

Health Compliance's Role in Multi-Unit, Cutting Edge AMC Investigations

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1

Overview

- We used to be HCCOs, too.
- AMC investigations are already challenging.
- When the AMC is a public entity and multiple units across the campus and / or system are involved, the challenges multiply and planning is critical.
- Today, we focus on challenges, strategies and case studies for the HCCO regarding multi-unit AMC investigations (which we are seeing more and more).



2

Why is a Public Entity AMC Investigation Different?

- Public Mission v. Profit-Driven Mindset
 - Heightened Commitment to Accountability/Scrutiny
 - State Government Officials
 - Media
 - Community
 - Public Board with Multiple Layers of Oversight
 - Leaders Without Healthcare Expertise
- Increased Financial, Operational & Reputational Stakes



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3

Why is a Public Entity AMC Investigation Different? (Cont'd)

- Multiple Units and Areas
 - Campus v. Health
 - System v. Campus
 - Campus v. Campus – One Entity
 - Training, expertise and methodology might differ between units
- Clinical, Teaching and Research Missions
 - Different leaders – different objectives
 - High level of expertise
 - Can create “silos”
 - Interdependence not always appreciated or valued
 - Different standards of evidence depending on issue



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Why is a Public Entity AMC Investigation Different? (Cont'd)

- More decision-making in which HCCO has little or no input
 - Academic Senate / Shared Governance
 - Independent Medical Staff
 - Non-Medical School / Medical Center Leadership



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5

Why is a Public Entity AMC Investigation Different? (Cont'd)

- Different respondents, different rules
 - Employed physicians
 - Faculty v. Non-faculty
 - Tenured v. Other classifications
 - Community physicians
 - Researchers
 - Fellows – Residents – Students
 - Other licensed professionals
 - Staff



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Why is a Public Entity AMC Investigation Different? (Cont'd)

- The Law and Associated Policies
 - Layer of Complexity
 - Unit-Specific Policies and Legal Standards Differ (e.g. SVSH Policy)
- Whistleblower Statutes:
 - State Agencies (Cal Gov't Code 8547.1)
 - Healthcare Whistleblower Statute (Cal H&S Code 1278.5)
 - Labor (Cal Labor Code 1102.5)



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7

Why is a Public Entity AMC Investigation Different? (Cont'd)

- Whistleblower Statutes and Policies:
 - Process rights for complainant
 - Process rights for respondent
 - Procedural steps might be required
 - Statutes / policies might overlap
 - Investigation itself alleged to be retaliation
 - Same with non-compliance with policy
 - Same with non-uniform application
 - Chilling effect on health compliance
 - State auditor oversight



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Why is a Public Entity AMC Investigation Different? (Cont'd)

State Public Records Act

- Ongoing investigation including draft findings not immediately disclosable
- Privileged discussions not disclosable
- But final findings may be disclosable



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9

Identify Points of Entry

- Campus v. Health System
 - Compliance Office – Hotline
 - Internal Audits / Reviews
 - Human Resources
 - Quality Reviews
 - Risk Management
 - Research Compliance / Integrity
- Medical Staff
- Patients – Patient Advocates
- Office for the Prevention of Harassment and Discrimination (OPHD)
- Lawsuits
- Government



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10

Managing Points of Entry

- Key – Communication
 - Campus and Health System
 - Campus and Central Office
 - HCCO and Leadership
- Clear Policy for Reporting and Logging Reported Concerns
- HCCO and Campus Counterpart Visibility and Coordination
- One Central Repository
- Ongoing and Timely Triaging and Tracking
- Leadership Commitment Critical



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11

Triaging Complaints

- HCCO, Campus Counterpart and Legal
 - Triage Initial Intake and Develop Investigative Plan
 - Ongoing Monitoring
 - Identify Trends
 - Ensure Timely Investigations
 - Escalate Issues as Appropriate
 - Report to Healthcare Compliance Committee/Campus Committee/Other Leadership



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12

Start of the Investigation

- Initial Intake and Investigative Plan
 - Identify reported issues and potential issues
 - Identify internal units involved and findings each affected unit require
 - Determine who should conduct investigation and to whom should they report
 - Internal Team
 - External Expertise
 - Determine what policies are implicated
 - Ensure Investigative Plan addresses all issues – Define Scope
 - Monitor and modify as needed



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Start of the Investigation (Cont'd)

- Initial Intake and Investigative Plan
 - Determine if the subject claims that units approved the conduct or that units were part of the retaliation / harassment vis a vis whistleblower statute
 - Assess whether a unit's prior failure to investigate / remediate at issue
 - Consider whether to conduct combined or concurrent or separate unit-specific investigations
 - Factors could include timing or distinctness of allegations
 - Determine if a document hold is appropriate
 - Are any of the affected units separate and distinct?



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14

Start of the Investigation (Cont'd)

Should Some/All of the Investigation Be Privileged?

- How to ensure findings and corrective actions can be used or disclosed and can serve as later defense?
- Will some parts of the investigation be self-critical?
- Do some parts of the investigation not serve the defense if disclosed?
- Does the investigation require analysis of complicated legal issues?



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Start of the Investigation (Cont'd)

If Investigation is Meant to Be Privileged:

- Legal must direct everything
- Legal can't just be cc'd by some / all units
- Legal advice must be sought by all units



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16

Middle of the Investigation

Witness Interviews

- Complications if more than one unit doing fact finding and issues overlap
 - One interview
 - One note taker
 - One interview memo
- Unit considerations might require separate/expedited interviews, e.g., medical staff
- If one part of investigation is privileged, can/should privilege cover entire interview?



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17

Middle of the Investigation (Cont'd)

- Monitor Investigation
- Manage Conflicts
- Continuously Consider Issues Including
 - Attorney-client privilege
 - Different unit policies / statutes
- Frequency of report outs and to whom
 - How to manage if multiple units are investigating different elements of complaint?



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18

End of the Investigation

Report/Findings

- Format of Final Report
- Report is Iterative Process
- Repayment
- Notification to External Parties
 - Consistent from unit to unit?
 - Timing?
- Presentation to Government



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19

End of the Investigation (Cont'd)

Report/Findings

- Who should receive executive briefings?
- Should some or all of the report be privileged?
- Is some or all of the report disclosable under public records act?
- Any procedural steps / notices owed under whistleblower policy or applicable unit policies?
- Have we considered past/current misconduct in all areas? Is this part of a larger pattern of misconduct?



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20

End of the Investigation (Cont'd)

Corrective Actions

- Have corrective actions been operationalized and documented?
 - Is there a multi-unit team working on remediation with deadlines and documented completion?
 - If P&Ps are changed, are they announced and recirculated for each applicable unit?
 - If multi-unit discipline is involved, are they tracked and documented?
 - Are some of the issues systemic such that corrective actions need to be systemic?



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21

End of the Investigation (Cont'd)

Corrective Actions

- Does health compliance and other units have sufficient detailed knowledge to convert investigative findings into corrective actions which can be operationalized?
- Do the findings reflect a tone at the top problem for some/all units?
- Are corrective actions being taken in accordance with policy, consistent and unbiased decision maker so as to avoid retaliation claim?



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22

End of the Investigation (Cont'd)

Corrective Actions

- Have we involved all fact finders and decision makers and experts from all units, both current and past?
 - Title IX, other compliance, OR, OGC?
- Have we considered past misconduct in other areas or past non-responsiveness? Is there clean-up to do on past items?
- Are all relevant leaders deciding whether to take remedial action?
 - P&T v. Medical Staff v. Department Chair v. IRB



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Case Study – Diversion

Physician Diverts Controlled Substances for Own Use

- Harm to patients, students or employees
- Reporting
 - DEA
 - Pharmacy Board
 - Medical Board
- Overbilling
- Medical Staff



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24

Case Study – Diversion (Cont'd)

Affected Units Could Include:

- Pharmacy
- Health Compliance
- Revenue Cycle
- Medical Staff
- Affiliates
- Department Chair
- Leadership

Tension between physician rehabilitation and patient care



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25

Case Study – Potential Fraud

Researcher Committing Fraud/Deceit or Bad Paperwork?

- IRB / IACUC Violations
- FDA Violations
- Research Misconduct
- COI / COC
- Grant Fraud / Foreign Influence
- Overbilling / Patient Harm

Fraud/bad paperwork can recur in numerous areas



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26

Case Study – Potential Fraud (Cont'd)

Affected Units Could Include:

- IRB
- IACUC
- Health Compliance
- Campus Compliance
- Research Compliance
- Contracts and Grants
- Medical Staff
- Internal Audit
- P&T
- Department Chair
- Leadership

Agencies and sponsors might need to be notified`



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Case Study – SVSH

SVSH

- Assault / Battery
- Title IX
- Clery Act
- ACA Section 1557
- Overbilling



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28

Case Study – SVSH (Cont'd)

Affected Units Could Include:

- OPHD/Title IX
- DPO/OED
- Health Compliance
- P&T
- Medical Staff
 - For CA medical board per se disruptive conduct & patient harm
- Campus Police
- Department Chair
- Leadership

Policies might be developing, peers might take broad view of care and view as teaching moment, notification to HHS/OCR



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Case Study – Busy Department

Busy Department

- Patient Harm
- Employee Wellbeing
- Overbilling
- Physician Compensation -- Stark Law
- Privacy
- Retaliation / Harassment



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30

Case Study – Busy Department (Cont'd)

Affected Units Could Include:

- Patient Experience
- Revenue Cycle
- Health Compliance
- Medical Staff
- Department Chair
- Leadership

Patient experience complaints or employee morale concerns could be tip of the iceberg



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Case Study – Disruptive Physician

Disruptive Physician

- Harm to patient, employee or student
- Retaliation / Harassment
- Overbilling

Star physician in AMC, policies newer or harder to enforce



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32

Case Study – Disruptive Physician (Cont'd)

Affected Units Could Include:

- OPHD/Title IX
- DPO/OED
- Patient Experience
- Health Compliance
- Medical Staff / Wellness Committee
- Department Chair
- Leadership



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33

Questions?



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34