Plan developed based on results of a risk assessment
3. Formal, systematic, and structured approach - involves planning, sampling, testing, and validating
4. Formal communication with recommendations and corrective action measures
5. Documented follow-up of corrective actions
6. Audit accountability is typically to the Chief Audit Executive and the Audit Committee



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4. AUDITING AND MONITORING (CONT'D)

Monitoring is an on-going process usually directed by management to ensure processes are working as intended. Monitoring is an effective detective control within a process.

1. Often less structured than auditing, though audit techniques may be employed
2. Usually completed by operations
3. Involves on-going checking and measuring
4. Periodic spot checks, daily/weekly/monthly tests
5. May involve internal audit or compliance



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AUDIT CONSIDERATIONS – AUDITING AND MONITORING

1. Is the compliance audit plan re-evaluated annually?
2. Are audits conducted that address organizational risks?
3. Does the audit plan include an assessment of billing systems (in an effort to identify any root causes of billing errors)?
4. Does operations perform routine monitoring around compliance?



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5. OPEN LINES OF COMMUNICATION

1. Open door policy
2. Confidentiality and anonymity
3. Mechanism to report anonymously (Hotline)
4. Track investigations and results (document why you may not investigate a matter)
5. Share issues and results with Board and other relevant departments, as necessary
6. Non-retaliation policy
7. Encourage internal reporting first before external reporting
8. Exit interviews



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AUDIT CONSIDERATIONS – OPEN LINES OF COMMUNICATION

1. Is an anonymous hotline in place?
2. Are instances of potential fraud and abuse investigated?
3. Is a non-retaliation policy in place and is it communicated to individuals?
4. Are employees asked about compliance issues during exit interviews?



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6. RESPONSE AND PREVENTION

1. Stop the non-compliant behavior immediately!
2. Enough facts to investigate?
3. Get internal/external counsel involved? Attorney/client privilege needed?
4. Consult other appropriate areas (e.g., Human Resources, Internal Audit)
5. Investigations are confidential
6. Retention/Destruction Policy
7. Report results to applicable leadership (remember anonymity)
8. Implement new/revised internal controls (e.g., policies, staff), where needed
9. Educate, where needed
10. Determine if it's enough risk to conduct future audit on
11. Document, document, document



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AUDIT CONSIDERATIONS – RESPONSE AND PREVENTION

1. Is education provided and documented to applicable parties after investigation of a matter?
2. Is there a Retention/Destruction Policy?
3. Are periodic reviews of problem areas conducted to verify that the corrective action that was implemented successfully eliminated existing deficiencies?



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7. ENFORCEMENT AND DISCIPLINE

1. Disciplinary standards well-publicized and available
2. Sanctions for non-compliant behaviors
3. Sanctions for failure to report non-compliance
4. Fair, equitable, and consistent - progressive discipline vs. automatic termination
5. Collaboration with Human Resources and Legal
6. External reporting obligations
7. Sanctions screenings



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AUDIT CONSIDERATIONS – ENFORCEMENT AND DISCIPLINE

1. Are disciplinary standards well-publicized and readily available to all personnel?
2. Are disciplinary standards enforced consistently across the organization?
3. Are employees, contractors, and medical and clinical staff members checked routinely (e.g., monthly) against government sanctions lists (e.g. OIG / GSA)



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8. RISK ASSESSMENT

1. Risk assessments should be ongoing and conducted on a regular basis – typically annual
2. Quantitative and qualitative methodologies
3. Ensure proper documentation of the risk assessment
4. Utilize results to determine compliance plan, including audit plan
5. Share risk assessments results with management and the Board



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EFFECTIVENESS ASSESSMENT

1. Audit / exercise to document how you are successfully achieving each of the 7 elements
2. Identifies gaps
3. Use governmental and association guidance
4. Review Corporate Integrity Agreements
5. Learn from the failure of others



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COMPLIANCE IN THE FSI

What we can learn from another highly regulated industry

FSI REGULATORY ENVIRONMENT

Compliance in the financial services industry today:

1. Patchwork state and federal regulatory agencies, laws, and regulations
2. Heightened scrutiny and enforcement
3. Focus on consumer protection and anti-money laundering
4. Reputational risk

IN THE HEADLINES

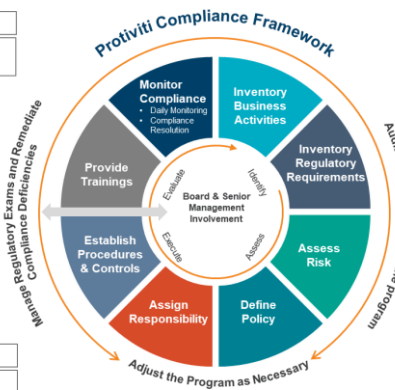
Top 5 U.S. Bank fined \$1 billion for questionable sales practices

Credit Bureau Settles for \$700 Million in Monetary Relief and Penalties

U.S. Prosecutors and Regulators Impose Second Largest Penalty Ever for Violations of U.S. Economic Sanctions

Lenders fined for unauthorized debits of consumer bank accounts

FSI COMPLIANCE FRAMEWORK



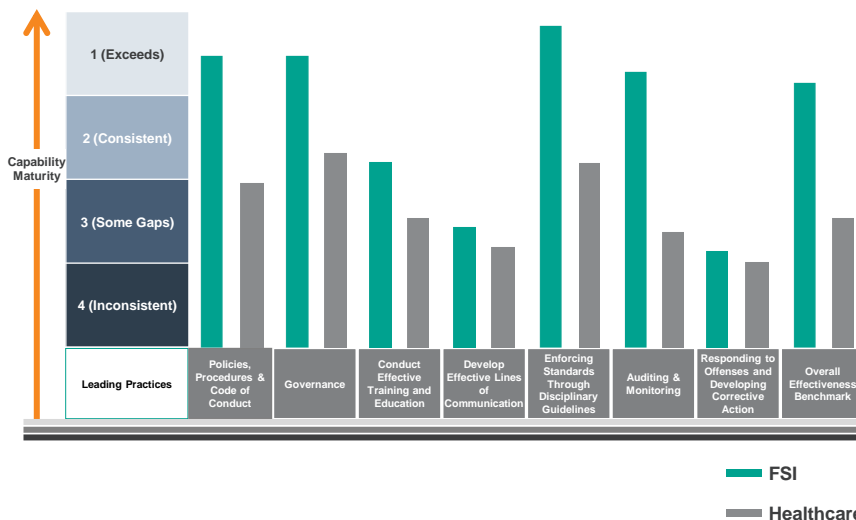
1. Incorporates the common elements from regulatory expectations surrounding compliance programs
2. Looks at compliance as a constantly-evolving lifecycle, rather than a process with a single endpoint
3. Provides a roadmap to evaluate the effectiveness of the compliance program

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COMPLIANCE MATURITY IN FSI/HEALTHCARE




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WHERE HEALTHCARE CAN LEARN FROM FSI


1. Organizational structure
2. Business process/legal and regulatory inventories
3. Risk assessment
4. Monitoring and testing
5. Management reporting
6. Customer complaints




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ORGANIZATIONAL STRUCTURE & ACCOUNTABILITY




1. Formal designation by the Board of a qualified Compliance Officer
2. Independent reporting lines for the Compliance Officer and department (e.g., to Legal or Risk, and/or directly to the Board)
3. Operational responsibilities of compliance personnel are limited, and appropriate segregation of duties exist
4. Independent compliance and internal audit functions
5. Compliance Committee structures




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REQUIREMENT & PROCESS INVENTORIES




1. Single source of truth
2. Legal/compliance involvement
3. Mapped to across enterprise to applicable operations, products/services, and controls
4. Regularly refreshed through formal change management controls
5. Foundation for effective compliance risk assessment and management plan




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RISK ASSESSMENT



1. Distinctly identifies and prioritizes relevant inherent risks
2. Considers both inherent and residual risks
3. Documents an objective scoring system
4. Ensures meaningful output



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MONITORING & TESTING

1. Monitoring and Testing – what’s the difference?
2. Effective monitoring and testing programs are objectively risk-based
3. Dedicated teams
4. Governance, Risk, and Compliance platforms for second line testing
5. Coordinated with, but not replaced by, first and third line of defense functions
6. Role in advising 1-A / 1-B monitoring and testing functions

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MANAGEMENT REPORTING

1. Technology-enabled, automated where possible
2. Defines and is centered on Key Risk Indicators and Key Performance Indicators
3. Informs stakeholders appropriately, at the right lever of seniority
4. Establishes risk tolerance thresholds and monitors for exceptions

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CUSTOMER COMPLAINTS



1. Complaints and customer feedback
 - i. External (e.g., regulatory agencies, customers, Better Business Bureau, etc.)
 - ii. Internal (allegations, exit interviews)
 - iii. Centrally tracked trended
2. Robust data models required for meaningful and thematic analysis
 - i. Root cause
 - ii. Applicable legal/regulatory requirements
 - iii. Whether customer harm occurred
3. A meaningful measure of risk in compliance reporting
4. Integrating with Issue Management data and reporting provides an improved perspective
5. Competitive advantage in improved customer service
6. Provides a tangible measure of “Culture of Compliance”



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FSI CONSIDERATIONS FOR HEALTHCARE



1. **Organizational Structure & Accountability:**
 - i. Is compliance sufficiently independent, granted appropriate authority to execute on its mandate?
 - ii. Is the Compliance Officer independent of the first- and third-line defense?
2. **Risk Assessment:**
 - i. Determine if and how the risk assessment drives all aspects of the compliance program (training, monitoring, control improvement, etc.)
 - ii. Are inherent risk and control ratings supported by objective, quantitative metrics wherever possible?
 - iii. Are results calibrated to ensure meaningful output?
3. **Reporting:**
 - i. Does current reporting provide for enterprise-wide perspective, with appropriate drill-down perspectives into high risk areas?
 - ii. Have KRIs/KPIs been fully defined / periodically revisited?

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FSI CONSIDERATIONS FOR HEALTHCARE (CONT'D)



4. Monitoring & Testing:

- i. Is a formal program documented and aligned to?
- ii. How are results considered as inputs to the risk assessment and training needs?

5. Risk Assessment:

- i. Determine if and how the risk assessment drives all aspects of the compliance program (training, monitoring, control improvement, etc.)
- ii. Are inherent risk and control ratings supported by objective, quantitative metrics wherever possible?
- iii. Are results calibrated to ensure meaningful output?

6. Customer Complaints:

- i. Is complaints data aggregated across systems, operations centers, and other sources to ensure a single and comprehensive record?
- ii. How does the institution define complaints vs. inquiries?
- iii. Does the institution define and provide training regarding complaints capture and evaluation for compliance impacts?

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WHY AUDIT COMPLIANCE PROGRAMS FOR EFFECTIVENESS?

1. Technology-enabled with a focus on innovation, automation, and analytics to improve quality of compliance management and streamline operations
2. Allows the organization to understand it's compliance, operational and business risks
3. Reflects an organization's commitment of doing the right thing and "the tone from the top"
4. "You get no bonus points for having a compliance program." **DHHS Inspector General Daniel R. Levinson remarks at the Health Care Compliance Association's Annual Compliance Institute (April 18, 2016)**

A strong compliance function leads to more than reduced risk of non-compliance and regulatory penalties, but leads also to improved customer experience, enhanced brand loyalty, and increased value for stakeholders. Compliance is table stakes, but it can also provide a unique competitive edge.

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Face the Future with Confidence

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