

Investigation, Response and Prevention Process

A. GOALS

- To discover the facts and circumstances related to specific risks of legal, regulatory and/or policy noncompliance.
- To analyze the facts discovered to determine whether the conduct was illegal or legal, whether or not in violation of the organization's code of conduct or other compliance standards/policies, and evaluate the organization's risks and obligations.
- To address disciplinary requirements.
- To address resolve non-compliance with appropriate actions and prevent reoccurrence.
- To promote accurate and detailed documentation of the investigation, response and prevention process.

B. PROCESS

1. Allegation

- a. Method received
 - i. Hotline
 - ii. Phone call
 - iii. In-person
 - iv. Letter
 - v. Email
- b. Source
 - i. PHC source
 - ii. External source
- c. Confidentiality considerations
 - i. Anonymous source
 - ii. Source requested anonymity
 - iii. Retaliation concerns voiced

2. Who will investigate based on initial understanding of allegation

- a. Chief Compliance Officer
- b. General Counsel
- c. Human Resources
- d. Manager
- e. Risk – Insurance
- f. Outside counsel
- g. External vendor
- h. other

3. Investigation methodology

COMPLIANCE

- a. Review of records/documentation
 - b. Audit
 - c. Interview(s)
4. Determine what actually occurred.
- a. Was this an illegal action?
 - i. Considerations:
 - Regulatory (OIG, CMS, OCR, DOJ, etc)
 - Antitrust
 - Billing/Coding
 - Clinical Investigation/Research
 - Vendor/Service Contracts (eligibility, BAA, illegal relationships)
 - Cost Reports
 - EMTALA
 - Environment (Hospital Operations/Physical Plant)
 - ERISA
 - Financial Reporting
 - Health and Safety
 - Privacy/Information Security
 - Labor, Employment , Human Relations
 - Licensure
 - Accreditation & Certification
 - Marketing & Advertising
 - Medicare Conditions of Participation
 - Physician Services/Practices Anti-kickback/Stark
 - Political Activities
 - Procurement
 - Joint Ventures
 - Records Management & Disclosures
 - Tax Compliance
 - Crime on premises
 - b. Was this a policy violation?
 - i. Considerations:
 - a) Policy issue?
 - Revision needed?
 - Assign responsibility
 - Re-education?
 - Assign responsibility
 - b) Process issue?
 - Re-education?
 - Assign responsibility
 - Process improvement?
 - Assign responsibility
 - c) Issue not currently defined in a policy but should be?
 - Assign responsibility

COMPLIANCE

- c. Individuals involved and/or responsible for allegation
 - i. Employee
 - a) Non-management
 - b) Management
 - c) executive
 - ii. Physician
 - a) Employed
 - b) Non-employed
 - iii. Contracted person
 - iv. Vendor/company
 - v. Student
 - vi. Volunteer
 - vii. Patient
 - viii. Visitor
 - ix. Board member

- 5. Actions and mitigation
 - a. Considerations
 - i. Immediate, potential physical danger
 - ii. Immediate, potential environmental danger
 - iii. Property damages
 - iv. Identity theft
 - v. Criminal intent
 - vi. Malicious intent
 - vii. Honest mistake/error
 - viii. Public relations
 - b. Notifications?
 - i. General counsel
 - ii. Outside counsel
 - iii. Federal agency
 - iv. State agency
 - v. Local agency
 - vi. CEO
 - vii. Board
 - viii. Vendor/company
 - ix. Public relations
 - x. Patient
 - xi. Visitor
 - xii. Medical staff
 - xiii. Staff (ALL, Medical Records, PFS, HR, etc.)
 - xiv. Risk-Insurance
 - xv. Manager/VP/EVP
 - xvi. Contracted individual
 - xvii. Individual(s) assigned responsibilities
 - xviii. Volunteers
 - c. Actions taken

COMPLIANCE

- i. Internal
 - Disciplinary
 - Process
 - Policy
 - Technical
 - Other
 - ii. External
 - Contractual
 - Legal
 - Other
6. Documentation and maintenance
- a. Date/time and how issue was brought to attention
 - b. Investigation steps
 - c. Investigation results
 - d. Persons involved
 - e. Actions taken
 - f. Preventative measures
 - g. Communication/letters/memos sent
 - h. External communication/letters/legal documents received
 - i. Timeline(s) for implementations
 - j. Follow-up to actions taken/implementations