



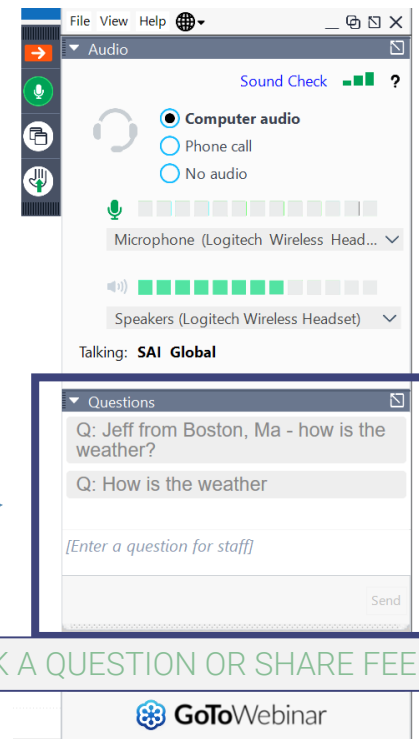
# Evaluating Hotline Program Effectiveness Against DOJ and OIG Standards

Tuesday, November 17, 2020

# Questions or Feedback?

Type your questions in the "Questions" tab.

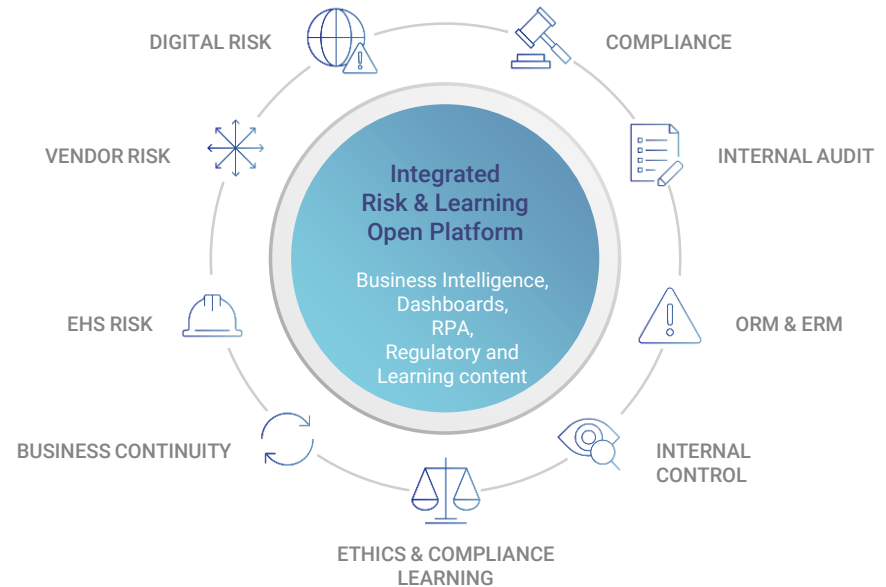
(We encourage this dialog throughout the webcast)



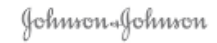
# SAI Global: Risk Management & Ethics Solutions Provider

## WHO WE ARE...

- Leading provider of Risk & Compliance solutions across the globe.
- Ethics content, training, codes of conduct, and technology at the heart of your compliance programs.
- HQ in Chicago and serving customers across North America, Europe, UK, Middle East, Asia Pacific & Latin America.
- Deep domain experience in Healthcare, Life Sciences, Financial Services, and Manufacturing



# Serving the Best-known Healthcare Brands



# PRESENTER



**Richard Kusserow**, CEO Management Services, LLC that worked with over 2,000 health care organizations to provide compliance program advisory services, including the development, operation and management of hotline operations. Previously served 11 years as DHHS Inspector General, where he was responsible for the largest hotline system in the federal government.

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# PRESENTER



**Laurel A. Eakes (Wolfe), CHC, CHPC**, assists organizations with their hotline operations at the Compliance Resource Center. She has over 25 years-experience in the managing and development of compliance and HIPPA programs for hospital systems, home health agencies, physician practices, DMEs, SNFs, Managed Care Organizations, etc. All these included managing hotline operations, including the investigation of complaints and allegations.

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# PROGRAM OVERVIEW

Hotlines are a critical for effective compliance programs

Compliance Officers responsible for ongoing hotline monitoring

This program provides tools for hotline program self evaluation

Content is drawn from:

- OIG compliance guidance documents
- DOJ “Evaluation of Corporate Compliance Programs” guidelines used by prosecutors
- Presenter experience with establishing, monitoring and evaluating hotline operations

Where appropriate points made are cited to the OIG & DOJ

# AGENDA

## ■ BACKGROUND ON HOTLINES

- Why a Hotline, views from DOJ, OIG, USSC
- Hotline Benefits

## ■ HOTLINE STRUCTURE, OPERATION & BEST PRACTICES

- Set-Up and Structure
- Promotion and Awareness
- Call In-Take and Reporter Feedback
- Interviews and Investigations
- Documentation of the Case
- Access to Information

## ■ HOTLINE ONGOING MONITORING & AUDITING

- Ongoing Hotline Monitoring
- Audit Guide for Evaluating Hotline Programs



# BACKGROUND AND INTRODUCTION

# WHY A HOTLINE

- **USSC:** Have and publicize a system that allows for anonymity or confidentiality, whereby employees may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.
- **DOJ:** “Compliance Program Effectiveness Guidelines” has 18 questions focused on hotline operations
- **OIG:** Maintenance of a process, such as a hotline, to receive complaints; and compliance communication, including hotlines, is a critical element of any compliance program
- **CMS** mandatory guidelines call for hotlines
- **SOX Act, HIPAA & Supreme Court** underscore importance

# COMPLIANCE COMMUNICATION

## OIG Compliance Guidance

- Open communication is essential for an effective CP
- Has organization fostered a culture encouraging open communication, without fear of retaliation?
- Is there a hotline permitting staff, contractors, patients, visitors, clinical staff members to report potential compliance issues?

## DOJ Prosecutors ask

- Are reporting mechanisms sufficiently funded?
- Are complaints thoroughly & timely investigated?
- How has company assessed seriousness of allegations it received?
- Do investigative findings result in appropriate follow-up & discipline?
- How is it determined if complaints or red flags merit investigation?
- Are reporting & investigating mechanisms sufficiently funded?

# **HOTLINE BENEFITS**

## **FOR EMPLOYERS AND EMPLOYEES**

- 1. Reporting anonymously/confidentially w/o fear of retaliation**
- 2. Provides alternative communication channel with employees**
- 3. Managers can't hide misconduct, if employees can report it**
- 4. Management benefits from employee experience and insights**
- 5. Demonstrates commitment of about employee concerns**
- 6. Identifies where operations warrant review**
- 7. Detect violations of Code, policies, laws and regulations**
- 8. Evidence of organization commitment to compliance**

# SET-UP AND STRUCTURE

# RELATED HOTLINE POLICIES

## ENSURE SUPPORTING WRITTEN GUIDANCE

- ***Duty to Report:*** Establishes affirmative duty to report violations of laws, regulations, Code, policies & other wrongdoing with penalties for non-compliance
- ***Investigation:*** Provides guidance on investigating reports
- ***Non-Retaliation:*** Guard against anyone taking reprisals against someone filing a complaint via the hotline.
- ***Anonymity:*** Guarantees right to reports w/o identifying
- ***Confidentiality in Reporting:*** Ensures those requesting confidentiality will have their identity guarded
- ***Records and Document Management:*** Proper maintenance
- Coordination of investigations policies with HR & Legal Counsel
- ***Hotline Auditing and Monitoring:*** Continuous review & updating

# INVESTIGATION POLICY

## **DOJ Prosecutors ask:**

- What processes for routing complaints for investigation?
- Are complaints thoroughly investigated in a timely manner?
- How are complaints determined to merit investigation?
- Is there timely and thorough investigations of allegations or suspicions of misconduct?

## **OIG Compliance Guidance**

- Develop policy/procedures for prompt, thorough investigation of alleged misconduct.

# PROTOCOLS WITH HR & LEGAL

## **DOJ Prosecutors ask:**

- How is it determined who should investigate?
- What resources are in place to investigate suspected misconduct?
- What processes for routing of complaints to proper personnel for investigation?

## **OIG Compliance Guidance**

- Establish methods for coordination of internal investigations.



# CONFIDENTIALITY

## USSC

- ❑ Have and publicize a system that allows for confidential reporting by employees reporting or seeking guidance regarding potential violations without fear of retaliation.

## OIG Compliance Guidance

- ❑ Should always strive to maintain confidentiality of employee's identity
- ❑ Once accepted, management assumes responsibility for that person

## DOJ Prosecutors ask:

- ❑ Did company have anonymous reporting mechanism, if not, why not?
- ❑ Are employees able to confidentially report allegations of a breach of company's code of conduct, policies, or suspected or actual misconduct?

# ANONYMITY

## USSC

- Have and publicize a system that allows for anonymous reporting regarding potential or actual criminal conduct.

## OIG Compliance Guidance

- Employees should be permitted to report matters anonymously
- Means no way to trace source of contact
- Attempts to identify anonymous sources should result in adverse action

## DOJ Prosecutors ask

- Are employees able to anonymously report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct?

# NON-RETALIATION/NON-RETRIBUTION

## OIG Compliance Guidance

- Need to take all necessary steps to prevent intimidation, threats, coercion, discrimination against, or any other retaliatory action against anyone for reporting to the hotline in good faith perceived wrongdoing
- Organization will take adverse action against those violating policy

## DOJ Prosecutors ask

- What evidence that complaint-handling process includes proactive measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers?

# HOTLINE SET-UP



- Establish reporting channels (e.g., telephone, online)
- Set-up records management
- Implement policies/procedures
- Develop auditing/monitoring protocols
- Roll-out hotline program
- Maintain/manage hotline program

# REPORTING SYSTEM

## MUST...

1. Be readily available (e.g. 24 hours a day, 365 days a year)
2. Be both live and web-based reporting
3. Provide ground rules to reporters
4. Not trace or record calls, phone numbers or IP addresses
5. Follow standardize question/reporting
6. Permit choice to remain anonymous or self identify
7. Provide a PIN for future communication
8. Provide protection of identity for confidential callers
9. Have reports of calls submitted the same day of call

# **USE OF VENDORS**

# MOST USE VENDORS

## 2020 COMPLIANCE BENCHMARK SURVEY FINDINGS

- 70% use hotline vendors
- However many still maintain an internal hotline
- 60% use a voice mail as hotline or supplemental to it
- Only 2% reported no hotline
- 58% Web-based reporting along with their hotline

# CHECKLIST FOR HOTLINE VENDORS

## DOES VENDOR...

1. Charge a fixed rate or sliding rate based upon number of calls?
2. Evidence knowledge/expertise of healthcare related issues?
3. Provide 24/7 service?
4. Provide both live operators & web-based reporting?
5. Carry liability insurance for any damage due to their negligence?
6. Permit cancellation by simple 30-day notice? If not, don't use them.
7. Identify a client relations person to address questions/issues?
8. Want you to use their phone number?
9. Offer language translation service for non-English speakers?
10. Assist with protocols on following up on complaints received?
11. Offer to sign a HIPAA PHI BAA? Do they know it's meaning?
12. Provide full written report same day of call?
13. Immediately call for urgent matters? If not, don't use them.
14. Deliver call reports by the most secure means?



# ADDRESSING VENDOR PROBLEMS COMMON COMPLAINTS

1. Using Vendor's Phone Number
2. Cancellation Difficulties
3. Impersonal Services & Use of IVR
4. Non-secure Report Delivery
5. Business Associate Agreement (BAA)
6. Don't understand Healthcare Issues
7. Receiving Someone Else's Reports
8. Don't understanding PHI issues
9. Budget Overrun



# **PROMOTION AND AWARENESS**

# HOTLINE PROMOTION & ACCESS

## OIG Compliance Guidance

- How well is the hotline publicized?
- Is hotline number made readily available to all employees by conspicuously posting it in common work areas?

## DOJ Prosecutors ask

- How is the reporting mechanism publicized?
- Does the company take measures to test whether employees are aware of the hotline and feel comfortable using it?
- How has the company assessed whether its employees know when to seek advice and whether they would be willing to do so?

# HOTLINE PROMOTION

- Promote the hotline through:
  - Signage/posters
  - Wallet cards, pens, mouse pads, giveaways
  - Phone stickers, badge labels, screensavers
  - Intranet
  - Compliance Week
- Raise awareness of the hotline through:
  - Annual training, new hire training, other related training
  - Code of Conduct
  - Employee newsletter
  - E-mail reminders
  - Real life scenarios

# TRAINING ON REPORTING

## USSC

- Take reasonable steps to communicate compliance periodically and in a practical manner by conducting effective training programs

## DOJ Prosecutors ask

- How is the reporting mechanism publicized to employees?

## OIG Compliance Guidance

- Purpose is to increase knowledge, comfort & confidence in reporting
- Explain hotline use to employees, vendors, contractors & medical staff
- Duty to report all violations of law, regulations, Code & policies
- Right to report, confidentially or anonymously
- Not retaliation for reporting will be permitted

# **CALL IN-TAKE AND REPORTER FEEDBACK**

# HOTLINE REPORTS

## **OIG Compliance Guidance**

- How many and what types of calls are received?
- How are hotline reports of complaints?

## **DOJ Prosecutor ask:**

- Have there been reports receive reports from employees?

# FACTORS AFFECTING REPORT VOLUME

- Recent/new training about the hotline
- Release of promotional material about the hotline
- Level of employee confidence in management address problems
- Events that excite employee awareness of workplace problems
- Concern about changes in work conditions
- Publicity, good or bad, about the organization
- Regulatory agency interest shown in the organization
- New and/or unpopular policies being initiated



# TYPICAL HOTLINE REPORTS

- Many complaints have multiple allegations
- 75% or more reports will have personnel-related issues (e.g. favoritism, unfair treatment, and employee relations issues).
- Many calls lack substantive or actionable information (e.g. Venting Calls)
- Critical to a working relationship established with HR to appropriately address these types of concerns.
- What is the typical volume???

# CALL PROCESS

## VERIFY FOLLOWING GUIDELINES ARE BEING FOLLOWED

- Ground rules reviewed (anonymity/confidentiality, no retaliation)
- Establish rapport (be empathetic, not sympathetic)
- Reporter fully debriefed
- Reporter permitted to tell their story
- Listen and take notes
- Clarify (who, what, where, when and how)
- Recap and review from notes
- Provider reporter with PIN and instructions on how to follow-up
- End call
- Complete report

# DEBRIEFING CALLERS

ENSURE THE FOLLOWING PRACTICES ARE BEING FOLLOWED

- Basic questions are asked (who, what, when where, why, how):
  - Open-ended questions to tell their story
  - Narrowly Focused Clarifying Questions
  - Opinion Questions
- Those taking calls avoid:
  - Leading questions suggesting a desired answer
  - Negatively phrased questions
  - Compounded questions
  - Overly complex questions
- Reports include...
  - All relevant information
  - Identify all key issues
  - Presented clearly & concisely

# REPORTER FEEDBACK

## CONTINUING CONTACT WITH REPORTER

- Provide reporter a secure means to follow-up and/or obtain additional information
- Maintain ability for follow-up questions of anonymous reporter
- Provide reassurance their issues are being investigated
- Provide only general, not detailed, feedback as to resolution

# **INVESTIGATING HOTLINE ALLEGATIONS**

# INVESTIGATING & RESOLVING HOTLINE COMPLAINTS

## OIG Guidance

- Promptly investigate all complaints and allegations
- Work with other departments and management to resolve
- Disclose when evidence of civil or criminal law violations
- Verify any corrective action measures taken
- Document complaint receipt, investigation, resolution & corrective action

## DOJ Prosecutors ask:

- Are investigative findings resulting in appropriate follow-up and discipline?
- How does company determine which complaints merit further investigation?
- What investigation resources are in place to investigate suspected misconduct?
- Are complaints thoroughly & timely investigated?
- What are processes for routing of complaints to proper personnel for investigation?
- How has company assessed seriousness of allegations it received?
- Is there a well-functioning & appropriately funded mechanism for timely and thorough investigations of any allegations?

# INVESTIGATING HOTLINE COMPLAINTS

## THINGS TO CONSIDER AND DO

- Promptly investigate alleged violations of laws/regulations
- Independently investigate Hotline complaints
- Must be able to review all relevant records
- Serious allegations involve interviews, document review
- Decide if need of assistance (Legal Counsel, auditors, or others)
- Have a policy on when legal counsel should be involved
- Document all steps taken
- File interview notes and key documents
- Maintain a log of the witnesses interviewed
- Establish a process to document privileged investigations
- Detected but uncorrected misconduct may result in serious liability
- Take prompt disciplinary action where warranted
- Ensure appropriate corrective action promptly implemented
- Legal Counsel should review evidence of violations of laws/regulations to determine whether to refer to authorities

# INVESTIGATIVE REPORTS



# HOTLINE LOG

## DOES IT...

- Describe caller issues in general terms?
- Identify who received information?
- Note date/times report is received, assigned & resolved?
- Identify to whom matter was referred for resolution?
- Keep track of calls from inception through resolution?
- Track a timeline on issues being tracked?
- Note how allegations were resolved?

# MANAGING HOTLINE INFORMATION

## OIG Compliance Guidance

- Evidence caller information was properly & timely investigated
- A log should be maintained by records date, time, nature of information provided, how was the matter resolved.
- Look for patterns of systemic problems
- Summary reports on results of hotline reports should be reported to CEO, compliance committee & board

# ACCESS TO HOTLINE REPORTS

## OIG Compliance Guidance

- Define roles for accessing hotline information
- Establish report dissemination protocols
- Establish investigator assignment protocols
- Establish/follow records management policy
- Maintain reports while being investigated
- Limited access controls
- Secure storage of all information (Beware loose paper)
- Transmission security (Beware of e-mail)

## DOJ Prosecutors ask

- Did compliance have full access to reporting & investigative information?

# MANAGING HOTLINE REPORTS

## DOJ Prosecutors ask

- How has company collected, tracked, analyzed, and used information from its reporting mechanisms?
- What are processes for routing of complaints to proper personnel for investigation?
- Does company periodically test the effectiveness of the hotline, for example by tracking a report from start to finish?
- What steps does company take to ensure investigations are properly documented?
- Is there root cause analysis of contributed to misconduct & what preventative steps are needed to prevent similar events in the future?

# MANAGEMENT OF HOTLINE REPORTS

## SHOULD INCLUDE...

- Case tracking number for the call report
- Date and time of receipt of the call
- Identity/phone number of the caller, if they provide it
- Location of the reported issue
- Department, program, or operation involved
- Description of the problem being reported
- Any monetary implications
- Name of designated action official assigned to the case
- Any action steps taken
- Final disposition
- Date the case was closed

# RECORDS MANAGEMENT

- Includes creation, distribution, retention, storage, retrieval, and destruction of documents
- CCO must be responsible for proper maintenance of all hotline cases, including documentation of information provided during the call, nature and results of any investigation, implementation & effectiveness of any corresponding corrective action measures
- Hotline cases involve a variety of legal issues, especially in relation to privacy and confidentiality, therefore, policies and procedures should be developed in consultation with Legal Counsel
- Records should be maintained and available for independent auditing and for any possible litigation reviews and audits

# **HOTLINE CASE MANAGEMENT INVOLVES**

- **Coordination of report intake and all parties involved in resolving complaints**
- **Standardization/consistency in evaluation, investigation & resolution of complaints**
- **Proper documentation of complaints**
- **Coordination of all types of complaint received**
- **Easily can produce tracking data and trend analysis**

# REPORTING TO MANAGEMENT

## OIG Compliance Guidance

- Hotline management requires regular summary reports be submitted to senior management, informing them of significant findings and recommendations arising from calls
- Summary reports of findings, actions, and recommendations should be included in reports to the governing body, the CEO, and Compliance Committees

## DOJ Prosecutors ask

- What types of reports, findings, and remediation processes have been reported to management on a regular basis?



# REPORTING TO MANAGEMENT/BOARD

## NEED TO KNOW STANDARD

- It is important to keep management and board informed of results from the Hotline investigation, however, do **not** report raw information, as it directly involves them in a way that could create problems and potential liability
- Identity of confidential reporters may be compromised
- Identity of individuals accused may be exposed that may prejudice their opinion of them (they may be found innocent)
- Those at the highest level involved with receipt of allegations bear responsibility as to how the matters were handled and results from investigations
- Follow the “Need to Know” standard

# **HOTLINE OPERATION ONGOING MONITORING & AUDITING**

# ONGOING HOTLINE MONITORING/AUDITING

## DOJ Prosecutors ask

- How has the company collected, tracked, analyzed & used information from its reporting mechanisms?
- Does company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?
- Are complaints thoroughly & timely investigated?
- How has company assessed seriousness of allegations it received?
- Is there periodically testing effectiveness of hotline (e.g. tracking a report from start to finish)?
- Are reporting & investigating mechanisms sufficiently funded?

# RESPONSIBILITY FOR ONGOING HOTLINE MONITORING & AUDITING

## OIG Compliance Guidance

- A primary CO responsibilities is to monitor and verify hotline operates in conformance with its objectives.
- OIG calls for ongoing monitoring of all program operations to verify following all protocols, policies and procedures
- Program manager are responsible for monitoring, so in the case of the hotline it is the Compliance Officer
- Also expects periodic ongoing auditing by independent reviewers, meaning it cannot be the Compliance Officer
- Results of reviews need to be provided to executive and board oversight committees in assessing the program effectiveness.

# REVIEW SUPPORTING DOCUMENTATION

- Forms used to track comments from callers
- Letters received from employees about compliance issues
- Reports used to track and trend calls
- Results of investigations and steps taken to investigate calls
- Filing and numbering systems
- Procedures for anonymous calls
- Hotline policies and procedures
- Documentation for calls made by employees directly to the CO
- Verify hotline posters are prominently displayed in work areas
- Determine if they clearly explain how the hotline can be accessed
- Review promotion (newsletters, Intranet, management letters, etc.)
- Examine compliance training programs to determine whether the availability and access to the hotline is explained, as well as their rights to file reports anonymously, confidentially, without fear of retribution and retaliation.

# REVIEW OF HOTLINE REPORTS

- Are all reports written & submitted same day of receipt of call?
- Has reports complete, sufficiently clear for appropriate action?
- Does information detail complaint & individuals named?
- Are reports acted upon promptly & thoroughly per nature of allegations or complaints?
- Was promised confidentiality maintained while matters were being investigated?
- Have there been any reports of reprisals from people who filed a hotline complaint or allegation?

# REVIEW OF TRACKING DATA

- Determine annualized call volume as percentage of employees
- Review trending data for significant variations in call volume & if such changes relate to management or policy changes
- If so, take steps to further investigate the reason for this
- Is the CCO & HR retrieving call reports in a timely manner
- Verify that investigation of matters are timely
- Ensure that all cases are brought to resolution

# HOTLINE SECURITY

- Examine how hotline reports are handled
- Are documents relating to hotline reports kept in a secure area with limited access?
- Is all hotline information kept in storage accessible only by lock and key?
- Is there a log kept on who had access to hotline information?



# CONCLUDING COMMENTS

# EFFECTIVE HOTLINE PROGRAMS TIPS

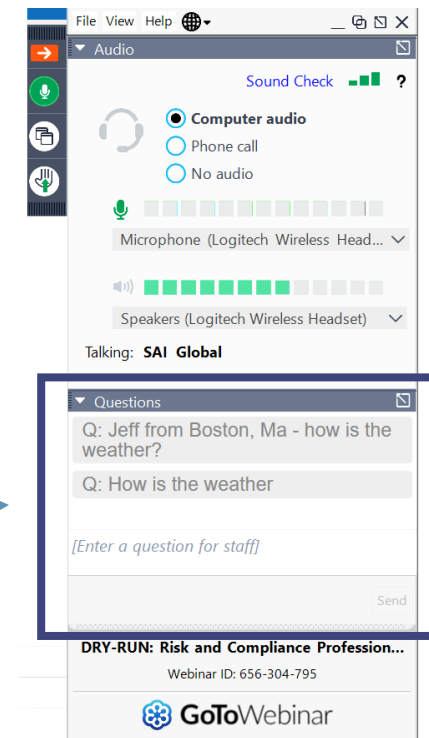
1. Implement related policies as noted in the presentation
2. Log and track all complaints/allegations from receipt through resolution
3. Ensure those investigating allegations are properly trained
4. Document all steps in resolving hotline complaints/allegations
5. Have hotline posters on employee bulletin boards
6. Ensure hotline topic is included in new employee orientation
7. Set time frames for completion/resolution of complaints
8. Ensure the hotline program is part of annual compliance training
9. Have hotline information made part of the Employee Handbook
10. Consider having a flyer go out to all employees on hotline availability
11. Include information about the hotline on Intranet
12. Use newsletter to promote the hotline
13. Maintain a document management system for compliance records
14. Ensure records are kept in a secure limited access area
15. Develop summary reports for management/Board on hotline results

# POLLING QUESTION



# Q&A Session

Type your questions in the "Questions" tab





# Thank you.

For more information, visit:

SAI Global for Healthcare: <https://www.saiglobal.com/risk/industries/healthcare-health-insurance>

Strategic Management Services: <https://www.compliance.com/>

With additional questions, please email: **[info.request@saiglobal.com](mailto:info.request@saiglobal.com)**