ORANGE COUNTY BAR ASSOCIATION

HEALTH CARE LAW SECTION WEBINAR

Current Trends in Healthcare Fraud Enforcement



Thursday, May 13, 2021



Current Trends in Healthcare Fraud Enforcement

OCBA Healthcare Law Section May 13, 2021





2 Program Agenda

- Big Picture: Federal Enforcement & Statutory Framework
- 2020 Enforcement Statistics
- Trends in Healthcare Fraud Enforcement
- What to Do When the FBI Comes Knocking
- Questions & Answers



³ Big Picture: Federal Enforcement



Criminal and Civil Enforcement

Fraud Enforcement

- DOJ & USAOs
- HHS OIG
- FBI
- State AGs
- CMS
- State Boards of Medicine

Referrals

- Qui Tam
- OIG Hotline
- OIG audits, evaluations
- Data mining
- Agency referrals
- Self-Disclosures

Federal HCFAC Program

- 1996 Health Insurance Portability and Accountability Act established the national Health Care Fraud and Abuse Control Program
- Designed to help coordinate federal, state, and local law enforcement with respect to health care fraud and abuse
- Annual Report, including healthcare fraud enforcement statistics (report with 2020 statistics coming in June)



Criminal, Civil, and Administrative

Criminal

- Beyond a reasonable doubt
- Initiated by indictment or information
- Resolved in Federal Court
- DOJ Prosecutes
- Results in imprisonment, fines, restitution
- Civil
 - Preponderance of the evidence
 - Initiated by complaint
 - Resolved in Federal Court
 - Prosecuted by DOJ
 - **Results in civil penalties, damages, injunctions, restraining orders**

Administrative

- Preponderance of the evidence
- Complaint or formal notice/demand letter
- Resolved by Administrative Law Judge or Departmental Appeals Board
- **Results in civil penalties, damages, exclusions, suspensions, debarments, and other adverse actions**





6 Statutory Framework



Criminal and Civil Enforcement

Criminal Statutes:

- Healthcare Fraud (18 U.S.C. § 1347)
- Wire Fraud/Mail Fraud
- FDA
- Anti-Kickback Statute

Civil Statutes:

- Federal False Claims Act
- State False Claims Acts
- FIRREA

Administrative Remedies:

- Stark
- Exclusion



Criminal Statutes Health Care Fraud: 18 U.S.C. § 1347

- □ Four Elements:
 - Defendant knowingly and willfully devised or participated in a scheme to defraud a health care benefit program, or a scheme or plan for obtaining money or property by means of false or fraudulent pretenses, representations or promises;
 - The statements made or facts omitted as part of the scheme were material;
 - Defendant acted with the *intent to defraud*; and
 - The scheme involved the delivery of or payment for health care benefits, items, or services.



Criminal Statutes Health Care Fraud: 18 U.S.C. § 1347

- "Knowing" Requirement
 - An act is done knowingly if the defendant is aware of the act and does not act or fails to act through ignorance, mistake, or accident.
 - The government is not required to prove that the defendant knew that his acts or omissions were unlawful.



Criminal Statutes Health Care Fraud: 18 U.S.C. § 1347

"Willful" Requirement

- Patient Protection and Affordable Care Act: "willful" does not require proof that defendants either had knowledge of the HCF statute or had specific intent to violate the law
- "(b) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
- Abrogated <u>Awad</u>, a 2009 Ninth Circuit case that suggested that HCF statute required specific intent.



Criminal Statutes Mail Fraud: 18 U.S.C. § 1341

- Knowingly participated in, devised, or intended to devise a scheme or plan to defraud, obtain money/property by means of false or fraudulent pretenses, representations, promises, or omitted facts.
- The statements made or facts omitted as part of the scheme were material
- □ Acted with intent to defraud (deceive and cheat)
- Defendant used, or caused to be used, the mails to carry out, or attempt to carry out, an essential part of the scheme



Criminal Statutes Mail Fraud: 18 U.S.C. § 1341

- No specific false statement necessary: "Under the mail fraud statute the government is not required to prove any particular false statement was made. Rather, there are alternative routes to a mail fraud conviction, one being proof of a scheme or artifice to defraud, which may or may not involve any specific false statement."
 - -United States v. Woods, 335 F.3d 993, 999 (9th Cir. 2003)



Criminal Statutes Wire Fraud: 18 U.S.C. § 1343

The only difference between mail fraud and wire fraud is that the former involves the use of the mails and the latter involves the use of wire, radio, communication in interstate or foreign commerce."

-Comment to 9th Circuit Model Criminal Jury Instructions





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Criminal Statutes Food and Drug Administration

□ 21 U.S.C. § 331: FDA Offenses

18 U.S.C. § 1519: Concealing and Falsifying Documents to Influence the FDA





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Criminal Statutes: 21 U.S.C. § 331: FDA Strict Liability

- 21 U.S.C. § 331 lists a number of offenses related to drugs and medical devices (among other goods):
 - § 331(a): Adulterated/misbranded
 - § 331(k): Alteration, mutilation, destruction, etc. of labeling
 - § 331(t): Importation of unauthorized drugs
- Often viewed as strict liability offenses
 - Park Doctrine / Responsible Corporate Officer Doctrine
 - "... the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." United States v. Park, 421 U.S. 658, 673–74 (1975).



Criminal Statutes: 18 USC § 1519: Concealing and Falsifying Documents to Influence the FDA

- Department/agency investigation or other matter (pending or contemplated);
- Defendant aware of investigation;
- Defendant knowingly altered, concealed, mutilated, or destroyed something with the intent to impede, obstruct, or influence the investigation, or any matter in related to the investigation.



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Health Care Reform Legislation

- The Patient Protection and Affordable Care Act updated the definition of "health care offense" to include violations of the following:
 - Anti-Kickback Statute
 - Food, Drug and Cosmetic Act
 - Certain provisions of ERISA





Anti-Kickback Statute: 42 U.S.C. § 1320a-7b

- Knowingly and willfully solicits/receives or offers/pays (i.e. payor or payee can be prosecuted)
 - The payee need not actually receive the money. He or she need only solicit the illegal remuneration.
- To induce and or in exchange for the referral
 - (1) the referral of patients or business, or
 - (2) the purchase, lease, order or arranging for the purchase, lease, or order of any good, facility, service or item
- For which payment may be made in whole or in part under a federal health care program (including Medicare and Medicaid)



Civil Statutes:

Federal False Claims Act 31 U.S.C. §§ 3729 et seq

- Elements:
 - The "submission of a "claim" to the United States;
 - The "falsity" of the claim;
 - "Materiality" of claim (objective test); and
 - "Knowledge" of the falsity of the claim.



Civil Statutes:

Federal False Claims Act – A Powerful Tool

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- "Preponderance of the evidence" vs "beyond a reasonable doubt"
- Very broad statutory definition of "knowledge"
 - Has actual knowledge of the information;
 - Acts in deliberate ignorance of the truth or falsity of the information; or
 - Acts in reckless disregard of the truth or falsity of the information
- No requirement of actual privity with the government. Liability can be imposed for "causing" false claims to be presented
- Government can get double or treble damages
- Empowers insiders to be whistleblowers



Civil Statutes:

California False Claims Act Gov. Code § 12651

- Elements
 - Presented a false or fraudulent claim to the public entity for payment or approval;
 - Falsity of the claim
 - Materiality
 - Knowledge of the falsity of the claim



Civil Statutes: FIRREA: 12 U.S.C. § 1833a

- Authorizes DOJ to bring a complaint seeking money penalties for violations of 14 different criminal statutes, including:
 - Mail Fraud

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- Wire Fraud
- False statements to government agency
- □ Can be used in conjunction with FCA



Administrative Remedies

Stark Physician Self-Referral Law

□ 42 U.S.C. § 1395nn

- Prohibits referring patients for certain designated health services payable by Medicare to an entity with which the physician or physician's immediate family has a financial relationship.
 - (November 2020 Final Rule created exception for certain valuebased compensation arrangements between or among physicians, providers, and suppliers)

Exclusion Statute

- □ 42 U.S.C. § 1320a-7
- H.H.S. OIG excludes from participation in all Federal health care programs those convicted of healthcare-related fraud, theft, or other financial misconduct



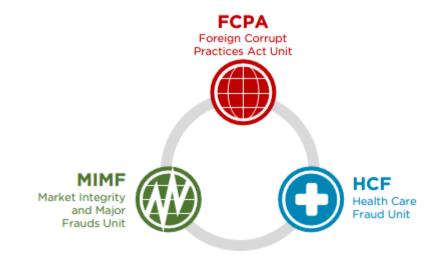


24 2020 Enforcement Statistics



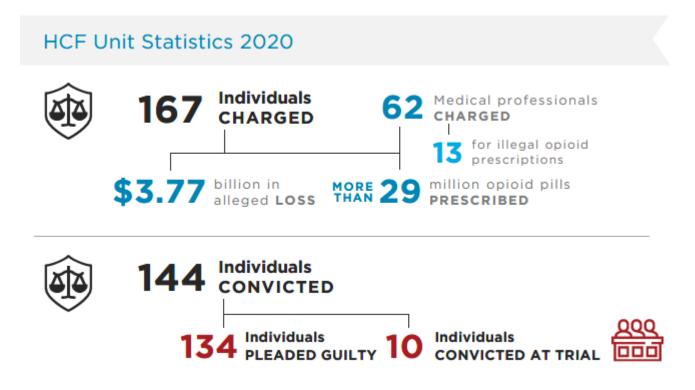
DOJ Criminal Division, Fraud Section – 2020 Year in Review

- Summary of 2020 DOJ Fraud Section Individual Prosecutions:
 - 326 individuals charged
 - 28 FCPA
 - 167 HCF (\$3.77 billion in alleged fraud loss)
 - 131 MIMF
 - 213 individuals convicted
 - 15 FCPA
 - 144 HCF
 - 54 MIMF
 - 16 trial convictions
 - 1 FCPA
 - 10 HCF
 - 5 MIMF





DOJ Health Care Fraud Unit



DOJ Criminal Division, Fraud Section – 2020 Year in Review



DOJ Market Integrity and Major Frauds Unit

PPP Enforcement | 2020 Fraud Section Totals⁸

67 CASES 97 DEFENDANTS CHARGED MORE \$260 MILLION of ATTEMPTED LOSS

THAN \$130 MILLION OF ACTUAL LOSS

THAN \$64 MILLION | of SEIZED / FROZEN FUNDS

DOJ Criminal Division, Fraud Section – 2020 Year in Review



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Civil Enforcement – False Claims Act

□ FCA Enforcement in 2020:

- \$2.2 billion in settlements and judgments
- \$1.8 billion related to health care industry
 - Lowest dollar amount since 2009,
 - BUT <u>record</u> number of FCA cases (922, with 570 involving healthcare) and 250 initiated by DOJ (most since 1994)
- Novartis \$591 million paid to resolve claims of kickbacks
- Gilead & Novartis \$148 million combined to resolve claims that they illegally paid patient copays





29 Trends in Healthcare Fraud Enforcement



CARES Act Enforcement - Criminal

- □ Factors that will influence enforcement:
 - Second-draw loans now available
 - Economic Aid Act altered lending terms
 - Hotbed of enforcement: SBA loan forgiveness applications (retroactive review of eligibility)
 - Xavier Becerra HHS Secretary (former CA AG)
- Special Inspector General for Pandemic Recovery created by CARES Act, coordinates investigations across agencies, among other duties
- □ SBA most criminal referrals (91) in two decades
- Increase in first two months of individuals charged in PPP-related cases



CARES Act Enforcement - Criminal

- Provider Relief Fund (\$178 billion for hospitals and healthcare providers)
 - February 11, first individual charged for misappropriating moneys from the PRF
 - April 8, second individual charged
 - Expect more to come
 - Even if not criminally liable, FCA liability a major concern



CARES Act Enforcement - Civil

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□ FIRREA civil penalties will play an important role

Expect uptick in FCA enforcement

January 12, 2021, DOJ announced its first-ever civil settlement of alleged FCA and FIRREA violations with a borrower of a PPP loan

PPP loans = compliance minefields (remember broad definition of FCA "knowledge")



DOJ Civil Division's FCA Priorities

- February 17, 2021, Acting Assistant AG Brian Boynton outlined 6 priorities for DOJ Civil Division's FCA enforcement priorities:
 - 1) Pandemic-related fraud
 - 2) Opioids
 - 3) Fraud targeting seniors
 - 4) Electronic health records
 - 5) Telehealth
 - 6) Cybersecurity





Litigation Spotlight: FCA Materiality

In Escobar, the Supreme Court made it clear that government knowledge of a violation may not only merely vitiate scienter, but can also deem it <u>immaterial</u>.

- "[I]f the Government pays a particular claim in full despite its <u>actual</u> knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 2003–04 (2016) (emphasis added).
- All Circuits—including the Ninth—have followed Escobar's lead on this. See, e.g., United States ex rel. Berg v. Honeywell Int'l, Inc., 740 F. App'x 535, 538 (9th Cir. 2018)
- DOJ continued focus on "actual knowledge." April 2, 2021 statement of interest: "With respect to materiality, what matters is whether the Government has continued to pay despite actual knowledge of <u>specific</u> <u>false claims</u>." United States of America, ex rel. JKJ Partnership 2011, et al. v. Sanofi-Aventis U.S. LLC, et al., case no. 3:11-cv-06476 (D.N.J.)



Recent FCA Enforcement Action

- Individuals facing enforcement:
 - Neurosurgeon ordered to pay \$4.4 million settlement for receiving kickbacks for using medical devices (including payments from Medtronic) and performing unnecessary surgeries





FCPA Enforcement

- Foreign Corrupt Practices Act (FCPA) Elements:
 - (1) offer, payment, promise to pay (anything of value)
 - (2) to a foreign official
 - (3) corrupt purpose
- 2017 announcement of partnership between DOJ's Healthcare Fraud Unit's Corporate Strike Force and FCPA prosecutors
- Charles Cain, Chief of SEC's FCPA Unit: Healthcare industry is "perfect storm," pay-to-play atmosphere
- 2020 cases:
 - Novartis \$340 million settlement
 - Alexion Pharmaceuticals, Boston-based pharma company \$21 million settlement (books and records violations)
 - Cardinal Health, Ohio-based pharma company (books and records violations in connection with operations in China)



Telehealth

Telehealth basics:

Business and Professions Code § 2290.5

- Standard of care is the same as in-person
- Practitioner must obtain verbal or written informed consent, which must be documented, prior to delivering telehealth care, SUSPENDED under Governor Newsom's Executive Order N-43-20
- Business and Professions Code § 2242
 - Prescriptions only with appropriate prior examination
 - "An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care."
- Doctor-patient relationship can be established over telehealth
- CMS Waiver
 - Broadens eligible providers to include all who can bill Medicare (e.g., physical therapists, occupational therapists, speech language pathologists, and others)
 - Permits audio-only telehealth





Telehealth Enforcement

- Common scheme: Sham telehealth visit (sometimes does not occur at all); doctor orders product; third-party entity pays Dr., collects paperwork, then bills gov't for medically unnecessary treatment (device, medication, etc.); big payout
 - Watch out for doctors who are misled about their role, then find themselves caught up
 - Must establish legitimate physician-patient relationship
 - Even if not criminally liable, major area of FCA enforcement
- Telehealth fraud was increasingly a priority
 - April 2019, Operation Brace Yourself unnecessary medical equipment (\$1 billion)
 - September 2019, Operation Double Helix fraudulent genetic testing (\$2.1 billion)
- September 30, 2020 national takedown
 - 345 defendants
 - \$6 billion in alleged fraud losses (\$4.5 billion related to telehealth)
 - Telehealth execs paid providers to order unnecessary equipment, genetic and other diagnostic testing, and pain medications after no interaction or brief telephone conversations
 - Companies received kickbacks and then purchased these orders, billing Medicare
- Assistant AG Boynton February 2021 address: "continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic"



DOJ COVID-19 Deceptive Marketing Initiative

COVID-19 Consumer Protection Act

- Prohibits deceptive acts or practices associated with the treatment, cure, prevention, mitigation or diagnosis of COVID-19
- April 15, 2021: DOJ & FTC civil complaint alleging violations of the COVID-19
 - Defendants advertised that vitamin D and zinc supplements could prevent or treat COVID-19



DOJ Cooperation Credit Policy

- Yates Memorandum (Individual Accountability for Corporate Wrongdoing)
 - To receive cooperation credit, corporations must identify <u>all</u> individuals involved in the misconduct
- Rosenstein Remarks at International Conference on FCPA Clarified Yates Memorandum
 - For cooperation credit, companies must identify individuals who were <u>substantially involved</u> in the wrongdoing
- Civil Division 2019 guidance on FCA updated in Justice Manual, cooperation credit earned by:
 - Voluntarily disclosing misconduct unknown to the government
 - Cooperating in an ongoing investigation
 - Undertaking remedial measures in response to a violation.



Regulatory Waivers

- Blanket waivers of sanctions under Stark
 - Only for referrals/relationships related to COVID-19
 - No need to notify CMS
- Telehealth waiver
- Many others (waiver of 3-day hospital stay requirement for skilled nursing facility coverage, loosening restrictions to "Hospitals Without Walls" billing, and many more)

KEY: NUMEROUS COMPLEX WAIVERS, MUST ENSURE COMPLIANCE

Watch for DOJ enforcement in this area



Everybody Knew ≠ Willfulness

United States v. Nora, No. 18-31078 (5th Cir. 2021)

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 - Nora, office manager, assigned to patient intake; also involved in Abide's (company) multi-faceted fraud scheme:
 - Abide would employ house doctors to bill Medicare for medically unnecessary plans of care
 - Nora assigned the house doctors
 - Abide employed a pay-for-referral system
 - Nora logged the referrals and sometimes delivered payment
 - Ghosting patients (official discharge then re-enrollment to avoid Medicare scrutiny for continuous re-certifications for 60-day home health services)
 - Nora was at least aware of the "ghosting"



Everybody Knew ≠ Willfulness

- Willfulness = "[T]he Government must prove that the defendant acted with knowledge that his conduct was unlawful."
 - Gov't must prove knowledge and willfulness
- The evidence did not prove that Nora understood Abide's various practices and schemes to be fraudulent or unlawful, and thus there was insufficient evidence to conclude that Nora acted with "bad purpose" in carrying out his responsibilities at Abide.
- □ Specifics:
 - Nora's training did not cover "health care laws or Medicare regulations at all, let alone regulations about kickbacks or activity relating to 'ghosting."
 - "[E]ven if a reasonable person in Nora's shoes should have known (or at least suspected) that ghosting was unlawful, that would only make Nora guilty of negligently participating in a fraud—it does not prove that Nora acted 'willfully' in facilitating ghosting and the fraud it furthered."
 - Just because "everyone knew" about the ghosting did not mean that "everyone in the office knew that the practice was **employed to evade Medicare regulations.**"



Relatedly... (home health fraud)

May 7, 2021 – California woman indicted on health care fraud charges

False home health certifications and related fraudulent billings to Medicare





Medical Judgment Falsity Under FCA

Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108 (9th Cir. 2020)

□ When can clinical judgments be false under the FCA?

- 11th Circuit
 - Plaintiff is required to demonstrate that there is an objective falsity: "a claim that certifies that a patient is terminally ill ... cannot be 'false' – and thus cannot trigger FCA liability – if the underlying clinical judgment <u>does not reflect an objective</u> <u>falsehood</u>" United States v. AseraCare, Inc., 938 F.3d 1296– 97 (11th Cir. 2019).

9th Circuit (and 3rd Circuit)

- Plaintiff must show something "more than just a reasonable difference of opinion." Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1120 (9th Cir. 2020)
 - Could include objective falsity, but need not rise to that
 - 3rd Circuit also rejects objective falsity requirement. United States ex rel. Druding v. Care Alternatives, 952 F.3d 89 (3d Cir. 2020).





What to Do When the FBI Comes Knocking

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Avoiding Obstruction Allegations

It is unlawful to intentionally endeavor or succeed in influencing, obstructing, or impeding the administration of justice in pending judicial or quasi-judicial proceedings





Common Federal Obstruction Statutes

- 18 U.S.C. §§ 1503, 1505: Obstruction of Agency Investigations
- □ 18 U.S.C. § 1510: Obstruction of Criminal Investigations
- 18 U.S.C. § 1512: Obstructing an Official Proceeding
- □ 18 U.S.C. § 1516: Obstruction of Federal Audit
- 18 U.S.C. § 1518: Obstruction of Criminal Investigations of Health Care Offenses
- 18 U.S.C. § 1519: Destruction, Alteration, or Falsification of Records in Federal Investigations



Responding to Subpoenas

- Corporate entities typically have no privilege against self-incrimination
- Companies cannot assert "production immunity"
- Suspend applicable document retention policies after learning of an investigation
- Engage outside counsel to respond to any government subpoena:
 - Credibility is the coin of the realm
 - Leave "Rambo" at home



Responding to Subpoenas

- Ensure validity of subpoena
- If the subpoend is drawn too broadly, try to narrow and/or seek a rolling or prioritized production
- Move quickly to initiate an investigation hold as soon as a valid subpoend has been issued
- Counsel should oversee the document gathering process



Responding to Search Warrants

- In some cases, your first contact with law enforcement will come during the execution of a search warrant ("heat of battle")
- Credibility: first impressions really do matter
- If your company is searched, never interfere with the agents. This could be viewed as obstruction of justice
- But you can (and should) review the warrant and make a record (see next)
- Be prepared: engage qualified counsel now to assist in preparing a search warrant response plan



Be Prepared: Search Warrants

- Train company employees
- Create search warrant response team within the company
- Designate one person within the team who will deal with the government agents
- Develop a checklist of who to call and what to do, how to effectively respond without interfering with agents, and how to handle business interruption issues
- Prepare for a professional response to set a civil tone for the investigation



In the Moment: Search Warrants

- □ Contact the members of the warrant response team
- Review the warrant
- Consider sending home employees who are not essential to the search or ongoing business operations
- Monitor agents executing the search and Document exchanges with agents
- Do not destroy, alter, remove or hide records
- Do not communicate about matters covered by the company's attorney-client privilege
- Try to reach an agreement to retain copies, or even originals, of documents seized
- Identify privileged files
- □ If privileged documents are taken, state your objection to the agent in presence of witnesses
- If the agents insist on taking privileged documents, attempt to reach an understanding whereby the privileged documents will be kept separate and under seal until privilege disputes can be resolved
- Consult legal counsel If agents ask for consent to go beyond the scope of the search warrant



After The Search Warrant

- Prepare a media response
- Debrief any employees who interacted with government agents during the search
- Retain outside counsel to conduct an internal investigation
- Request an inventory
- Request the affidavit





Parallel Proceedings: "Do's and Don'ts"

- Government Investigation that Proceeds Civilly & Criminally at the Same Time
- Also can refer to administrative proceedings
- And/or federal and state proceeding at same time
- Proceedings are usually not just parallel but also joint



Q&A Session

- Questions about best practices?
- Panicked calls from clients?
- Call Vince Farhat @ (310) 785-5382



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