

WHAT MAKES A COMPLIANCE PROGRAM “EFFECTIVE”?

HEALTH CARE COMPLIANCE ASSOCIATION
HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE
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Session Goals

- Review new and past guidance on compliance programs, measuring effectiveness, and program evaluation
- Discuss government expectations, risks of non-compliance, and industry enforcement activity related to compliance
- Strategies and tips to evaluate your compliance program to determine sufficiency and effectiveness

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Changing Landscape: Compliance 2.0

Recent enforcement and other developments have impacted the healthcare industry, including:

- Evolution of the compliance and ethics profession from Compliance 1.0 to Compliance 2.0
- Enforcement agencies widening the compliance lens
- Regulatory defense vs. Proactive operational machine
- Robust and effective compliance program
- Subject Matter Expertise, Empowerment, Independence
- Significantly enhanced expectations for enterprise-wide compliance programs and support at all levels
 - Board
 - Leadership
 - Management

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“The absence of a high-functioning compliance program may be used to establish [FCA] intent.”

Thomas Beimers
(Former Senior Counsel with HHS OIG)

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FCA Penalties

The stakes are high!

- Increased False Claims Act (FCA) financial penalties for non-compliance
- DOJ adjusted max from \$21,916 to \$22,363 (1/29/2018)

Defense Contractor 12 claims / year		Healthcare Provider 2,000 claims / year	
Triple Damages	\$300,000	Triple Damages	\$300,000
Penalty (21,916 x 12)	\$262,992	Penalty (21,916 x 2,000)	\$43,832,000
Total Recovery	\$562,992	Total Recovery	\$44,132,000

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OIG's Permissive Exclusion Authority

On April 18, 2016, OIG issued a revised policy statement containing the new criteria that OIG intends to use in implementing its permissive exclusion authority under 42 U.S.C.A. § 1320a-7(b)(7) (Revised Policy).



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OIG Permissive Exclusion Authority and Compliance Programs

- The existence of a compliance program that incorporates the seven elements of an effective compliance program does not affect the risk assessment
- The absence of a compliance program that incorporates the seven elements of an effective compliance program indicates higher risk
- If the entity has devoted significantly more resources to the compliance function, this indicates lower risk

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“The self-disclosure protocol has always been a very important part of demonstrating that we’re really on top of our compliance work and that when a firm sees a problem it doesn’t wait in the hopes that it can just be avoided, but it comes forward and makes whole the taxpayer and insures that the firm is able to move forward ethically and legally.”

Daniel Levinson – Former HHS Inspector General, Remarks at HCCA Annual Compliance Institute (2017)

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Emphasis on Corporate Governance on Settlements

- In January 2017, a Tennessee federal Judge approved a \$60 million settlement agreement between CHSI and certain directors and executives with the class of CHSI stockholders
- The settlement also requires that CHSI **“adopt meaningful corporate governance reforms,”** including:
 - The appointment of two new mutually acceptable independent directors to the Board
 - The establishment of a healthcare law compliance coordinator, subject to the approval of OIG
 - The compliance coordinator will work with the Chief Compliance Officer to coordinate and oversee implementation of the Company’s compliance programs, with particular emphasis on Medicare and Medicaid compliance programs

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“Today is very much prevention day and we’re talking about corporate integrity agreements and because of the recent developments with CIAs and the way that we’re now able to focus attention in a much more laser-like way, I think the evolution of CIAs from a broader tool to understand whether a system is operating reasonably well, to being able to focus on particular areas of vulnerability is a real step forward when it comes to CIAs . . .”

Daniel Levinson – Former HHS Inspector General
Remarks at HCCA 2017 Annual Compliance Institute

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Corporate Integrity Agreement (CIA)

Compliance Program Expectations Articulated in CIAs

- CIA is an Agreement with HHS-OIG in connection with civil healthcare fraud settlement
- Requires entity or individual to implement, enhance, or continue certain integrity obligations
- The duration and form of CIA and IA vary based on the case.

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CIA Trends

Importance of CIA Trends in Non-CIA Programs

- OIG uses CIAs to communicate prudent approaches to compliance program design and compliance-related initiatives
- Emerging trends in CIA's reflect OIG's escalating compliance expectations for entities participating in federal healthcare programs
- Providers should monitor and address emerging compliance trends:
 - Fortify compliance infrastructure
 - A company's proactive efforts to monitor and address such emerging compliance trends often benefits the company when evaluated by Government enforcement agencies

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CIA Trends

Emerging CIA Trends

- Use of Independent Monitors
- Compliance Experts
- Management Certifications and Increased Stipulated Penalties for False Certifications
- Risk Assessment and Mitigation
- Heightened IRO Qualifications

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Compliance Program Expectations

- ***“You get no bonus points for having a compliance program”***
 - Former HHS Inspector General Daniel R. Levinson, remarks at the Health Care Compliance Association’s Annual Compliance Institute (2016)
- The expectation has shifted from incentivizing the adoption of compliance programs to incentivizing the operation of **effective** compliance programs
- OIG, DOJ, CMS, and other third parties are evaluating the effectiveness of compliance programs

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Elements of an Effective Compliance Program

Traditional “7 Elements”:

1. Designating a Compliance Officer and Compliance Committee
 2. Implementing written policies, procedures and standards of conduct
 3. Conducting effective training and education
 4. Developing effective lines of communication
 5. Conducting internal auditing and monitoring
 6. Enforcing standards through well-publicized disciplinary guidelines
 7. Responding promptly to detected offenses and implementing corrective actions
- 8. “8th Element” – Compliance Program Effectiveness**

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Government expectations of Organizations and their Compliance Programs communicated through release of new guidance documents on measuring effectiveness and program evaluation

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Guidance Documents

Measuring compliance program effectiveness has long been recommended by several authorities. There has been a recent increase in government focus on compliance program effectiveness and evaluating compliance programs, as seen with the release of several new documents:

- *OIG Measuring Compliance Program Effectiveness (2017)*
- *DOJ Evaluation of Corporate Compliance Programs (2017 and 2019 update)*
- *DOJ Evaluation of Corporate Compliance Programs in Criminal Antitrust Investigations (2019)*
- *Others: CMS; CMS Parts C and D (Medicare Advantage Programs); ACA; Federal Sentencing Guidelines; Department of Treasury Office of Foreign Asset Control (OFAC) New Framework for Effective Sanctions Compliance (2019)*

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OIG Guidance Document
Measuring Compliance
Program Effectiveness: A
Resource Guide

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**OIG
published
guidance
(2017)**

- In March 2017, the Office of Inspector General (OIG) released a compliance program evaluation memorandum, entitled “**Measuring Compliance Program Effectiveness: A Resource Guide**” following a roundtable meeting with compliance professionals and the government.
- Designed to help organizations with potential approaches to move beyond basic compliance program development.
- Addresses the [new] federal government approach to measuring whether provider compliance programs are effective in accomplishing their goal of detecting, deterring and remediating fraud and abuse.

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**OIG
published
guidance
(2017)**

- The federal government approach in evaluating compliance programs seems to be rapidly evolving to consideration of more objective and quantifiable measures.
- This demonstrated compliance program effectiveness is critical for both maintaining compliant operations on an ongoing basis, but could also lead to consideration for more favorable settlements in the event providers become targets in federal investigations.

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The OIG guidance suggests that, “with the current high stakes health care enforcement climate, the time is now for providers to take stock of their own compliance program efforts and make any necessary enhancements consistent with this new federal government focus in order to avoid the much more serious problems that can occur when compliance controls break down”.

- HHS Office of Inspector General, at release of 2017 guidance

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OIG published guidance (2017)

- Provides a framework for types of inquiries OIG will make in context of investigations.
- Includes 7 elements, covering over 400 compliance program metrics with 700 different action items and questions, which offer insight into the OIG's evaluation process.
- OIG stresses that this is “not a checklist”.
- Provides benchmarking and tracking of specific compliance program elements to determine the extent to which they are sufficiently developed and effective.
- Guidance provides ideas and measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs.
- Not every metric will apply to each organization. Compliance programs need to be specifically tailored to the needs of the organization, and take into account the company's risk areas, resources and industry.

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OIG published guidance (2017)

OIG Compliance Program Elements described in the 2017 Guidance:

1. Standards, policies, and procedures
2. Compliance program administration
3. Screening and evaluation of employees, physicians, and other agents
4. Communication, education, and training on compliance issues
5. Monitoring, auditing, and internal reporting system
6. Discipline for non-compliance
7. Investigations and remedial measures

*Note: Each element contains several suggested items. View the full document:
<https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>*

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DOJ Guidance Document(s) Evaluation of Corporate Compliance Programs

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DOJ published guidance (2017)

- In February 2017, the Criminal Division's Fraud Section of the Department of Justice (DOJ) released guidance in a published memorandum, **"Evaluation of Corporate Compliance Programs"**.
- The DOJ is required to evaluate a compliance program in the context of a criminal investigation to determine its existence, effectiveness, and remedial efforts to implement or improve its program. The framework was provided on common questions the DOJ may ask in making an individualized determination.
- The document set forth 115 sample topics and questions in a framework, divided by 11 sections.

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**DOJ
published
guidance
(Contd.)**

- **Approach assumes *investigative posture***
 - Includes questions pertaining to infrastructure
 - Includes questions specific to issue under investigation
- **Practical Use**
 - Roadmap to approach DOJ will take in the contexts of investigations
 - Provides insight as to what DOJ considers critical
- **Valuable tool**
 - Consider your most recent internal investigation

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**Changes to
the new DOJ
published
guidance
(2019)**

In April 2019, the DOJ released an updated version of this document. The new document:

- Continued to focus on the importance of compliance programs
- Placed importance on having an effective, well-tailored, quality program
- Provided more examples to assist prosecutors in evaluating programs
- Provided a design and framework to providers on program structure to help satisfy a criminal investigation
- More closely aligns with the concepts of other guidance (e.g., Justice Manual, Sentencing Guidelines, FCPA Guide)

View the full document: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

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**DOJ
Guidance:
Three
Fundamental
Questions

(2019)**

The 2019 Guidance includes twelve sample topics and is primarily structured around three fundamental questions:

1. Is the program well-designed?
2. Is the program being applied earnestly and in good faith?
3. Does the program actually work in practice?

To help determine 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).

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**DOJ
Guidance:
Fundamental
Question 1**

DOJ considers addressing real life risks, structure and testing of program, learning from mistakes, well integrated into the organization.

1. Is the program well-designed?
 - A. Risk assessment
 - B. Policies and procedures
 - C. Training and communications
 - D. Confidential reporting and investigation
 - E. Third-party management

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**DOJ
Guidance:
Fundamental
Question 2**

DOJ considers constant evaluation and evolution based on risks, effective implementation, real program to mitigate risks.

2. Is the program being implemented effectively?

- A. Commitment by senior and middle management
- B. Autonomy and resources
- C. Incentives and disciplinary measures

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**DOJ
Guidance:
Fundamental
Question 3**

DOJ considers other factors in addition to the compliance program, but is focused on the investigation, lessons learned, and remediation.

3. How does the program work in practice?

- A. Continuous improvement, periodic testing, and review
- B. Analysis and remediation of underlying misconduct

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Other Effectiveness Guidance

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DOJ Guidance: Antitrust Investigations (2019)

- In July 2019, the DOJ published guidance on Evaluation of Compliance Programs in Criminal Antitrust Investigations.
- Similar to their previously published documents in 2017 and 2019.
- **The Antitrust Guidance is primarily structured around three fundamental questions:**
 1. Is the corporation's compliance program well designed?
 2. Is the program being applied earnestly and in good faith?
 3. Does the corporation's compliance program work?

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DOJ Guidance: Antitrust Investigations (2019)

The new document set forth certain factors within the three key questions, that Division prosecutors should consider when evaluating the effectiveness of an antitrust compliance program. These include:

1. Design and comprehensiveness of the program
2. Culture of compliance within the company
3. Responsibility for, and resources dedicated to, antitrust compliance
4. Antitrust risk assessment techniques
5. Compliance training and communication to employees
6. Monitoring and auditing techniques, including continued review, evaluation, and revision of the antitrust compliance program
7. Reporting mechanisms
8. Compliance incentives and discipline
9. Remediation methods

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CMS Parts C & D

- The Centers for Medicare and Medicaid Services (CMS) require Medicare and Medicaid Advantage Plans and Prescription Drug Benefit Plan Sponsors to provide oversight for its first tier, downstream, and related entities, including oversight of compliance and fraud, waste, and abuse program requirements.
- CMS issued guidelines for these plan sponsors to establish program audit processes and protocols, which included how CMS evaluates compliance programs during an audit.
- CMS questions are intended to serve as a guide in evaluating the effectiveness of a compliance program. Further, plan sponsors should ensure they have implemented all elements of an effective compliance program.

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**CMS
Parts C & D
(Contd.)**

Attestations and elements closely follow the OIG’s elements of an effective compliance program:

1. Compliance Officer, Compliance Committee, Governing Body
2. Written Policies and Standards of Conduct
3. Effective Training and Education
4. Effective Lines of Communication
5. Effective Systems for Routine Auditing and Monitoring and Identification of Compliance Risks
6. Procedures and Systems for Promptly Responding to Compliance Issues
7. ...and now “Program Effectiveness”

Note: Recent reviews inquire whether hospital policies address The Treasury Departments’ Office of Foreign Asset Control (OFAC) sanction guidance.

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**DOT OFAC
Guidance
(2019)**

Department of Treasury Office of Foreign Assets Control (OFAC) Published Guidance on Sanctions Compliance

- OFAC released published guidance outlining its view of effective sanctions compliance programs.
- The OFAC guidance, “A Framework for OFAC Compliance Commitments,” calls for designated sanctions compliance programs focused on OFAC regulations, and states unequivocally that the absence of a sanctions compliance program will have a great impact on the fines levied, if a company is found guilty of a violation. Regulations do not require a formal sanctions compliance program.
- Similar to guidance from the Department of Justice (DOJ), and focused on many of the same controls: leadership support, risk assessments, controls, monitoring and periodic review.
- Provided considerations compliance professionals should consider, if applicable.

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Yates Memorandum:

Individual Accountability for Corporate Wrongdoing

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Yates Memo

(2015)

- In September 2015, former Deputy Attorney General, Sally Yates, issued a memorandum (the Yates Memo) regarding individual accountability for corporate wrongdoing.
- Provides guidance for both civil and criminal investigations. Emphasizes the need to hold individuals who perpetrated corporate wrongdoing accountable, “particularly in the aftermath of the financial crisis.”
- Although Sally Yates is no longer with DOJ, the Yates memo continues to be DOJ policy. Attorney General Jeff Sessions in 2017 said “The DOJ will continue to emphasize the importance of holding individuals accountable for corporate wrongdoing.”

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Yates Memo

Individual Liability Case Examples

- Former Tenet Senior Vice President fraud indictment in relation to Medicaid patient referral scheme and false CIA certifications. **Significant monetary penalties, residence seizures, and up to 50 years in prison.**
- Former CEO of Tuomey Healthcare **\$1 million** to settle alleged Stark violations.
- eClinicalWorks' **\$155 million** settlement split between company and three founders for false certifications and kickback violations. Note other settlements.
- Cardiologist and practice paid **\$2 million** and released claims to an additional **\$5.3 million** in suspended Medicare funds to settle fraud and kickback allegations.
- Insys Therapeutics criminal prosecution with the **indictment of six former executives and a guilty plea from two sales representatives and a spouse** related to kickbacks related to the opioid drug fentanyl.
- Forest Park Medical Center **criminal indictments** against 21 individuals for kickback scheme involving marketing and office space for physician-owned entity.
- Integrated Medical Systems and former president to pay **\$2.5 million** for kickbacks and false claim violations with federal contracts.
- Complementary Medical Systems (a mental healthcare firm) and two of its principles paid a combined **\$6.3 million** for fraud related to supervision.

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Designing / Enhancing Your Compliance Program

Tips and Best Practices

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Sample OIG Review of Compliance Program Element

- **What to Measure:**
 - Compliance culture and support
 - Involvement of Board Members and senior leadership
- **How to Measure:**
 - Board interviews
 - Qualifications of compliance officer
 - Certification in Healthcare Compliance., etc.
 - Authority of compliance officer to:
 - Engage outside legal counsel
 - Initiate a working group
 - Implement a bill hold

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OIG's Review of CIA Compliance Common Monitoring and Site Visit Inquiries

- Assess “placement” of compliance within the organizational structure
- Validate Compliance Officer’s standing and authority within organization
- Evaluate communication between Compliance Officer and Board
- Evaluate resources dedicated to compliance program
- Compliance Committee Meeting Minutes
- Review disclosure log and underlying investigation and reports
- History of development and implementation of corrective action plans

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**Best Practices
and Key
Takeaways:**

**DOJ
published
guidance
(2019)**

1. Properly resourced
2. Independent access to the Board or Audit Committee
3. Integrated with other functions
4. Adopt a risk-based approach (real risks)
5. Implement metrics that matter
6. Train managers and gatekeepers differently
7. Adopt stringent third-party controls, monitor third parties
8. Communicate policies and procedures to third-parties
9. Maintain a robust whistleblowing process
10. Perform program evaluations

Credit: Kristy Grant-Hart

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**Best Practices
and Key
Takeaways
from all recent
published
guidance**

Recent guidance documents suggest a focus on:

- Compliance Programs overall and their effectiveness
- Compliance Program Administration and design
- Overall policies and procedures, and inclusion of specific topics in policies (e.g. COI, record retention, regulatory compliance)
- Exclusion screening
- Medical staff, credentialing
- Training and education, clear communication, education, risk-based and area specific training
- Auditing and monitoring
- Third-parties, due diligence, hospital operations
- Incentives and discipline
- Investigations, appropriateness and scope.
- Remedial measures, responsiveness to investigations, root causes, learning from mistakes

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Best Practices and Tips to Get Started

Compliance Officers and Programs should look to:

- **OIG's 7 elements of a compliance program.** All activities ideally can be planned or structured through these elements.
- **Published Effectiveness Guidance Documents** (recent OIG, DOJ and past OIG, Supplemental Guidance, Sentencing Guidelines).
- **Recent Enforcement Activity** (CIAs and settlements), audit reports for trends and takeaways. If possible, model program from recent CIAs.
- **Government planned work** (OIG Work Plan) and new or changed rules.

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Best Practices: Compliance Program Administration (Officer and Committees)

- **Have proper reporting structure:** CCO should report to the Board or Audit Committee, not to the General Counsel. Dotted administrative line acceptable. Have autonomy.
- **Have access to leaders and Board.** Be empowered and properly leveled as a leader in the organization.
- **Have appropriate experience and qualifications to perform role/functions.**
- **Have access to budget and resources, and the authority to hire outside counsel, auditors or outside experts** (recommend budget ability for things like hotline, tracking or auditing systems, conflicts of interest, exclusion screening).
- **Ensure appropriate and dedicated committee structures.** Consider sub-committees for certain higher risk areas. Be sure these areas know their roles and responsibilities.
- **Understand roles of departments** (e.g., Audit and Legal)
- **Constantly benchmark and measure program.** Use resources.

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Best Practices:

Training and Education; Open Communication; Policies and Procedures

- Provide appropriate and understandable training and education. Have general and risk-based training. Train at all levels. Use for remediation, re-train where necessary. Maintain a tracking system.
- Ensure policies and procedures are well designed and accessible. Clearly communicate expectations and procedures in policies. Ensure policies are being followed.
- Hotline to be confidential and anonymous. Treat calls seriously.
- Volume of reports of potential compliance issues should correlate to the size of the organization. Pay attention to the ratio of calls made to the hotline versus direct contact to your department.
- Ensure employees have several avenues to obtain information, and report concerns. Seek out information on issues.
- Protect against retaliation, communicate whistle-blower policies.

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Best Practices:

Auditing and Monitoring

- Maintain a Work Plan, and adjust work as necessary.
- Consider different ways to review and monitor (e.g., audit, mini-risk assessments, pose questions to check in with industry activity, risk assessments on policies and standards and the ability to be compliant, department self-audits).
- Seek input from leaders and managers on concerns they may have and/or what they need help with.
- Consider overall questionnaire to address overall risk.
- Properly plan and scope audits, rely on guidance and facts.
- Audit follow-up (what is old may become new again).
- Use data, where possible, to track and trend and use.
- Monitor third-parties.

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Best Practices:

Enforcing Standards;

Discipline;

Investigations and Remediation

- Effectively manage Conflicts of Interest Disclosures.
- Ensure proper screening processes exist for exclusions.
- Consider Management Certifications.
- Distribute guidance and regulatory/industry materials.
- Work with HR on discipline recommendations and discuss possible incentives.
- Include root causes and individual actions in your reviews.
- Ensure investigations are properly scoped, carried out by qualified staff, and followed-up on appropriately and timely.
- Maintain proper documentation.
- Maintain confidentiality. Protect against retaliation.
- Considerations for applying privilege. Work with Counsel.

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General Tips for Compliance Professionals

- Be available and present
- Be sure your program is effective and ever-evolving
- Be credible and use facts backed by research
- Explain the “why”
- Utilize data (internal and external) in your program
- Continue to learn always, invest in ongoing education
- Stay on top of regulatory updates and industry enforcement activity (learn from others)
- Share non-compliance examples in outside organizations to educate
- Understand risk levels and your organization’s risk tolerance
- Communicate clearly, ensure understanding of complex topics
- Don’t be an alarmist, unless necessary

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General Tips for Compliance Professionals

- Plan proper responses where possible and be able to answer off-the-cuff (factually)
- Practice listening, clarify facts through questions (the devil is in the details)
- Provide a forum and communication channels where possible
- Listen to employees, take all complaints and Hotline calls seriously
- Maintain confidentiality wherever possible
- Communicate importance of non-retaliation, safeguard employees
- Know when and where to seek help or outside guidance/expertise
- Build relationships, but be careful to not let them impact your role
- Share wins with Board Members and leadership

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QUESTIONS?

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