Effective Internal Investigations

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Essential to:
- Demonstrating an organization’s commitment to ethical behavior, quality care, patient safety and compliance
- Serving as a deterrent to wrongdoing
- Encouraging reporting of suspected violations by demonstrating that concerns will be addressed promptly and honestly
- Identifying appropriate disciplinary measures
- Determining the root cause of misconduct
- Acquiring sufficient information to self-report to the government, as appropriate

Disclosure Program

Policies and procedures to require and encourage reporting
- Code of Conduct
- Reporting Obligations
- Reporting Adverse Events
- Research Misconduct
- Non-retaliation

Mechanisms/communication channels for receiving concerns and allegations
- Integrity Line Hotline/Web-portal
- “Open Doors”
- Safety Center/Patient Safety
- Human Resources
- Patient Relations
- Supervisors/Other Members of Management
Disclosure Program

Types of cases
- Workplace Environment
- Patient Safety/Quality of Care
- Compliance and Business Ethics
- Information Privacy and Security
- Patient Relations
- Informational Requests

Anatomy of an Investigation

Based on our experience and information gained from recent third-party review of Parkland’s Investigation Process.

Review and Assignment
- Allegations/concerns should be reviewed promptly and assigned to an investigator, as appropriate
- Immediate attention to “emergency” issues
- Based on content of allegation/concern, determine which functional area is best suited to follow-up
- Determine if investigation should be conducted under attorney-client privilege
- Consider if organization desires all issues to be tracked
- Consider uniform case management platform – allows for more efficient data collection and analysis
- Utilize third-party benchmarking data

Assignment to an Appropriate Investigator
- Investigator must have appropriate subject matter knowledge
- Consider written triage process/guidelines that specify how issues should be assigned

Impartiality and the Appearance of Fairness
- Investigator should have no reason to be biased
- Written guidance to address perceived bias/conflict of interests
Investigator Training
- Effective investigative techniques – planning, evidence gathering, interviewing technique, credibility assessments, confidentiality, report writing
- Indicator – substantiation rate of investigations differs from trusted benchmarks
- Develop detailed guidance on Investigative Process

Insulation Against Interference
- Important that senior officials do not make effort to interfere or influence investigation
- Only provide information to managers and others which is strictly necessary

Case Management/Prompt Completion of Investigations
- Important to ensure corrective action, if necessary, is taken as soon as possible
- Enhances confidence that allegations will be addressed appropriately
- Use third party benchmarking data to set target for closure time
- Identify any systemic issues and/or resource needs contributing to long closure times

Communication of Findings/Investigation Reports
- Investigator must determine whether allegation is substantiated in whole, in part, or not at all
- Results must be communicated to those who need to know – those who will determine corrective action and those who have oversight responsibility
- Provide sample report as a reference for investigators

Document Management and Records Retention
- Important to have a document management process and retention policy for investigation files

Review of Investigation Data
- Time taken to close investigations
- Percentage of allegations substantiated
Privilege Considerations

Protectable Material
- Attorney-Client Privilege
- Attorney Work Product
- Peer Review Privilege
  - Medical, Nursing, Pharmacy
- Quality Assurance Privileges
  - Medical Committee
  - Compliance Office Activities
  - Patient Safety Organization
- Physician-Patient Privilege
- Health Information
  - HIPAA
  - Physician-Patient Privilege

General Rules
Waiver of Protection

Common Privileges
- Attorney-Client Privilege
  - Discussions seeking legal advice between an attorney and a client or their representatives are privileged
- Attorney Work Product Privilege
  - Material and mental impressions developed in anticipation of litigation
- Peer Review Privilege
  - Discussions and records of peer review committees evaluating competence of care providers are privileged
- Quality Assurance Privileges
  - Discussions and records of medical committees conducting a specific investigation or evaluating quality of medical and health care services are privileged
  - Discussions and records of compliance office regarding compliance activities are privileged
  - Discussions and records regarding patient safety data concerning adverse events, errors and outcomes are privileged
  - Discussions and records of formal joint medical or quality assurance committees of one or more health care systems are privileged

Physician-Patient Privilege
- Physician-Patient confidential discussions concerning professional services/care are privileged
- Medical Records are also protected

Health Information
- HIPAA: Any information about health status, provision of health care, or payment for health care that can be linked to a specific individual (patient, care, and payment) is privileged
- Physician-Patient discussions concerning professional services/care are privileged
Privilege Considerations

Medical Committee Related Privileges

Quality Committee Structure

Privilege Considerations

General Rules

- Limit discussion to members or designated representatives of the board, committee, or formal team handling the matter
  - Representatives, agents, or team members must be necessary to addressing the issue or carrying out the purpose at hand
  - Formalize the relationship with the representatives, agents, or team members
  - Utilize the Need-to-Know approach

- Place appropriate legends denoting the applicable privilege(s) on all material (electronic and hard copy)

- Take reasonable steps to ensure any such information is kept in a confidential manner
  - Physical location; access; staff

Privilege Considerations

General Rules

- The subject matter/content of the discussions must be handled in accordance with the confidentiality rules applicable to the underlying privilege/exception
  - If peer review protected, then handle as peer review protected material
  - If Medical Staff or Compliance Privileges, then handle accordingly
  - If attorney-client privileged, then handle as attorney-client material, etc.

- Limit discussions and handling as required to protect the applicable privilege
Privilege Considerations

Waiver of Protections

- Waiver of Privileges
  - Violate the general rules
  - Client can waive privileges
  - Upjohn Warning
- Generally, disclosure to individuals that are not members or designated representatives of the board, committee, or formal team handling the matter can waive the protection
  - May constitute violations of individual privacy rights
- Waiver does not result from disclosures to licensing, accreditation, and similar agencies including disclosures in formal state or federal proceedings such as:
  - Disciplinary hearings/administrative proceeding, civil or criminal proceedings
  - Court orders
  - Physician/nursing/pharmacy licensing and accreditation bodies or agencies