



The Role of Internal Investigations in Ethics and Compliance Programs

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Overview



Defending the Medical Practice: Navigating Government Investigations, Responding to Reports of Misconduct, Internal Investigations Best Practices, Maintaining the Attorney-Client Privilege, Assessing Codes of Conduct and Policies

The Opioid Addiction Crisis has caused more than 633,000 deaths since 1999, more than ten times the total loss of life from the Vietnam War.

In the face of this crisis, law enforcement and other regulators are attempting to respond to persistent opioid prescription. As a result, health care providers, health care companies, medical groups, and insurances companies find themselves under increasing scrutiny.



Opioids accounted for four out of the seven top controlled prescription drugs distributed nationwide at the retail level (hospitals, pharmacies, practitioners, treatment programs, and teaching institutions) by number of dosage units from 2009 to 2017.

The Department of Justice (DOJ) has recently formed a number of specialized units to address the growing opioid epidemic.



Government Investigations

- Specialized units are targeting organizations and individuals involved at every stage of opioid distribution.
 - Manufacturers
 - Distributors
 - Medical facilities – (including hospitals and pain management clinics)
 - Physicians and medical staff
 - Pharmacies
- Since 2017, the Department of Justice (DOJ) has charged more than 200 doctors and 220 other medical personnel for opioid-related crimes.
 - The cases involved tens of millions of illegally prescribed pills.

Government Investigations, cont.

- Who conducts the investigation?

Prosecutors

- Department of Justice (DOJ)
 - Assistant United States Attorneys (AUSAs)
- State Attorneys General
 - Deputy Attorneys General

Special Agents

- Drug Enforcement Administration (DEA)
 - DEA Diversion Investigators
- Federal Bureau of Investigation (FBI)
- Department of Health and Human Services (HHS – OIG)
- Internal Revenue Service Criminal Investigators and Revenue Agents (IRS)



Government Investigations, cont.

- Investigations can be civil or criminal in nature

Criminal

- Controlled Substances Act (21 U.S.C. §§ 846, 841, 843)
- Health Care Fraud (18 U.S.C. § 1347)
- Anti-kickback Statute (42 U.S.C. §§ 1320a-7b(b))

Civil

- False Claims Act (31 U.S.C. §§ 3729-3733)
- Physician Self-Referral Law (Stark Law – 42 § 1395nn)
- Prosecutors and investigators often conduct both types of investigations concurrently (“parallel investigations”)



Government Investigations, cont.

- What does a **civil** investigation look like?
 - Notice of Inspection/Administrative Warrant
 - Request for patient files
 - Request for patient/drug/physician profiles
 - Review receiving/distribution records
 - Review of policies/procedures (including security of Schedule II controlled substances)
 - Review of inventories (initial/bi-annual inventories)
 - Review of Prescription Drug Monitoring Program (PDMP) records
 - Subpoena for billing/financial records
 - Interviews of patients/medical/pharmacy staff

Government Investigations, cont.

- What does a **criminal** investigation look like?
 - Notice of Inspection/Administrative Warrant
 - Request for patient files
 - Request for patient/drug/physician profiles
 - Review receiving/distribution records
 - Review of policies/procedures (including security of Schedule II controlled substances)
 - Review of inventories (initial/bi-annual inventories)
 - Review of Prescription Drug Monitoring Program (PDMP) records
 - Subpoena for billing/financial records
 - Interviews of patients/medical/pharmacy staff
 - Execution of search warrants

Potential Outcomes of Government Investigations

- Civil Sanctions

- Increased reporting requirements/monitoring (Memorandum of Agreement) (Corporate Integrity Agreements)
- Fines
- Suspension of DEA number or medical license
- Exclusion from the Medicare/Medicaid Program
- Shut down of medical practice/pharmacy

- Criminal Sanctions

- Fines
- Suspension of DEA number or medical license
- Shut down of medical practice/pharmacy
- Probation
- Imprisonment



Red Flags for Outside Investigators

- Excessive number of opioid prescriptions (in relation to patient, symptoms)
- Prescription of opioids inconsistent with type of medical practice (ex. psychiatrist)
- Prescription of opioids to multiple members of same family/personal relationships
- Multiple prescriptions filled on same day/close proximity
- Multiple pharmacies used in close proximity
- Identical quantities and dosages across all patients
- Patient deaths in close proximity to prescription

Red Flags for Outside Investigators, cont.

- Excessive patient traffic at unusual hours (early morning, late at night)
- Out-of-town patients/travel in groups
- Lack of specificity in patient records (e.g., lower back pain)
- Lack of appropriate patient evaluation and treatment prior to prescribing opioids
- Lack of monitoring for patients who have been prescribed opioids
- Cash payments
- Billing code inconsistencies
- Lack of verification for prescriptions
- Disgruntled employees
- Social media activity

Origin of Health Care Compliance Programs

- Adapted from other industries:

- Securities
- Banking
- Defense



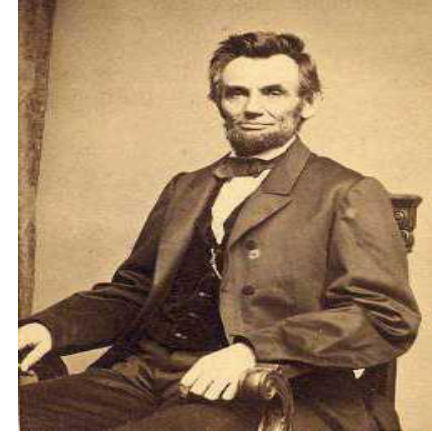
- Common factors:

- All heavily regulated by the government/significant government oversight
- Require governmental approval to operate or rely heavily on government as “purchaser of services”

- Goal of Compliance Programs

- Detect and prevent misconduct and support an ethical culture of accountability and transparency

False Claims Act “Redux”



- The False Claims Act (FCA) or “Lincoln Law”
 - Civil War era law designed to capture and recover for the government, monies paid to individuals for services never delivered or of inferior quality
 - 1990s – FCA became government vehicle of choice for recovering damages for fraud and abuse in federal health care programs
 - Unique aspects of the FCA
 - “Whistleblowers” or “Relators” - may bring suit (Qui Tam) on behalf of the government
 - Whistleblowers are eligible to receive a portion of the proceeds recovered by the government

Why bother?

- Demonstrates organizational commitment to doing the right thing
- Reduces risk of running afoul of laws, statutes, regulations
- Good business strategy
 - Early detection of potential risks
 - Organized approach to potential and actual breaches
 - Recognized (positively) by the government when assessing organizational responsibility for overpayments



Roles and Relationships

- **Chief Compliance Officer** – manages the compliance function for the organization; goal is to prevent and detect actual or potential actions that do not conform to legal, policy or business principles
- **General Counsel** – chief legal officer for the organization; provides advice and counsel to the Board and management on the legal and regulatory risks that govern, relate to or impact the organization
- Both functions must be independent; the most successful compliance programs have independent GCs and CCOs who work collaboratively
- **Outside Counsel** – typically engaged by GC

Conflicts for the Attorney/CCO?

- Privilege Issue(s)
 - Privilege doesn't apply for attorney/CCOs
 - In CCO role, attorney is not legal counsel for the corporation/organization
 - All discussions with outside counsel must include GC
- “Legal Advice”
 - Attorney/CCO should not give legal advice
 - Attorney/CCO must manage expectations and scope of role



CCOs and Professional Responsibility

- For Attorney/Compliance Officers – Code of Ethics for Health Care Compliance Professionals
 - **R2.3 – HCCPs shall investigate with appropriate due diligence all issues, information and reports, and/or conduct that relate to actual or suspected misconduct, whether past, current, or prospective.*
 - **R1.4 – If, in the course of their work, HCCPs become aware of any decision by their employing organization which, if implemented would constitute misconduct, adversely affect the health of patients, residents or clients, or defraud the system, the professional shall: (a) refuse to consent to the decision; (b) escalate to the highest governing authority as appropriate; (c) if serious issues remain unresolved after exercising “a” and “b”, consider resignation; and (d) report the decision to public officials when required by law.*
 - **R2.5 - HCCPs shall not aid or abet retaliation against any employee who reports actual, potential, or suspected misconduct, and they shall strive to implement procedures that ensure the protection from retaliation of any employee who reports actual, potential or suspected misconduct.*

Responding to Reports of Misconduct



- Any of the red flags identified above should trigger an internal inquiry
- The scope and methodology for response may vary depending on the severity of the misconduct or nature of report and may include:
 - An internal investigation conducted by human resources or management.
 - An internal investigation conducted by in-house counsel.
 - An internal investigation conducted by a special committee of the Board.
 - An internal investigation conducted by an outside entity.
 - This may include an investigations firm or legal counsel

Responding to Reports of Misconduct, cont.

- Selecting the type of response may depend on the following considerations (among others):
 - Severity of the misconduct
 - Timing
 - The need for confidentiality
 - Cost
 - Potential for operational disruption



Internal Investigations Best Practices

- Maintaining the integrity of the investigation is essential to a successful outcome
- Ensure the integrity of an investigation by:
 - Establishing a communications plan early on
 - Providing investigators with unfettered access to information
 - Maintaining confidentiality where appropriate
 - Identifying the need for and providing individual legal counsel to key employees
 - Allowing the investigation to proceed to its natural conclusion

Internal Investigations Best Practices, cont.

- How in-house counsel can assist the outside investigator and ensure an effective outcome:
 - Request and follow an investigation plan
 - Clearly communicate expectations and deadlines
 - Request updates or require weekly/monthly reports
 - Participate in scoping interviews early on
 - Identify key employees and potential witnesses
 - Identify potential sources of information – including available analytics
 - Facilitate access to witnesses and data
 - Discuss and decide upon the desired final work product up front



Maintaining the Attorney-Client Privilege

- A communications plan or protocol is key to preserving the attorney-client privilege during an investigation.
- Review the plan often and ensure compliance.
- Use Upjohn warnings or ensure that your investigator is providing and documenting any warnings.
- When retaining outside consultants such as forensic accountants, medical doctors, private investigators and other professionals endeavor to include such services in the legal counsel offered.
 - Document purpose of engagement, reporting authority, invoicing, and file retention in the retention letter.

Organizational Representation – Ethical Considerations



Rules 1.7 and 1.8 (Current clients)

- (a) Except as provided in paragraph (b), a lawyer shall not represent a client if the representation involves a concurrent conflict of interest. A concurrent conflict of interest exists if:
- (1) the representation of one client will be directly adverse to another client; or
 - (2) there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client, a former client or a third person or by a personal interest of the lawyer.

Organizational Representation – Ethical Considerations, cont.

Rules 1.7 and 1.8 (Current clients)

(b) Notwithstanding the existence of a concurrent conflict of interest under paragraph (a), a lawyer may represent a client if:

- (1) the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
- (2) the representation is not prohibited by law;
- (3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
- (4) each affected client gives informed consent, confirmed in writing.

Maintaining Attorney-Client Privilege

- Reporting out results of internal investigations often implicate a potential waiver of the attorney-client privilege.
- Disclosure may very well be in the best interest of the organization.
- Any disclosures should contain a disclaimer similar to the following:
 - Note: During the course of its investigation, Medical Provider Group A considered evidence, communications, and other information that might be subject to attorney-client privilege, the attorney work product doctrine, and/or other privileges and protections. In making these reports publicly available, Medical Provider Group A and its Board do not intend to waive any applicable privileges or protections. Additionally, the names have been redacted to protect the privacy of those individuals.

Assessing Codes of Conduct

- Often an internal investigation results in a review of the organization's code of conduct and will include recommendations associated with the conduct at issue.
- Ensure that your code of conduct is regularly reviewed and provide annual training to employees regarding expectations and updates.
- Ensure that your code of conduct reflects up to date best practices with respect to prescription drug practices and reporting misconduct.
- An effective code will clearly state the organization's overall ethical philosophy, expectations that apply to ALL members of the organization, and potential ramifications for non-compliance.



Assessing Applicable Policies

- Many investigations will include an early request by the investigator to review the organization's policies with respect to internal investigations, reporting misconduct, and the conduct at issue.
- Ensure that you have policies.
- Ensure that they are reviewed and updated regularly.
- Ensure that you follow your policies.
- Ensure that your policies are consistent with each other.
- Ensure that your policies are easily accessible to employees and referred to often.

Other Organizational Considerations



- How is the organization demonstrating its commitment to helping national public health crisis?
 - Create a culture of prevention, detection, and support
 - Implement anti-diversion controls and prevention programs
 - Understand your role in the supply chain
 - Support nonprofit organizations dedicated to combatting opioid abuse
 - Participate in Generation Rx or other similar prescription drug education and awareness programs
 - Develop drug take-back and education programs

Hypothetical Fact Pattern

Putting your skills to the test...

Preliminary Issue

- An anonymous caller to Philadelphia General Hospital's "hotline" claims there is unusual and inappropriate dispensing of opioids going on "everywhere." The caller doesn't provide specifics---departments, staff, providers, etc.
- You are an attorney who is also the Compliance Officer:
 - What are the issues you are concerned about, and,
 - What are the immediate next steps you take?



Immediate Actions



- Engage General Counsel
 - Determine appropriateness of privileging the investigation
 - If “yes:”
 - GC provides CCO with “In Anticipation of Litigation” memo
 - Identify “experts” including outside counsel
 - Develop an internal communications protocol
 - Who will be brought in?
 - Who are the key decision-makers?
- Evaluate other reporting obligations
- Identify potential sources of information

The Investigation Commences

- The CCO identifies staff to be interviewed and begins to set up appointments. Despite all efforts to keep the investigation confidential, there is speculation among staff that “heads will roll” because of discrepancies in controlled substance dispensing.
- The hospital CEO gets wind of the investigation and calls in the CCO.
- During the course of their conversation it’s clear the CEO would be most appreciative if the whole investigation “went away” or at least slow things down and hope it all goes away.
- And by the way, who’s the troublemaker who started all this?

Concerns and Initial Questions

- Can the allegations be quickly verified?
- Does the initial data warrant disclosure to law enforcement?
- Is there a potential whistleblower involved?
- Any False Claims Act implications?
- Could litigation be anticipated?
- Who should be involved in the investigation? Stakeholders?
- Should the investigation be privileged?
- What documents, reports and data are needed to move the investigation forward?



Questions?



A reminder about the benefits of ACC membership...

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- Special events
 - Spring Fling, Fall Gala, Diversity Summer Program, Golf Outing, Pro Bono clinics, Charity Softball Game & Family Fun Day, and more!
- Access to ACC resources, including:
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 - ACC Docket Magazine
 - InfoPAKs
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