April 1, 2021 Virtual Learning Opportunity

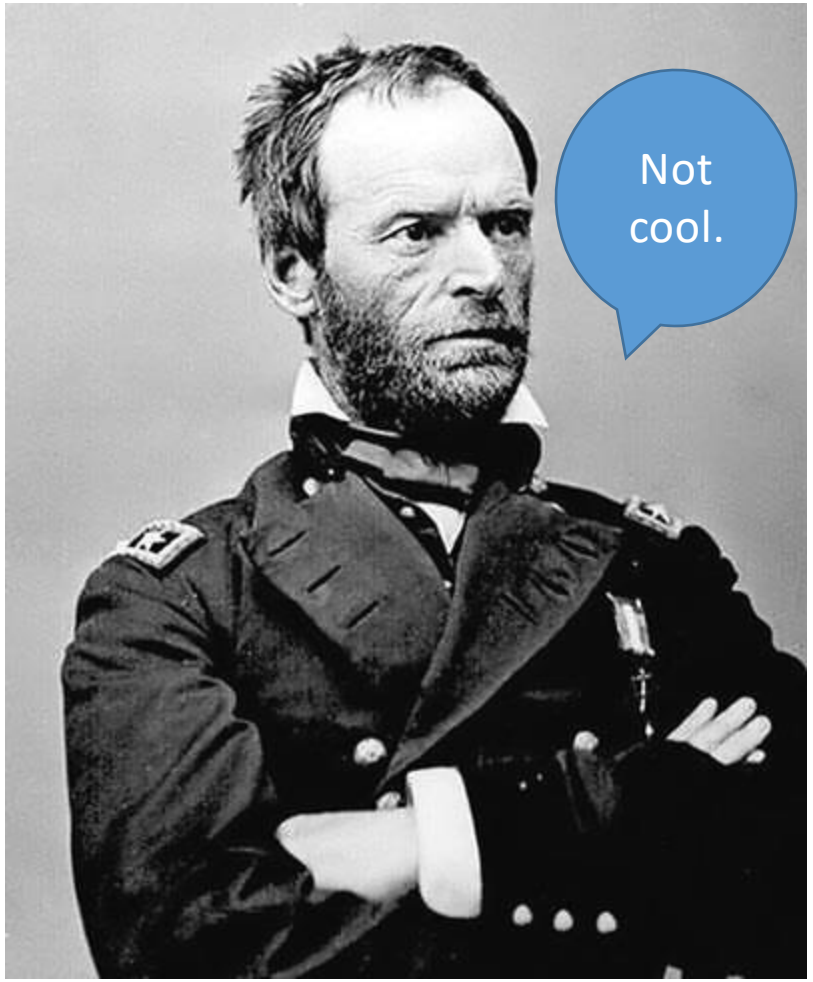
Fraud & Abuse Laws 2021

Kirk Cheney

General Counsel

Pennant Services, Inc.

Journey with me back to 1863…



False Claims Act (FCA)

18 USC § 1347 and 31 USC § 3729

The FCA makes it unlawful to:

- Knowingly submit a false claim to the Government for payment or approval;
- Knowingly make/use a false record or statement relating to a false claim; or
- Knowingly retain an overpayment;

- Overpayments must be repaid within 60 days after they are identified.

False Claims Act Penalties

- FCA imposes both civil and criminal liability punishable by:
    - 3x the amount of damages the Gov't sustains as a result of your agency's false claim(s);
    - Penalties between $11,665 and $23,331 ***per claim***;
    - **Exclusion** from participation in Medicare and Medicaid.
    - Criminal penalties may result in individuals or entities facing fines, imprisonment (up to 10 years), or both.

But surely my company would never seek to defraud the government!

- **"Knowingly"** in the FCA is a broad term. It is interpreted to mean:
    - Actual knowledge of the false information;
    - Deliberate ignorance of the truth or falsity of the information; or
    - Reckless disregard for the truth or falsity of the information.

False Claims Act Examples

- Charging or submitting claims for services that were not rendered or performed
- Charging or submitting claims for services that were not medically necessary
- Charging or submitting claims for services for which patients do not meet the medical criteria to receive those services
- Double billing (charging more than once for the same service)
- Changing patient diagnosis for billing purposes
- Upcoding patient visits
- Forging physician signatures on required medical documentation
- Billing for premium equipment but providing inferior equipment
- Failing to report and return an overpayment by the government for the sale of a good or service (violating the 60-day rule)
- False certifications of compliance with applicable federal and state laws
- **Paying kickbacks to physicians or other medical providers to refer patients for services in violation of the Stark or Anti-Kickback laws**


Healthcare companies
DOJ/OIG

THE UNITED STATES DEPARTMENT of JUSTICE

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

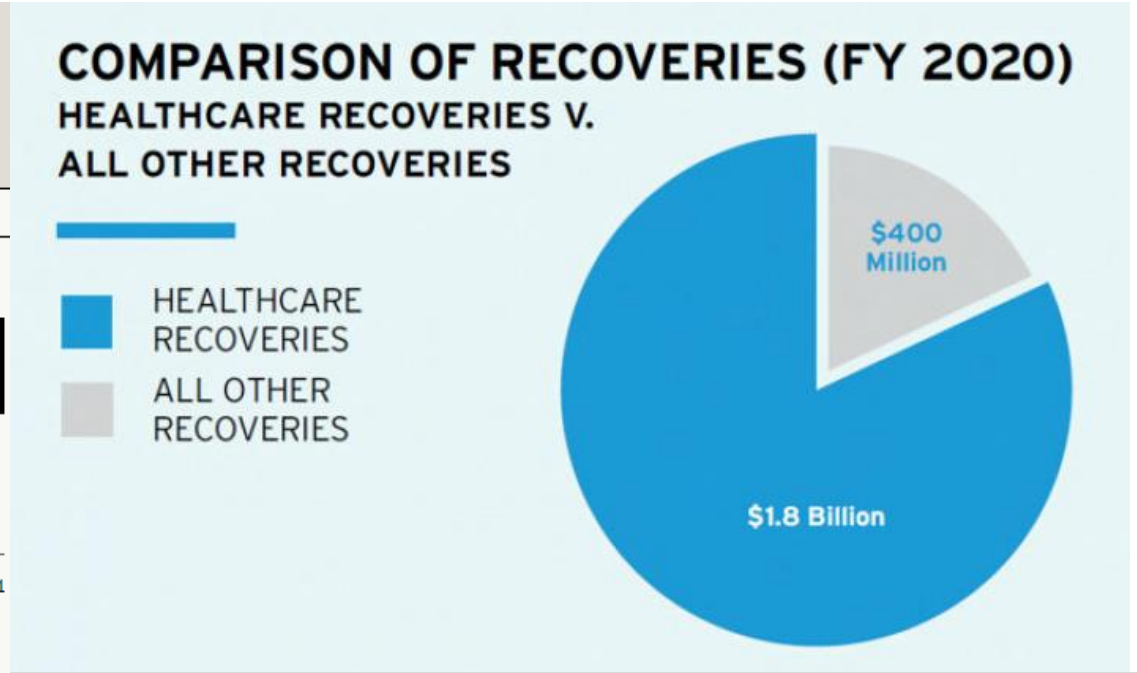
FOR IMMEDIATE RELEASE — Thursday, January 14, 2021

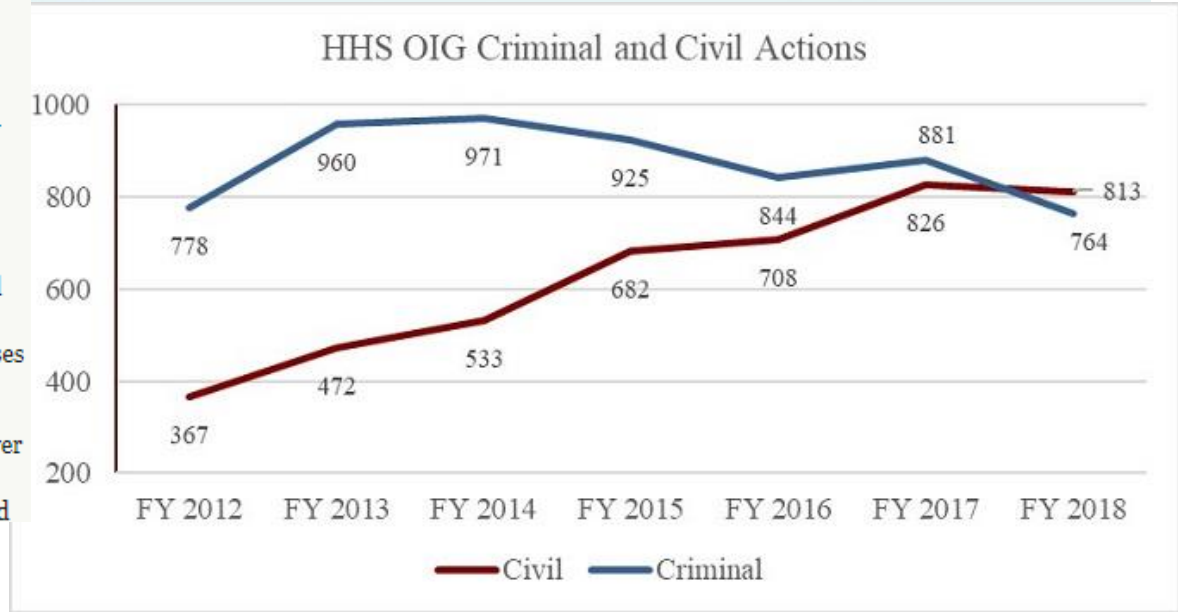
Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020

The Department of Justice obtained more than $2.2 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2020, Acting Assistant Attorney General Jeffrey Bossert Clark of the Department of Justice's Civil Division announced today. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $64 billion.

"Even in the face of a nationwide pandemic, the department's dedicated employees continued to investigate and litigate cases involving fraud against the government and to ensure that citizens' tax dollars are protected from abuse and are used for their intended purposes," said Acting Assistant Attorney General Clark. "The continued success of the department's False Claims Act enforcement efforts are a testament to the dedication of the civil servants who pursue these important cases as well as to the fortitude of whistleblowers who report fraud."

Of the more than $2.2 billion in settlements and judgments recovered by the Department of Justice this past fiscal year, over $1.8 billion relates to matters that involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. The amounts included





Anti-Kickback Statute (42 USC § 1320a-7b)

- You cannot give or get (or offer or solicit) anything of value to induce referrals of Medicare/Medicaid business
  - Felony
  - Up to 10 years in jail
- Anything of value (not just cash)
  - Money
  - Items, gifts, perks, services, space
  - Waivers of copays or deductibles
  - Over/underpayments

Some Recent Examples

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Thursday, February 6, 2020

Patient Recruiter Sentenced to Prison for Role in More than $1 Million Illegal Kickback Conspiracy

A patient recruiter was sentenced to 60 months in prison yesterday for receiving more than $1 million in illegal kickback payments from numerous home health agencies from around the country in exchange for providing information on Medicare beneficiaries to home health agencies, who then used that information to submit fraudulent claims to Medicare.

- Patient recruiter
  - 4 years in prison
  - Recruited patients for HHAs; HHAs paid him for leads
- "Speaker fees" for doctors

In the second matter, Novartis will pay $591,442,008 to resolve FCA claims that it paid kickbacks to doctors to induce them to prescribe the Novartis drugs Lotrel, Valturna, Starlix, Tekturna, Tekturna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT. In addition, Novartis will forfeit $38.4 million under the Civil Asset Forfeiture Statute. Novartis also made extensive factual admissions in the settlement and agreed to strict limitations on any future speaker programs, including reductions to the amount it may spend on such programs.

In a case pending in the Southern District of New York, the United States alleged that Novartis hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors. Novartis paid physicians honoraria, purportedly as compensation for delivering a lecture regarding a Novartis medication, but, as Novartis knew, many of these programs were nothing more than social events held at expensive restaurants, with little or no discussion about the Novartis drugs. Indeed, some of the so-called speaker events never even took place; the speaker was simply paid a fee in order to induce the speaker to prescribe Novartis drugs.

"For more than a decade, Novartis spent hundreds of millions of dollars on so-called speaker programs, including speaking fees, exorbitant meals, and top-shelf alcohol that were nothing more than bribes to get doctors across the country to prescribe Novartis's drugs," said Acting U.S. Attorney Audrey Strauss for the Southern District of New York. "Giving these

Recent Examples Cont'd.

- Athena Health
  - $18.25 million settlement
  - Sports tickets; referral programs

FOR IMMEDIATE RELEASE Thursday, January 28, 2021

Electronic Health Records Technology Vendor to Pay $18.25 Million to Resolve Kickback Allegations

A national electronic health records (EHR) technology vendor based in Watertown, Massachusetts, athenahealth Inc. (Athena), has agreed to pay $18.25 million to resolve allegations that it violated the False Claims Act by paying unlawful kickbacks to generate sales of its EHR product, athenaClinicals, the Justice Department announced today.

In a complaint filed in conjunction with today's settlement, the United States alleged that Athena violated the False Claims Act and the Anti-Kickback Statute through three marketing programs. First, Athena invited prospective and existing customers to "Concierge Events," providing free tickets to and amenities at sporting, entertainment, and recreational events,

Stark Law (Physician Self Referrals)

- If a physician (or their immediate family member) has a financial relationship with an entity:
  - The physician may not refer patients to that entity for designated health services; and
  - The entity may not bill Medicare for those services
- Designated health services include most medical services (hospital services, labs, supplies, therapy, home health, drugs, etc.)
- Strict Liability (intent not required)
- Penalties
  - Civil penalties of $15,000 per service
  - 3x fines
  - Refund of improper payments

Beneficiary Inducement Law

Cannot give things of value to Medicare or Medicaid beneficiaries if one purpose is to induce them to use your services.

Exception: Nominal value no more than $15 per item, or $75 in the aggregate on an annual basis per beneficiary—but cannot be conditioned upon use of our services.

Patient Freedom of Choice

- A Medicare or Medicaid patient "may obtain services from any qualified Medicaid provider that undertakes to provide the services to them." 42 U.S.C. § 1395a; 42 CFR 431.51
- Discharge planning rules (42 CFR 482.43) (revised in 2019):
  - Apply to hospitals and home health agencies, similar rules for skilled nursing
  - Hospital must inform patient of freedom to choose and must respect patients' preferences
  - Must share a list of appropriate local post-acute providers
  - List must include quality data
  - List must not be "qualified or limited"

Classic AKS Safe Harbors

42 CFR § 1001.952

- Employment relationships
- Space or equipment rentals
- Personal services arrangements
- Others
- Key theme:
  - Fair market value
  - Does not take into account the volume or value of referrals

Classic Stark Exceptions

42 CFR § 411.357

- Employment relationships
- Space or equipment rentals
- Personal services arrangements
- Physician incentive/group practice rules
- Fair market value payments
- Non-monetary compensation up to $429 annually per physician

Pop Quiz

- ALF has “preferred provider” relationship with one home health agency. All residents are encouraged to use that home health agency. Is this OK?
- Hospice has several patients at a SNF. Bingo machine breaks. SNF’s activities director says “Be a good partner and buy us a new one.”
  - What’s the motivation?
- Your referral source has a vacant room. They ask you to rent it—for a generous monthly rate—although you really have no use for it.
  - Leases must meet a specific safe harbor.
  - Written contract, at least one year.
  - Must have a legitimate business purpose and a fair market value rate.
- SNF expects home health agency to provide free CNA staffing to supplement SNF’s staff. Good?

So…what has changed?

- 6 new safe harbors/exceptions
  - Care coordination
  - VBA with substantial downside financial risk
  - VBA with full finance risk
  - Patient engagement and support
  - Donation of cybersecurity technology
  - CMS-sponsored arrangements

- Flexibility added to 5 existing safe harbors/exceptions
  - Local transportation
  - Warranties
  - Personal services and management contracts
  - Donation of EHR/EMR items

Core Value-Based Concepts

- Value-based enterprise ("VBE")
  - Two or more entities (e.g., providers or payors) who collaborate to achieve a value-based purpose for a target patient population
  - Requires a contract, an oversight body, regular monitoring
- Value-based purpose
  - Coordinating and managing care; improving care; reducing cost; transitioning to value-based payment models
- Target patient population
  - A set of patients identified in advance using legitimate and verifiable criteria to further the value-based purpose
- Ineligible: lab, pharmacy, drug, medical device/supply companies

VBEs: Why Go to the Trouble?

- Care coordination
  - Can exchange in-kind remuneration (e.g., personnel, software, services)
  - Recipient must pay 15% of the cost/fair market value
  - Cannot be used for marketing or patient recruitment
  - Must support the value-based purpose and be monitored for success
- VBEs with financial risk
  - Can exchange remuneration without the 15% cost-sharing requirement
- Patient engagement and support
  - VBE participant can provide up to $500 of items ("tools and supports") per target patient per year to support the value-based purpose
    - Health tech, nutritious food, transportation vouchers, home supports, etc.
  - Item must be recommended by patient's licensed "health care professional"
  - Cannot be used for marketing or patient recruitment

Local Transportation - Revised

- On its face, free transportation = kickback or patient inducement
- Safe harbor now allows for free or discounted local transportation, on certain conditions
  - Written policy, consistently applied, without regard to referrals
  - Only for existing patients
  - Basic transportation (not luxury)
  - No advertising
  - To obtain medically necessary items or services.
  - Within 25 miles (general) or 75 miles (rural)
  - No mileage limit from inpatient facility to patient residence after 24 hours of observation status