Fraud and Abuse Compliance for the Health IT Industry

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Conflict of Interest

James A. Cannatti III, J.D.
Has no real or apparent conflicts of interest to report.

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Agenda

- Learning Objectives
- Disclaimer
- What is Fraud, Waste, and Abuse?
- Why Does It Matter to the Health IT Industry?
- What are the Fraud, Waste, and Abuse Laws?
- Overview of Other Criminal Laws Applicable to Health IT
- Developing a Culture of Compliance

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Learning Objectives

- Discuss the Federal health care fraud and abuse laws that apply to those in the health IT industry
- Analyze the consequences of violating those fraud and abuse laws
- Examine recent cases involving application of relevant fraud and abuse laws
- Identify ways to develop a culture of compliance in your health IT organization

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What is Fraud, Waste, and Abuse?

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Why Does It Matter to the Health IT Industry?

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Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback Statute
- Physician Self-Referral Statute
- Civil Monetary Penalties Law
- Exclusion Statute

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False Claims Act

- In a nutshell…

  "It's illegal to submit, or cause someone else to submit, a false claim to the Federal Government"

- Statute: 31 U.S.C. §§ 3729-3733

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False Claims Act

- *Knowingly* **presenting** or **causing to be presented** a false or fraudulent claim to the Federal Government
- Qui Tam provisions
- Penalties: Fines up to 3x the program's loss, plus $21,916 per claim
- Underlying conduct can also be grounds for civil monetary penalties and exclusion

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Federal Anti-Kickback Statute

- In a nutshell…

  "It's a crime to buy or sell Federal health care program business"

- Statute: 42 U.S.C. § 1320a-7b(b)
- Safe Harbor Regulations: 42 C.F.R. § 1001.952

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Federal Anti-Kickback Statute

- Felony, intent based
- *Knowing and willful* **offer**, **payment**, **solicitation**, or **receipt** of remuneration to induce Federal health care program business

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Federal Anti-Kickback Statute

- Penalties:
  - Criminal
    - Fines up to $25,000 per violation
    - Up to a 5 year prison term per violation
  - Civil/Administrative
    - False Claims Act liability
    - Civil monetary penalties and exclusion
    - Civil assessments of up to 3x amount of kickback

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Physician Self-Referral Statute

- In a nutshell…

  "Physicians cannot refer Medicare and Medicaid patients for certain items and services to entities if they have a financial stake in the item or service"

- Statute: 42 U.S.C § 1395nn
- Regulations: 42 C.F.R. §§ 411.350-.389

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Physician Self-Referral Statute

- aka the “Stark Law”; strict liability law
- Prohibits **physicians** from referring patients to receive “**designated health services**” payable by Medicare/Medicaid from entities with which the physician or an immediate family member has a **financial relationship**, *unless an exception applies*

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Physician Self-Referral Statute

- Penalties:
  - Overpayment/refund obligation
  - False Claims Act liability
  - Civil monetary penalties and exclusion for *knowing* violations
  - Civil assessments of up to 3x the amount claimed

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The Boston Globe

May 31, 2017

Westborough health records vendor settles false-claims suit for $155M

Westborough-based eClinicalWorks, one of the country's largest vendors of electronic medical records systems, has reached a $155 million settlement with federal prosecutors over allegations that the company made false claims about its software and paid kickbacks to customers who promoted it.

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December 13, 2017

21st Century Oncology to Pay $26M for Fraud, Kickback Allegations

John Commins, December 13, 2017

The payment will resolve Stark Act and False Claims Act allegations against the Florida-based provider, which self-disclosed the violations and cooperated with the government investigation.

Physician-led **21st Century Oncology Inc.** will pay the federal government $26 million to resolve False Claims Act allegations of inflated attestations for electronic health records, and alleged Stark Act violations involving kickbacks for referring physicians, the **Department of Justice said**

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Civil Monetary Penalties Law

- In a nutshell…

  "OIG can impose money penalties for certain kinds of misconduct, fraud, or substandard care"

- Statute: 42 U.S.C. § 1320a-7a
- Regulations: 42 C.F.R. pt. 1003

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Civil Monetary Penalties Law

- Administrative proceedings
- Numerous grounds for penalties, including:
  - False claims and improper billings
  - Anti-Kickback Statue and Stark violations
  - Substandard Care
  - Beneficiary inducements

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Civil Monetary Penalties Law

- Penalties generally range from around $10,000 to $75,000 per violation (*updated annually for inflation at 45 CFR Part 102*)
- OIG also has CMP authority for penalties up to $1M per violation for information blocking (42 U.S.C. § 300jj-52)

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Exclusion Statute

- In a nutshell…

  "We don't do business with untrustworthy individuals and entities"

- Statute: 42 U.S.C. § 1320a-7, 1320c-5
- Regulations: 42 C.F.R. pts 1001 (OIG) and 1002 (State agencies)

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Exclusion Statute

- Administrative proceedings
- “Death knell”
- Covers all Federal health care programs
- Two types: mandatory and permissive

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Other Applicable Criminal Laws

- 18 USC § 371: Conspiracy to Defraud the United States
- 18 USC § 1001: False Statements
- 18 USC § 1035: False Statements Relating to Health Care Matters
- 18 USC § 1341: Mail Fraud
- 18 USC § 1343: Wire Fraud
- 18 USC § 1347: Health Care Fraud

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Healthcare IT News TOPICS

June 18, 2015

Meaningful Use

Former CFO heads to prison on MU fraud

U.S. District Judge Michael Schneider sentenced White, 68, to 23 months in prison.

White, of Cameron, Texas, pleaded guilty on Nov. 12, 2014 to making a false statement that Shelby Regional Medical Center in Center, Texas, was a meaningful user of electronic health records, when the hospital did not meet the requirements of the federal EHR Incentive Programs.

Schneider also ordered White to pay restitution in the amount of $4,483,089 to the meaningful use program, administered by the Centers for Medicare & Medicaid Services.

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Cultivating a Culture of Compliance

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Compliance Building Blocks

1. Prevention
2. Detection
3. Enforcement

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Questions

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