



Health Care Investigations

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Overview

Why the Health Care Environment creates unique challenges?

What are the basic tenets of a health care investigation?

What else can affect an investigation?

Lessons learned



Unique Challenges

Health Care: Gallery A versus Gallery B

Best in Class and Ranking

Patient Injured in your care

Preferred Choice for Care

Trustworthiness of Physicians and Staff

Best Place to Work

Unhappy workforce

Success Stories

Deceptive Practices

Healthcare in 2019: Radical Transparency

Inaction = Risk

Failure to act decisively is seen as failure to act.

Managing in an environment that is continually evolving

The regulatory environment is complex...and the regulatory environment is far behind care and technology

Knowledgeable patients

Keep up with changes in risk and risk acceptance

Drivers of Change

Health care is under the microscope.

RISKS

SVSH

Harm to Patient

Harm to Staff

Harm to
Institution

Harm to Public

Jackson Health's HIPAA Violation Costs US\$
2.15 million fine

By CISOMAG - October 29, 2019 35 0

**\$400,000 HIPAA Penalty Agreed with Denver FQHC
for Security Management Process Failures**

**OCR Fines Florida Contractor Physicians' Group
\$500,000 for Multiple HIPAA Compliance Failures**

**\$999,000 in HIPAA Penalties for Three Hospitals for
Boston Med HIPAA Violations**

**St. Joseph Health to Pay OCR \$2.14 Million to Settle
HIPAA Case**

SHARE



Tenets of a Healthcare Investigation

Tenets

The safety and care for the patient is paramount.

Inaction = Risk.

Communication and consensus for action is central to resolution.

Recognize when institutional interest diverges from interest of physician or researcher.

Doing the right thing rather than wrapping it up.



Prioritizing health care investigations





Patient Care

Immediate Harm or Threat to Patient Safety

Governing Authority or other Available Action

Medical Staff

Leadership action

Standard of Care

Policies

Medical Staff

Medical Board

Expert Opinion

Patient Experience

Perception = reality

Inherently trusting or inherently skeptical

Patient Care Environment and Culture

Patient Experience

Patient Expectations

Staff Interaction

Staff Expectations

Patient Experience Initiatives

Culture within the clinic/unit

Staff discontent might mean more

Regulatory Expectations

Code of Conduct

Policies and Procedures

Laws, Regulations, and Codes

Community Relationships

Patient Relationships

Personal Experience

Social Media – Who Reviews?

Community Interaction

Branding

Inurement

Court of Public Opinion

Public Standard

Media

Organizational Culture

Culture v. Strategy

What's for lunch?

No amount of planning can overcome culture.

Subcultures

Leadership

Tone at the top

During an investigation

Code of Conduct

Training

Policies

Payment

Appropriateness of Claims

False Claims

Care “quality”

Patient Financial Relationships

Public expectation v. understanding

Patient knowledge of treatment and billing

Stark and AKS

Outside Activities

Conflicts of Commitment

Conflicts of Interest

Vendor Influence



What else can affect an investigation?

Every investigation has a running clock

Actions of the _____ (patient, employee, 3rd party)

Pressures from leadership.

Pressure from those subject to investigation.

External Reporting Requirements.

Establishing Standards for Findings.



Other considerations

Coordination with Counsel and the exercise of Attorney Client Privilege.

Represented Workforce and the coordination with Human Resources.

Managing talk outside of the investigation.

Subject Matter Expertise.





Lessons Learned

Reactive v. Prospective Environment

Risk Reactive versus Risk Based

- Government (HHS) expects more than reactive

7 elements versus Effective Program

Risk Assessment, Measurement and Monitoring

- Not just dollars and cents, not just “traditional” problems

Leadership Engagement and Buy In

Partnership

During the Investigation

If there are systemic issues are we working to fix them immediately?

Could it happen again?

Have you involved all fact finders and decision makers and experts?

- Title IX, other compliance, OR, OGC?

Making a potential whistleblower an ally

After the Investigation

Are all relevant leaders fully informed, including past misconduct in other areas?

Are all relevant leaders deciding whether to take remedial action?

- P&T v. Medical Staff v. Department Chair v. IRB

Have changes been operationalized?

- Is there a team working on remediation with deadlines and documented completion?
- If P&Ps are changed are they announced and recirculated?

Does the compliance team have sufficient detailed knowledge to convert investigative findings into corrective actions which are operationalized?

7 elements of a Compliance Program

Written Policies and Code of Conduct

Compliance Officer and Oversight

Training and Education

Open Lines of Communication

Monitoring, Auditing and Internal Reporting

Enforcement through well-publicized disciplinary guidelines

Corrective Action Plans

How these are tied to an investigation—constant testing of integrity and effectiveness.

Tone at the top

Resourcing and volume of activity

Subject Matter Expertise