



HFMA/NEHIA

2024 Compliance & Internal Audit Conference Investigations Governance: Compliance Role and Expectations

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HFMA / NEHIA Joint: 2024 Compliance & Internal Audit Conference

Investigations Governance: Compliance Role and Expectations

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Presenter Biographies

Dhara Satija



Dhara Satija is director in the Paul Hastings Life Sciences and Healthcare Consulting Group where she leads the group's healthcare consulting practice. She has over 15 years of consulting experience serving healthcare and life sciences clients across an array of issues, including projects ranging from strategy and operations to regulatory and corporate compliance, risk management, and investigation and litigation support. In particular, Dhara has led projects related to: development and implementation of compliance programs (*i.e.*, written standards, training, and monitoring/auditing); design and delivery of internal compliance audits, investigations, and corrective action plans; support for provider self-disclosures/voluntary refunds; government-initiated audits; litigation support services; and Corporate Integrity Agreement (CIA) requirements. Dhara has led several life sciences and healthcare companies with compliance program effectiveness/maturity assessments, compliance risk assessments, Enterprise Risk Assessment (ERA), and Enterprise Risk Management (ERM).

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Maria Joseph



Maria Joseph currently serves as the Chief Compliance and Privacy Officer at Weill Cornell Medicine, bringing over a decade of experience with the institution. She has played a critical role in developing, implementing, and maintaining Cornell's robust clinical compliance and privacy programs. Additionally, Maria provides comprehensive oversight, ensuring adherence to regulatory standards across the WCM campus and Cornell Health. Prior to her role at Weill Cornell Medicine, Maria served as Assistant Vice President and Corporate Compliance Officer at Northwell Health. There, she led compliance and privacy initiatives for a extensive network of physician practices and the ACO program. Maria Joseph holds a Bachelor of Arts in Business Administration from Baruch College and an Executive MBA from Baruch-Zicklin School of Business. She is currently pursuing a law degree and holds multiple specialized certifications in compliance.

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Jane Yoon



Jane H. Yoon is a partner in the Litigation practice of Paul Hastings and is based in the firm's New York office. Ms. Yoon represents corporate entities and their executives in connection with government and internal investigations into allegations of potential violations of the federal anti-kickback statute, health care fraud, the Food Drug & Cosmetic Act, HIPAA, and the False Claims Act. These matters range from conduct surrounding patient support/assistance programs, specialty pharmacy arrangements, clinical trials and investigator-initiated studies, promotional communications, and the full range of interactions between manufacturers, providers, third-party vendors, patients, and payers. Ms. Yoon also handles matters relating to allegations of billing fraud and Medicare risk adjustment practices under Medicare Advantage.

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Today's Objectives:

During this presentation, we will cover:

1. Overview of regulatory and enforcement trends
2. Understand compliance's role and regulatory expectations across the investigations process (investigating, remediation, and reporting)
3. Best practices and practical considerations for managing investigations

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OVERVIEW OF
REGULATORY
LANDSCAPE AND
ENFORCEMENT
TRENDS

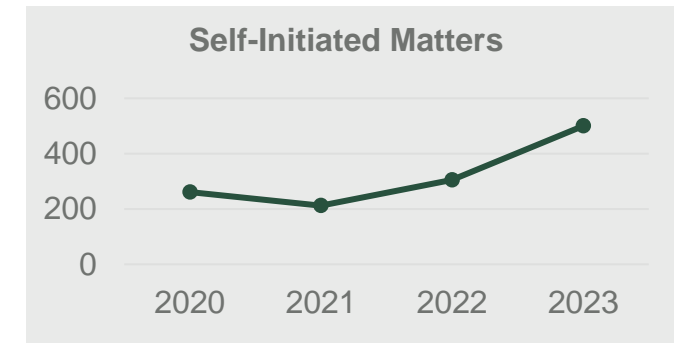
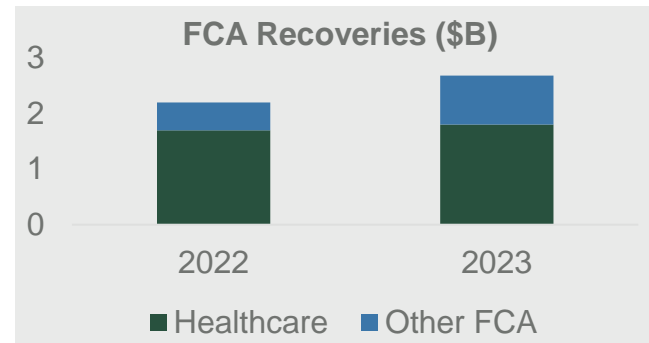


False Claims Act Enforcement Trends

Of the more than \$2.68 billion in settlements and judgments recovered by the DOJ in 2023, **over \$1.8 billion (67%) relates to matters that involved the healthcare industry.**

Recoveries Trend: This represents an increase over 2022 by \$.48B overall and \$.1B related to the healthcare industry.

Self-Initiated Matters: DOJ self-initiated 500 new matters in 2023, the most in any year.



Qui Tam-Initiated Matters: The vast majority of DOJ's 2023 recoveries resulted from qui tam-initiated matters

- In 2023, DOJ recovered \$2.3B from qui tam-initiated matters and \$356M from DOJ-initiated matters

DOJ Enforcement Priorities for 2024

In remarks delivered on February 22, 2024, Assistant Attorney General Brian M. Boynton announced DOJ's FCA enforcement priorities for 2024.

Cybersecurity Fraud

“The first priority I’d like to mention is cybersecurity. In October 2021, the department announced the **Civil Cyber-Fraud Initiative**... These cases have come from a variety of sources, including from whistleblowers and from companies making voluntary disclosures... We expect these cases to continue to be a **significant area of enforcement in the coming years.**”

COVID-19 Fraud

“The False Claims Act has been a critical part of the department’s **COVID-19 Fraud Enforcement Task Force** and has been used to pursue a variety of pandemic related fraud schemes. A significant focus has related to the Paycheck Protection Program (PPP)... Our pandemic fraud work has also extended to... [lawsuits against defendants] that sought to use the pandemic as an opportunity to defraud federal health care programs.”

Healthcare Fraud

“One area of focus is the use of **financial inducements to generate referrals**... Another area that I want to highlight is our use of the False Claims Act to combat schemes involving **nursing homes**... Another significant health care fraud priority for the department is protecting the **Medicare Advantage Program**... Finally, I would like to emphasize the department’s commitment to holding accountable **third parties** that cause the submission of false claims.”

Evolving DOJ guidance & initiatives

2023

2024

JAN
2023

Revisions to the DOJ Criminal Division's Corporate Enforcement Policy ("CEP"), expanding the FCPA Corporate Enforcement Policy to all corporate criminal matters.

FEB
2023

DOJ Criminal Division issued its Voluntary Self-Disclosure Policy for corporate criminal enforcement ("VSD Policy"), which applies to all United States Attorneys' Offices.

JUN
2023

The DOJ Civil Division released formal guidance in 2019 explaining how it awards credit for cooperation during FCA investigations. The DOJ begins explicitly referencing cooperation in its settlement agreements when crediting entities with voluntary disclosure, cooperation, and remediation in FCA.

OCT
2023

DOJ Criminal Division announced a new safe harbor for voluntary self-disclosures made in connection with mergers and acquisitions ("M&A Safe Harbor Policy").

APR
2024

DOJ Criminal Division announced a first-of-its-kind voluntary disclosure pilot program ("Individual VSD Pilot") that would extend non-prosecution agreement eligibility to individuals with potential criminal exposure in connection to corporate misconduct.

AUG
2024

DOJ Criminal Division launched a Corporate Whistleblower Awards Pilot Program ("Whistleblower Pilot") providing awards to individuals with original and truthful information about corporate misconduct.

SEP
2024

DOJ Criminal Division announced updates to its Evaluation of Corporate Compliance Programs ("ECCP"), documenting prosecutor focus on whether and how a company is meaningfully evaluating both its risk profile and the effectiveness of its program.

Individual VSD pilot

Eligibility

- Individuals with criminal exposure—**not including CEOs, CFOs**, high-level foreign officials, domestic officials at any level, or individuals who **organized or led the criminal scheme**

Program Requirements

- **Voluntary, truthful, and complete self-disclosure** of original information regarding misconduct that was unknown to DOJ in certain high-priority enforcement areas
- Provision of **full cooperation** and **substantial assistance** against those equally or more culpable
- **Forfeiture** of any **ill-gotten gains** and compensate victims

Incentive

- When the conditions are met, the DOJ will enter into a **non-prosecution agreement (“NPA”)** with the disclosing individual
- When the conditions are not fully satisfied, the DOJ may exercise discretion to extend an NPA, with supervisory approval and consistent with principles set forth in the Justice Manual



“To put us in the best position to enforce the law and hold culpable individuals and corporations accountable, we are using longstanding law enforcement tools to encourage corporate insiders not only to cooperate, but to come forward and disclose corporate wrongdoing before we discover it through other means.” – **Nicole Agrentieri, Acting Assistant Attorney General, DOJ Criminal Division**

High-Priority Enforcement Areas

- Schemes involving Financial Institutions, including Money Laundering
- Schemes related to Integrity of Financial Markets involving Financial Institutions
- **Foreign Corruption Schemes, including FCPA violations**
- **Healthcare Fraud and Kickback Schemes**
- Federal Contract Fraud Schemes
- Domestic Corruption Schemes involving **Bribes or Kickbacks** paid by or through Public or Private Companies

Whistleblower Pilot

Eligibility

- **Individuals** with **original, truthful information voluntarily** provided in writing about criminal misconduct relating to **specific subject areas of enforcement** leading to a **forfeiture** exceeding \$1 million in net proceeds, and not subject to another **exception** (e.g., DOJ family member)
- **Numerous carve outs** (e.g., subject to attorney client privilege, compliance and audit professionals within 120 days of internal report, etc.)

Program Requirements

- **Original, truthful, and complete** information regarding criminal misconduct unknown to the DOJ
- Provided **voluntarily**
- Related to a pre-defined **subject area**
- Provision of **full cooperation** and **substantial assistance** against those equally or more culpable
- Resulting in a **forfeiture** exceeding **\$1 million** in net proceeds

Incentive

- Escalating award, **up to 30%** of net proceeds forfeited, depending on **significance** and **assistance**



“When a company discovers misconduct within its ranks, we want that company to come forward, so we can gather the evidence necessary to prosecute the individuals responsible . . . any company that hesitates to report voluntarily should remember that we have other tools to uncover that misconduct. Thanks to the whistleblower program announced today, we now have a new investigative tool — and a powerful one at that..” – **Lisa Monaco, Deputy Attorney General**

Subject Areas

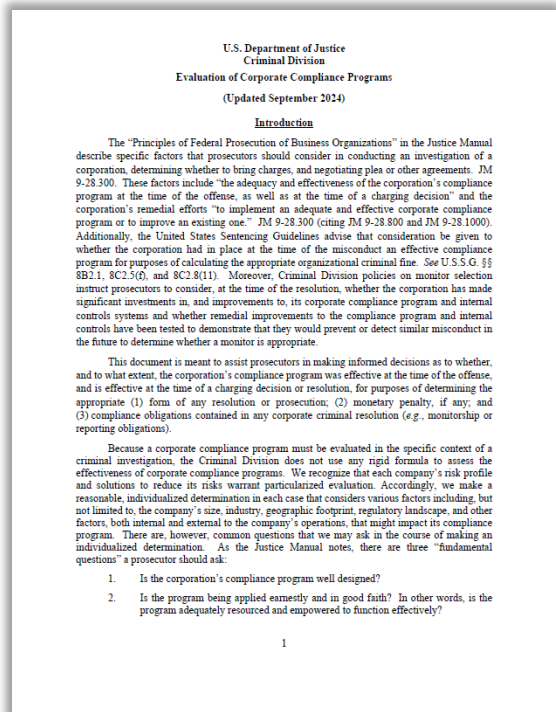
- Violations involving Financial Institutions, including Money Laundering or Fraud
- Foreign Corruption Schemes, including FCPA violations
- Healthcare Fraud and Kickback Schemes, including Private or other Non-Public Programs or otherwise not covered by the FCA
- Domestic Corruption Schemes involving Bribes or Kickbacks paid by or through Public or Private Companies



September 2024 DOJ Updates

On **September 23, 2024**, the DOJ announced updates to its Evaluation of Corporate Compliance Programs (“ECCP”), accompanied by remarks from Principal Deputy Assistant Attorney General Nicole M. Argentieri.

The remarks highlighted three key areas of update:










Click on the image to see the full document





September 2024 DOJ Updates (cont.)

In addition to key changes flagged in the announcement, the update includes other revisions of interest including:

 Policy Design	<p>Enhanced language emphasizing the focus on a company’s process for updating policies and procedures to reflect lessons learned (from the company or others in the industry) and emerging risk (See pg. 6)</p>
 Policy Access	<p>Specifically adding language evaluating how a company “confirm[s] that employees know how to access relevant policies” (See pg. 7)</p>
 Training	<p>Additional questions evaluating whether a company’s training program is tailored to relevant employees, integrates “lessons learned,” and how the company evaluates “employee engagement” with training (replacing prior language on whether employees had been tested on training) (See pg. 9)</p>
 Third Party Management	<p>Integrates additional language specifically evaluating both the timeliness of vendor review, and prosecutor consideration of how the company is “leveraging available data to evaluate vendor risk during the course of the relationship with the vendor” (See pg. 14)</p>
 M&A	<p>Enhanced language around whether the company “account[s] for migrating or combining critical enterprise resource planning systems as part of the integration process,” specifically asking “[t]o what extent . . . compliance and risk management functions play a role in designing and executing the integration strategy.” (See pg. 16) Further, prior inquiries around post-close compliance policies and procedures have been expanded into a new section on “Post-Transaction Compliance Program” – looking at the oversight of the new business, including its integration into the company’s risk assessment, compliance program, and monitoring / audit program. (See pg. 16)</p>
 Autonomy and Resources	<p>Language adjusted to specifically note that compliance resource should have sufficient qualifications as well as seniority, and that the seniority “and stature” should be “both actual and perceived” (See pg. 21)</p>
 Program Effectiveness	<p>Additional language added noting prosecutors should “also consider whether the company’s compliance program had a track record of preventing or detecting other instances of misconduct.” (See pg. 28)</p>

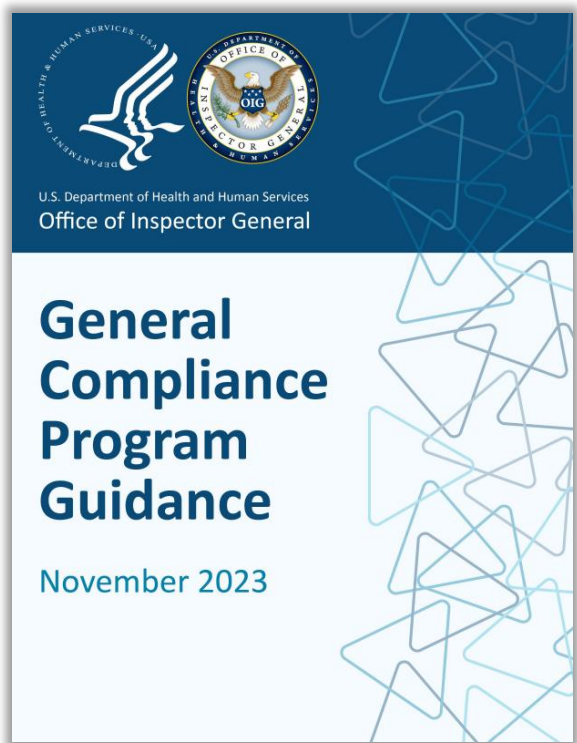
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IMPACT OF OIG
GENERAL
COMPLIANCE
PROGRAM
GUIDANCE ON
INVESTIGATIONS
GOVERNANCE



November 2023 OIG Guidance

On November 6, 2023, OIG published General Compliance Program Guidance (“GCPG”) for the healthcare compliance community. The GCPG includes coverage of:



Although largely a reiteration of pre-existing guidance, the GCPG articulates standards / best practices relevant to investigations governance that, in some ways, are more demanding or novel

OIG Guidance Across the Investigation Process

Establish and publicize procedures for identifying, investigating, and remediating non-compliant conduct

Intake / Triaging

Among HR, Counsel, and Compliance

Compliance involvement in all healthcare compliance investigations

Process integrity

Appropriate steps to prevent destruction & limits conflicts

Engagement of counsel based on scope & severity

Root Cause Analyses

Prevent reoccurrence & strengthen vulnerabilities

Board, Compliance Committee, and CEO Reporting

Incorporation into Trainings and Auditing & Monitoring Plans



Thorough, Independent, and Complete Investigations

Sufficient resources to thoroughly investigate + flexibility to design & coordinate

Per DOJ guidance, independent, objective, appropriately conducted & appropriately documented

Disciplinary Measures

Consistent discipline across individuals

Government disclosures

W/in 60 days of credible evidence of material violations

Governance of Reporting – Intake / Triage



While investigations may be triaged to various functions, the Compliance officer should be involved in and log / track all healthcare compliance investigations

- “The **compliance officer may take responsibility for reviewing some reported concerns, some reported concerns may be referred to** other leaders or departments, for example, **Human Resources**, and some reports, such as those involving substantial legal violations, may be referred **to counsel or law enforcement**.
 - **The compliance officer should remain involved in all health care compliance investigations in which counsel takes the lead.**” – GCPG, p. 52
- “**All disclosures of compliance concerns...should be recorded in a log maintained by the compliance officer ...** The disclosure log should include **pertinent information regarding each disclosure**, such as the date received, the individual or department responsible for review, a *description of the investigation’s findings*, any *corrective actions* taken, any policy or process *changes made as a result of the investigation*, the date resolved, and, if applicable, any resulting referral or disclosure to Federal or State authorities.” – GCPG, p. 51

Governance of Investigating – Process Integrity



Compliance officer or counsel should take steps to preserve evidence + engage external counsel as needed + limit employee or officer conflicts + maintain a record

- “The compliance officer or counsel should **take appropriate steps to secure or prevent the destruction of documents or other evidence** relevant to the investigation.” – GCPG, p. 61
- “Based on the potential scope and severity of the suspected violation and the necessary investigative tasks, **entities should consider whether they need to engage external counsel**, auditors, or health care experts to aid with the investigation” – GCPG, p. 61
- “**If counsel or the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects should be removed** from their current work activity until the investigation is completed (unless an internal or Government-led undercover operation is in effect).” – GCPG, p. 61
- “Regardless of the size or severity of the violation being investigated, **a contemporaneous record of the investigation should be maintained**” – GCPG, p. 61

Governance of Investigating – Thorough, Independent & Complete Investigations



Compliance officer or counsel should take steps to preserve evidence + engage external counsel as needed + limit employee or officer conflicts + maintain a record

- **Compliance Officer responsibilities** “should include...independently investigating and acting on matters related to **compliance**, including the **flexibility** to design and coordinate internal investigations (e.g., responding to reports involving, for example, compliance concerns or suspected legal violations) and to make recommendations for process and policy changes and corrective action” – GCPG, p. 39
 - “**The compliance officer also should have the authority to interview anyone** within or connected to the organization in connection with a compliance investigation or designate an appropriate person to conduct such an interview.” – GCPG, p. 40
- “Compliance programs should include **processes and resources to thoroughly investigate compliance concerns...**” - GCPG, p. 60
- “**Properly Scoped Investigation by Qualified Personnel** – How has the company ensured that the **investigations have been properly scoped, and were independent, objective, appropriately conducted, and properly documented?**” – DOJ *Evaluation of Compliance Program Guidance*, cited in GCPG, p. 36

Governance of Remediation – Root Cause Analyses

There should be sufficient engagement of Compliance to determine / address root causes of misconduct

- **“Throughout an investigation of any noncompliant conduct the compliance officer should be gathering information to aid them in determining the root causes of the conduct.** The compliance officer should...ensure that any ongoing noncompliant conduct is stopped and...should also work with the appropriate individuals to determine the root cause of the conduct so that the entity can make the required changes to prevent a recurrence...[and] determine whether the conduct exposed any compliance weaknesses that could place the entity at risk for other, unrelated misconduct.” – GCPG, p. 63
- **“The Compliance Committee should ensure that the entity takes the necessary steps to prevent recurrence of the misconduct and to strengthen any identified areas of vulnerability.”** – GCPG, p. 63
- **“Root Cause Analysis** – What is the company’s root cause analysis of the misconduct at issue? Were any systemic issues identified? Who in the company was involved in making the analysis?” – DOJ *Evaluation of Compliance Program Guidance*, cited in GCPG, p. 36

Governance of Remediation – Disciplinary Measures

 *Compliance should monitor & maintain a record of consistent individual discipline for similar noncompliant behavior*

- “The entity should include in its guidance and compliance communications its commitment to take disciplinary action or impose other, remedial consequences on a fair and equitable basis. **The compliance officer should monitor investigations and resulting discipline to ensure consistency.** Managers and supervisors should be made aware that they have a responsibility to impose consequences for noncompliant behavior in an appropriate and consistent manner” – GCPG, p. 53
- “**Accountability** – What disciplinary actions did the company take in response to the misconduct and were they timely? ..What is the company’s record (e.g., number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue?...” – DOJ *Evaluation of Compliance Program Guidance*, cited in GCPG, p. 36

Governance of Reporting – Internal Stakeholders



Compliance should communicate reports to Compliance Oversight Mechanisms + communicate investigations risks / results to inform assessments and trainings

- “The compliance officer **should regularly include information about concerns received and investigations** conducted in their communications with the **Compliance Committee** and in their reports to the **CEO and the board.**” – GCPG, p. 52
- “[I]t is important that **the compliance officer act promptly to notify appropriate leaders**...upon receipt of reports or reasonable indications of suspected noncompliance to determine whether a material violation of applicable law has occurred. – GCPG, p. 60
- “Between compliance risk assessments, **the compliance officer should continue to scan for unidentified or new risks, by, for example...evaluating audits and investigation results.** When the compliance officer or the Compliance Committee identifies a new risk...**the Compliance Committee can decide whether and how to address the newly identified risk.**” – GCPG, p. 57
- “An entity also may **develop and require trainings reflective of risks** specific to the entity’s business, role in the health care delivery system, or any risks **revealed through prior investigations or audits.**” – GCPG, p. 47

Governance of Reporting – External Stakeholders

Involve Compliance in voluntary disclosure decision-making

- **“Compliance programs should include processes and resources to...take the steps necessary to remediate any legal or policy violations that are found, including reporting to any Government program agencies or law enforcement where appropriate...”** – GCPG, p. 60
- **“Allegations of noncompliant conduct should be investigated and the outcome of the investigation should determine whether, and what kind of, reporting to the Government is necessary.”** – GCPG, p. 60
- **“As a general matter, if credible evidence of misconduct from any source is discovered and, after a reasonable inquiry, the compliance officer or counsel has reason to believe that the misconduct may violate criminal, civil, or administrative law, then the entity should promptly (not more than 60 days after the determination that credible evidence of a violation exists) notify the appropriate Government authority of the misconduct”** – GCPG, p. 61

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BEST PRACTICES
AND PRACTICAL
CONSIDERATIONS
FOR MANAGING
INVESTIGATIONS



What are various types of Investigations and related sources?

Type	Description
Internal	No government agency involved; company found the issue or allegations themselves; driven by business risk more than legal risk (although both are present)
External	Government agency involved; driven more by legal risk than business risk
Compliance Investigation	Cases involving allegations or suspicions of intentional violations of company policy or law, as well as serious ethical violations (as determined by the company compliance committee)
Personnel Cases	Cases involving complaints about an employee's managerial approach or personal behaviors that are not likely violations of company, law, or serious ethical violations.
Combined Cases	Combined cases involving both compliance and HR elements = Issues/allegations separated out and assigned to HR, compliance, or legal, as appropriate and agreed to by the relevant decision-makers.

Case categories can include:

- Patient Quality and Safety
- Information Security
- Human Resources
- Financial Integrity
- Corruption
- Anti-Competition
- Regulatory Quality
- Vendors and Distributors
- General Compliance
- Government Inquiries & Enforcement

Key considerations

Leading practices

- ✓ Define the scope of the Investigation
- ✓ Keep the audience in mind
- ✓ Limit knowledge about the Investigation
- ✓ Consider need for privilege and create documents to bolster privilege
- ✓ Ask open ended questions and invite additional information
- ✓ Memorialize witness interviews
- ✓ Link recommendations to Investigation's findings
- ✓ Explain conclusions with supporting facts

Common pitfalls

- ✗ Ignore or forget to collect full spectrum of documents
- ✗ Shy away from making credibility determinations
- ✗ Jump to conclusions
- ✗ Fail to follow up on information as it develops
- ✗ Rush to take action before an Investigation is over
- ✗ Put the whistleblower in a position to claim retaliation
- ✗ Forward privileged documents widely
- ✗ Share results of Investigation without considering privilege waiver
- ✗ Make recommendations that will not be implemented
- ✗ Go too hard or too easy on a witness

Fostering a speak-up culture

Fostering an effective speak-up culture is not only crucial for meeting regulatory guidance, but it is also a key factor in mitigating risks and building employee trust.

Regulatory guidance: In most recent September 2024 update, the DOJ further emphasizes that companies should actively encourage employees to speak up and report misconduct. The willingness of employees to report is a crucial indicator of an organization's commitment to compliance.

Essential components of an effective speak-up program:

1. **Accessible reporting channels:** multiple pathways ensure employees feel comfortable expressing concerns, whether in person online or by phone
2. **Clear reporting process flow:** communicating the steps taken after an incident is reported and expected timelines to employees will help them understand how their concerns will be addressed
3. **Transparency and feedback:** communicating to the reporter how the issue is resolved and when appropriate any corrective actions taken
4. **Consistent messaging and management commitment:** ensuring leadership visibly supports the program and holds individuals accountable for maintaining a culture of openness will deepen trust in the process

Ensuring employees feel heard and confident that concerns are addressed internally strengthens organizational integrity and reduces the likelihood of issues going external.

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Q&A



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Thank You!