



# Investigations & Relevant Laws

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# Objectives

1

Identify federal laws enacted to assist in mitigating healthcare fraud and abuse.

2

Discuss techniques of conducting an internal investigation.

3

Describe different techniques to conducting an internal investigation related to fraud and abuse allegations.

# Financial Disclosures

No relevant relationships with ineligible companies to disclose within the past 24 months

# Disclosures



All opinions presented are my own and do not represent those of my employers.



This information is intended for educational purposes. The information presented should not be construed as legal advice, nor advice on state or federal laws and regulations. Legal counsel should be obtained for those needing legal clarification for professional practice concerns.



All attempts were made to present the most up-to-date information.



All questions should be theoretical with the intent of an academic discussion.

# What Guides Our Actions?

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**law** = formal rules that govern how we behave, what we must and must not do, creating an enforceable standard of behavior <sup>C1</sup>

**morality** = framework of values, principles, beliefs, customs, & ways of living, not usually enforced by the state in the U.S., which usually guides us unconsciously <sup>C1</sup>

**ethics** = process of conscious reflection for determining what action to take based on values, principles and purpose <sup>C1</sup>

law ≠ morality ≠ ethics

<sup>C1</sup> What is the difference between Ethics, Morality, and the Law? The Ethics Centre, 2020 <https://www.youtube.com/watch?v=Xki2fRA0bY8>

# What Guides Our Actions?

**morality** = framework of values, principles, beliefs, customs, & ways of living, not usually enforced by the state in the U.S., which usually guides us unconsciously <sup>C1</sup>

**conscience** = commitment to act in accordance with our morality <sup>C2</sup>

- having moral principles
- being bound to these principles

<sup>C1</sup> Beard M. What is the difference between Ethics, Morality, and the Law? The Ethics Centre, 2020 <https://www.youtube.com/watch?v=Xki2fRA0bY8>

<sup>C2</sup> Sulmasy DP. Conscience, tolerance, and pluralism in health care. Theoretical Medicine and Bioethics. 40(6); 2019. 507-521. <https://pubmed.ncbi.nlm.nih.gov/31741165/>

# Morals in Medicine

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## *Professional*

- Public servants must act in the public interest. <sup>C3</sup>
- Nonmaleficence forbids selfish action or inaction <sup>C4</sup>
- Discernment entails recognizing ethical, legal, and moral dimensions of each healthcare decision <sup>C4</sup>

## *Personal*

- PAs are people with morals
- Healers provide care with compassion - empathetic action to alleviate suffering <sup>C5</sup>
- Moral judgements are made in context <sup>C6</sup>
- Dissonance between morality and action is distressing <sup>C6</sup>

<sup>C3</sup> Savulescu J. Conscientious objection in medicine. British Medical Journal, 332(7536);2016., 294 <https://pubmed.ncbi.nlm.nih.gov/16455733/>

<sup>C4</sup> Lo B. Resolving Ethical Dilemmas: A Guide for Clinicians. 2020. Philadelphia: Wolters Kluwer eISBN 9781975142155 <https://meded.lwwhealthlibrary.com/book.aspx?bookid=823>

<sup>C5</sup> McGonigal K. The Practical Science of Compassion. Compassion in Therapy Summit. 2021

<sup>C6</sup> Taylor CR, Dell'Oro R. Health & Human Flourishing: Religion, Medicine, and Moral Anthropology. 2006. Georgetown University Press ISBN 9781589010796

<https://meded.lwwhealthlibrary.com/book.aspx?bookid=823>

# Morals in Medicine

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## moral distress

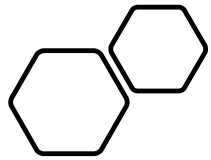
- psychological distress of being in a situation in which one is constrained from acting on what one knows to be right <sup>C7</sup>
- leads to anger, anxiety, frustration, helplessness, fatigue, burnout <sub>C4</sub>

[!] Actions dissonant with conscience elicit moral distress

<sup>C7</sup> Petriceks AH. A clinical catharsis: Moral distress and the uses of tragedy in palliative care. Palliative and Supportive Care. 2022;1-2. doi:10.1017/S1478951522000359 <https://pubmed.ncbi.nlm.nih.gov/35317882/>

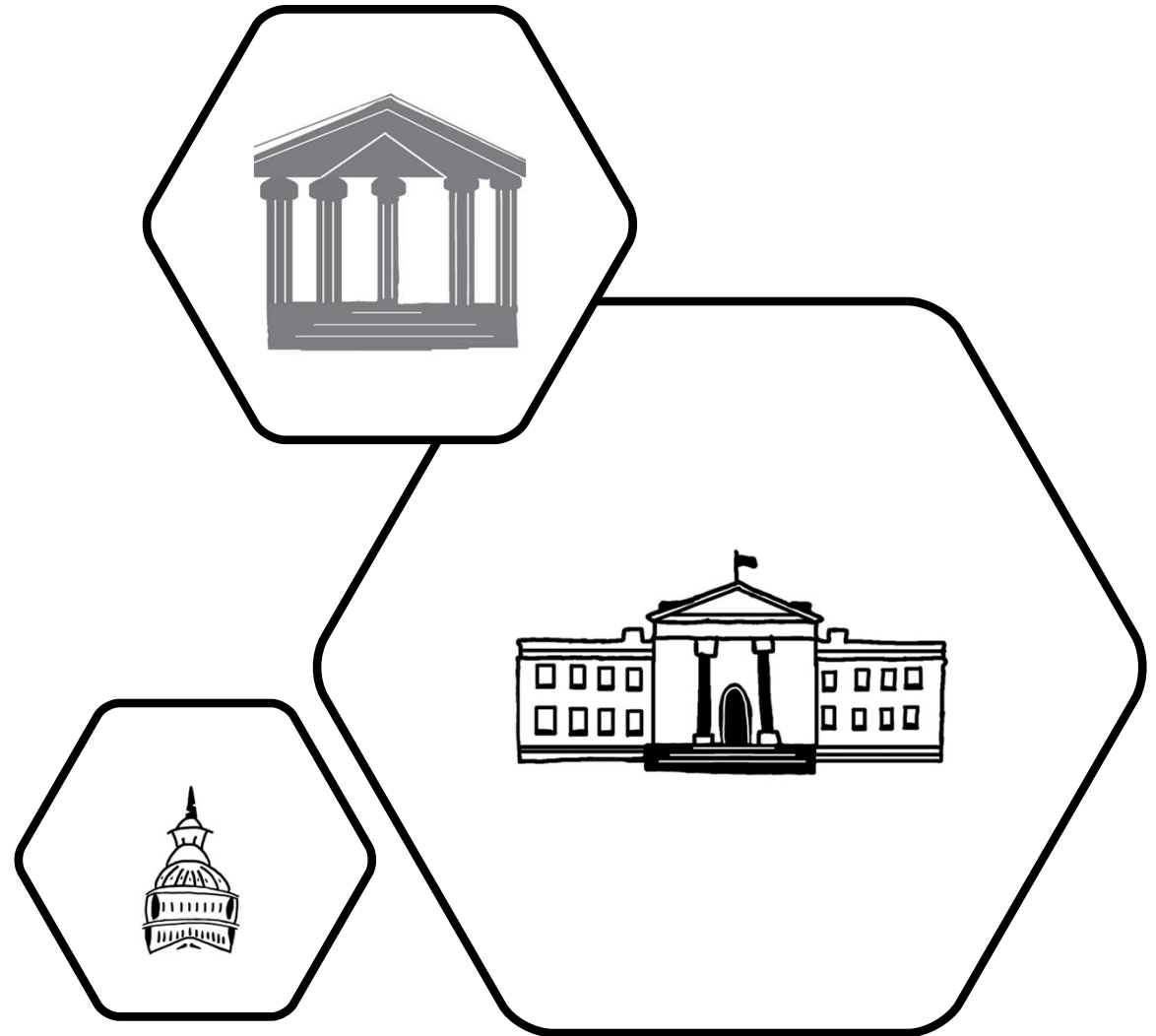
<sup>C4</sup> Lo B. Resolving Ethical Dilemmas: A Guide for Clinicians. 2020. Philadelphia: Wolters Kluwer eISBN 9781975142155 <https://meded.lwwhealthlibrary.com/book.aspx?bookid=823>





# Branches of Government

The U.S. Constitution created 3 branches of government



**(a) LIABILITY FOR CERTAIN ACTS.—**

**(1) IN GENERAL.**—Subject to paragraph (2), any person who—

**(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

**(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

**(C)** conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

**(D)** has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

**(E)** is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

**(F)** knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

**(G)** knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410<sup>[1]</sup>), plus 3 times the amount of damages which the Government sustains because of the act of that person.

# False Claims Act

A federal law enacted in 1863 by Congress during the Civil War

**(b) DEFINITIONS.**—For purposes of this section—

**(1)** the terms “knowing” and “knowingly”—

**(A)** mean that a person, with respect to information—

- (i)** has actual knowledge of the information;
- (ii)** acts in deliberate ignorance of the truth or falsity of the information; or
- (iii)** acts in reckless disregard of the truth or falsity of the information; and

**(B)** require no proof of specific intent to defraud;

**(2)** the term “claim”—

**(A)** means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

- (i)** is presented to an officer, employee, or agent of the United States; or
- (ii)** is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government—
  - (I)** provides or has provided any portion of the money or property requested or demanded; or
  - (II)** will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

**(B)** does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property;

**(3)** the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

**(4)** the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

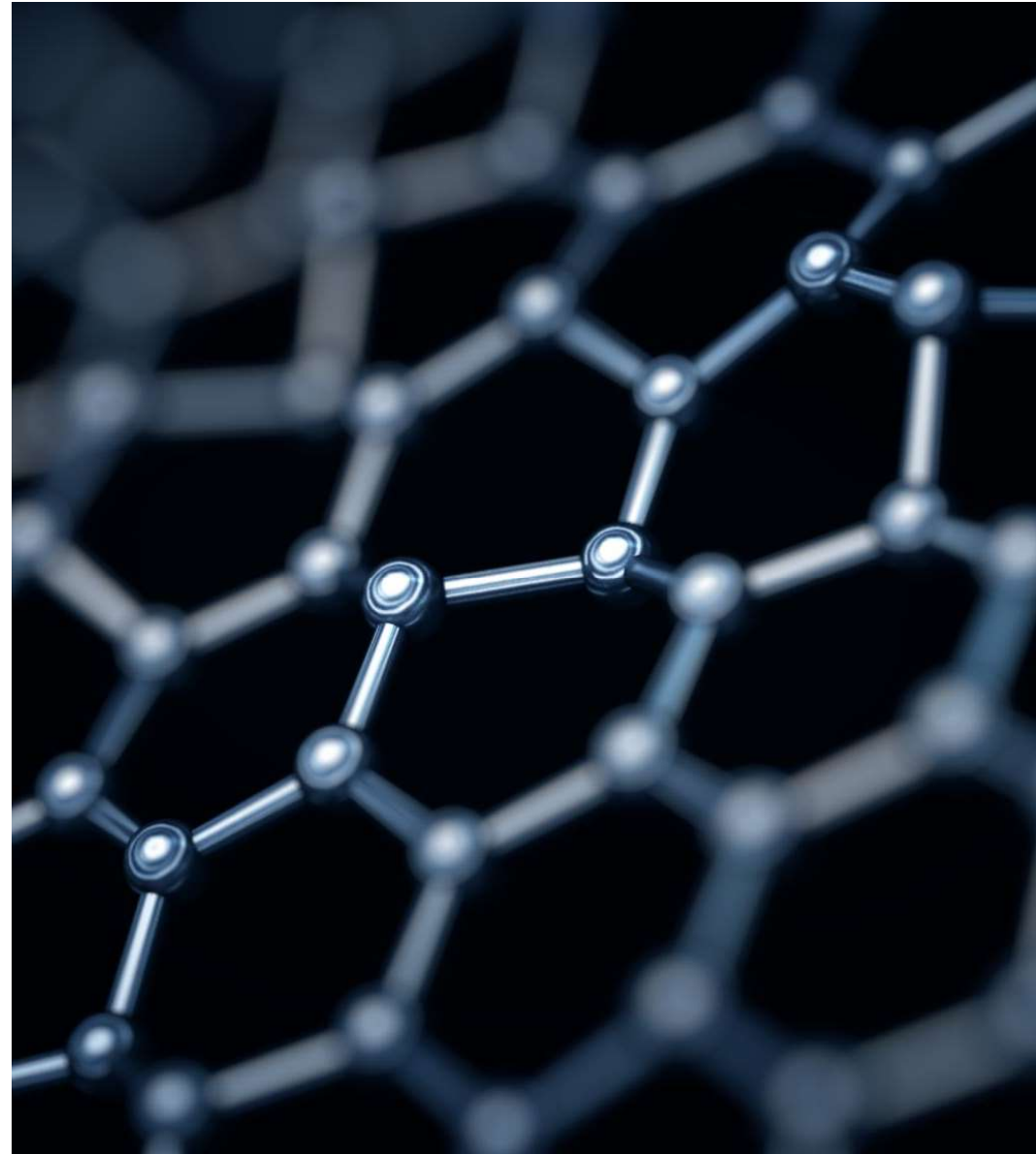
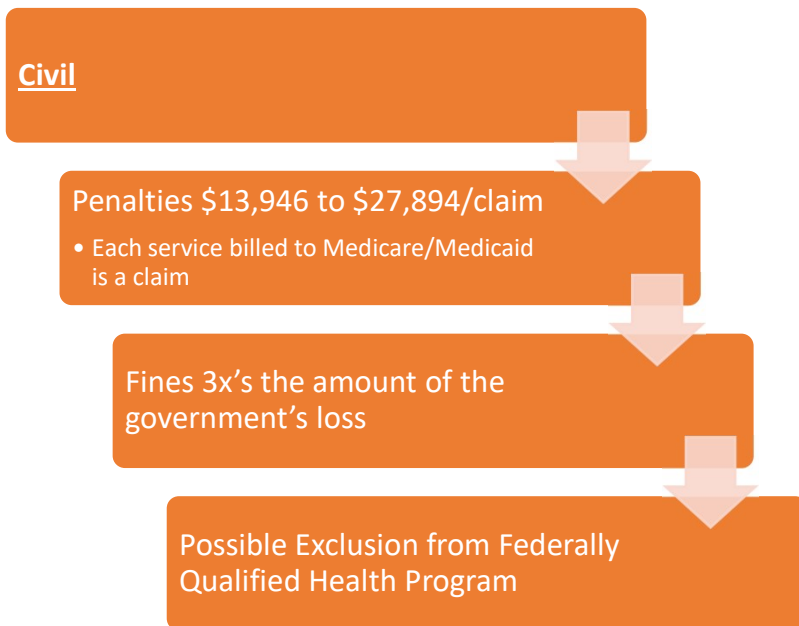
# False Claims Act

# Knowingly

- *United States ex rel. Schutte v. SuperValu, No. 21-1326 (6-1-23),*
- *United States ex rel. Proctol v. Safeway, Inc., No. 22-111 (6-1-23)*
  - *Actual Knowledge*
    - *What are you aware of?*
  - *Deliberate ignorance*
    - *Aware of substantial risk that statement is false, but do not confirm if the statement is false or true*
  - *Recklessness*
    - *Consciously aware of justifiable risk, the statement is false, but submit the claim.*

[U.S. Supreme Court explains meaning of “knowingly” under the False Claims Act | BCLP - Bryan Cave Leighton Paisner \(bclplaw.com\)](#)

# False Claims Penalties





# Anti-Kickback Statute

01

Is a federal criminal law, although some states have state law

02

The law applies to the federal health care program

03

“Prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.”

•INTENT

04

Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies

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# Anti-Kickback Statute

Up to 10 years in prison

\$25,000/claim-Max 100K

Additional \$10,000-\$50,000 under Civil Monetary Penalties Law

Mandatory Exclusion Federally Qualified Health Program

AND Penalties under the False Claims Act

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# Flying too close to the sun: Navigating changes to CMS' Open Payments program

Kevin A. Hickman, PA-C, MHA, MJ (Health Law), CHC

## ABSTRACT

Increasingly, physician assistants (PAs), advanced practice nurses, and physicians are financially involved with healthcare product manufacturers. Although the relationships themselves might not be illegal, when the transaction influences the healthcare provider's medical decision-making, patients can be harmed and the healthcare provider and manufacturer can face accusations of violating federal and state law. In 2019, the federal government recouped \$2.6 billion from healthcare fraud and abuse by healthcare stakeholders. PAs' and NPs' behaviors violating the Anti-Kickback Statute (AKS) and False Claims Act (FCA) were partially responsible for the reported amount. To increase the transparency of the financial relationships between healthcare providers and healthcare manufacturers, the federal Centers for Medicare and Medicaid Services, under statutory obligation, created the Open Payments program, which will begin reporting PAs' and advanced practice nurses' financial relationships with manufacturers in 2022.

**Keywords:** physician assistant, NP, False Claims Act, Anti-kickback Statute, healthcare fraud, Open Payments program

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## Sunshine Act



# Doctors and Medical Facilities in Lehigh Valley Pay \$690,441 to Resolve Healthcare Fraud Allegations

Wednesday, August 17, 2016

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**For Immediate Release**

U.S. Attorney's Office, Eastern District of Pennsylvania

[Eastern District of Pennsylvania | Doctors and Medical Facilities in Lehigh Valley Pay \\$690,441 to Resolve Healthcare Fraud Allegations | United States Department of Justice](#)

As part of the settlement agreement, the defendants also agreed that, for the next thirty months, they will not submit claims to federal payors for any services performed by non-physician providers under the rate that applies for services rendered "incident to" the services of a physician, regardless of whether or not the claims could be billed properly in that manner.

# TELEHEALTH

[Justice.gov](#) > [U.S. Attorneys](#) > [Southern District of Georgia](#) > [Press Releases](#) > [Georgia Nurse Practitioner Convicted of Health Care Fraud In Complex Telemedicine Fraud Scheme](#)

PRESS RELEASE

## Georgia nurse practitioner convicted of health care fraud in complex telemedicine fraud scheme



Wednesday, February 2, 2022

For Immediate Release

[Southern District of Georgia | Georgia nurse practitioner convicted of health care fraud in complex telemedicine fraud scheme | United States Department of Justice](#)



# TELEHEALTH



Patient identities were  
obtained through  
telemarketing scheme

NP would:

Sign name to false  
medical record  
claiming evaluation

Placed orders for over  
3,000 orthotics for  
these identities

Resulted in \$3million in  
fraudulent claims

# Cost of Greed

## Convicted

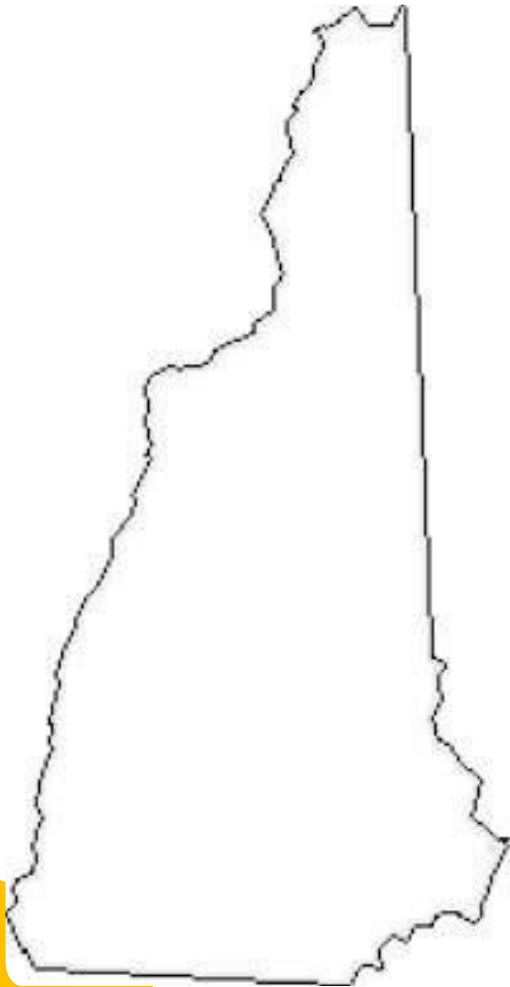
84 months in federal prison

\$1,635,161.61 in restitution

3 years supervised release

“Sherley Beaufiles let greed take the wheel when she raked in massive profits by ordering unnecessary medical devices for patients she never examined or spoke to,” said U.S. Attorney Estes. “She targeted the elderly and medically vulnerable with her schemes, and is now being held accountable.”

[Southern District of Georgia | Georgia nurse practitioner sentenced to prison, ordered to pay more than \\$1.6 million in restitution in complex telemedicine fraud scheme | United States Department of Justice](#)



# KICKBACKS

- Physician assistant paid more than \$40,000 for over 30 speeches between 2013-2014
- 2015 the PA was reprimanded by the Board of Medicine for overprescribing opioid drug and barred him from prescribing opioids.
- License eventually permanently revoked
- He was indicted in 2017
- Medicare and Medicaid programs paid \$2.6 million for Subsys.
- Sentenced to four years in federal prison

In the Headlines:  
FCA, AKS, Stark Law

## **Sutter Health to pay \$30 million to settle secret kickback lawsuit; whistleblower to get slice**

BY SAM STANTON AND CATHIE ANDERSON

NOVEMBER 14, 2019 03:53 PM



### **FEDS: SURGEONS' GROUP DOUBLE-DIPPED**

According to the lawsuit, Sacramento Cardiovascular, a group of three surgeons, cut a deal with Sutter starting in 2006 that provided free physician assistants to the group in exchange for the surgeons referring patients to Sutter hospitals.

Sutter agreed to pay each of the assistant's salaries of \$170,000 annually, while Sac Cardio "did in fact bill third party payers, including Medicare," for some of the assistants' services.

# In the Headlines: FCA, AKS, Stark Law

*SACRED HEART HOSPITAL*

*United States v. Edward Novak, et al.*

United States District Court, Northern District of Illinois, Eastern Division (2015)

But the defendants took the conspiracy to the next level when they began loaning out mid-level medical professionals — physicians assistants and nurse practitioners — to doctors free-of-charge in return for patients, the government **argued in its own closing statement** on Thursday, calling it “kickbacks on steroids.”

# OIG Advisory Opinion

- [R1292 Redacted Advisory Opinion \(hhs.gov\)](#)
- Arrangement is limited to non-surgical/speciality
- Safeguards
  - NPs are in communication with physicians
  - Physicians required to round daily
- Not likely to increase costs



# How did we get here?

Whistleblowers

Government analytics

Subpoenas

Electronic surveillance

Enforcement

- Department of Justice
- Office of Inspector General
- State Agencies

# Qui Tam Relators

- Typically, an employee of the organization
- Brings a suit on behalf of the government
- Government decides whether to join the case after investigating
- Relators are awarded 15-25% of what the government collects
- 25-30% if the government did not join the case
- False Claims Act protects against retaliation against those attempting to prevent fraud



# Different types of investigations

Internal  
investigations

External  
investigations

Parallel  
investigations

## Internal Investigations: Triggers

- Initiated after a concern such as:
  - Non-compliant activity
  - Fraud
  - Improper conduct
  - Overpayments
  - Whistleblower
  - Stakeholder complaint

# Internal Investigations: Purpose

- Fiduciary responsibility
- Create attorney-client privilege
- Need to determine
  - The facts
  - Extent of the misconduct
  - Financial impact
  - What laws/regulations have been violated
  - The cause
  - Timely resolution
  - Accountability
  - Foster transparency and decision-making process
  - Who needs to be notified
  - Mitigate potential fine amounts
  - Creates a foundation of possible defenses

# Internal Investigations: When Someone comes knockin'



What do I do if someone brings me a concern?



What should I document?



Who should receive the concern?



Who leads the investigation?

# Internal Investigations: Probing Questions

Who was involved in the actions?

What exactly have you witnessed? Where?

Is this still occurring?

Have you voiced your concerns? To Whom?

Can you describe what has happened? Is there documentation?

# Internal Investigations: Initial Steps

## Who to report this concern to?

- Human Resources
- Compliance Office
- General Counsel
- Your boss

## How to report this information?

- Should I send an email?

Need to determine credibility

Will require initial review of records or personnel interviews



Internal  
Investigations:  
Starting the  
process

- Investigator will:
  - Need to determine credibility
  - Review initial review of records or personnel interviews
  - May invite you to participate in interviews
  - May interview you

Internal  
Investigations:  
Communication

- Who is leading the investigation
- Documentation preservation
- Documentation requests
- Witness interviews
- Education- identify and remediate

# Internal Investigations: Your Rights



**There is an extent of confidentiality when reporting concerns**



**You are expected to participate in investigations**

Your employer may be able to terminate your employment for not comply with an interview related to your work.

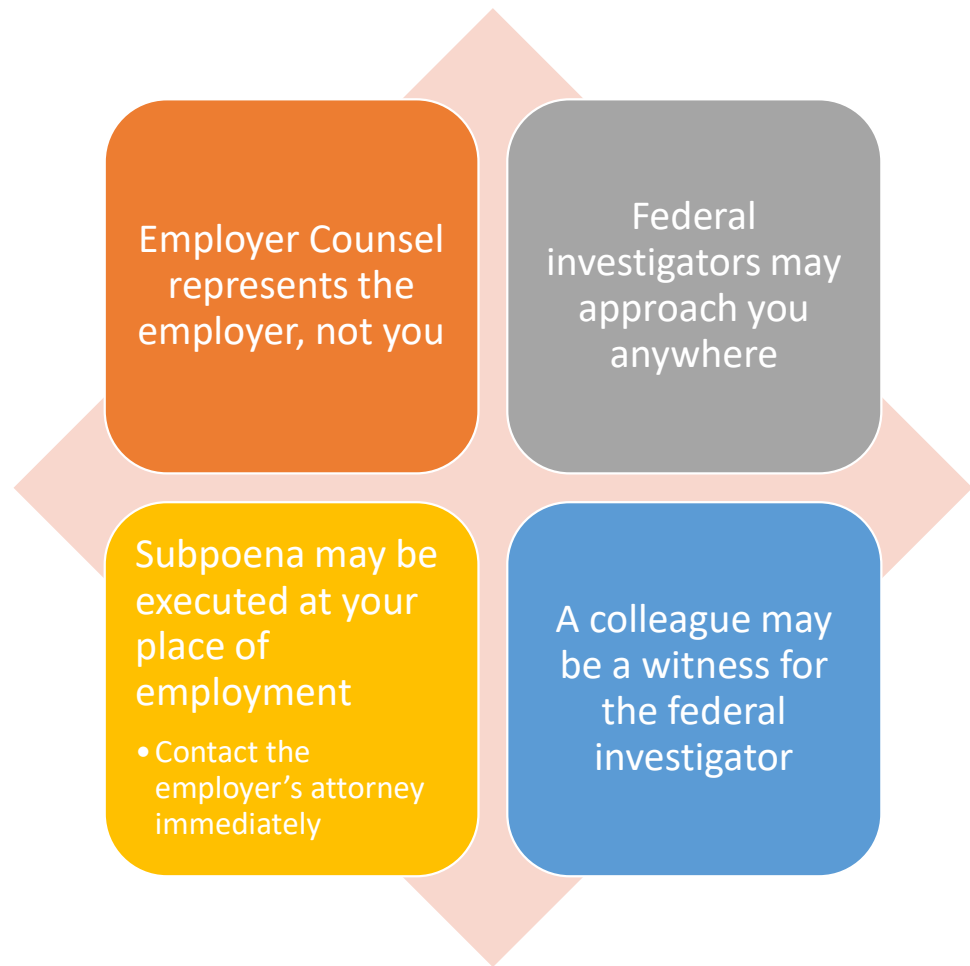


**You have the right to obtain an attorney**



**Retaliation?**

# Quick Note on External Investigations



# Resources

- [guide to conducting internal investigations jan 2020.pdf \(omm.com\)](#)
- [Microsoft PowerPoint - HCCA Board Audit Committee Compliance Conference - Feb. 24-25 2020 Fort Lauderdale - 4851-9527-0325 1.p \(hcca-info.org\)](#)
- [Guide to Conducting an Effective Internal Investigation.doc \(acc.com\)](#)
- [Flying too close to the sun: Navigating changes to CMS' Open... : JAAPA \(lww.com\)](#)
- [Newsroom | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services \(hhs.gov\)](#)
- [Press Releases | United States Department of Justice](#)