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**HCCA NEW ORLEANS REGIONAL
CONFERENCE**
Healthcare Fraud Enforcement Panel

Friday, April 21, 2017
New Orleans Downtown Marriott Convention Center

A.G. (Alec) Alexander, III Corey R. Amundson,
Partner Acting United States Attorney
Breazeale, Sachse & Wilson, LLP Middle District of Louisiana

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Goals

- Overview of the Federal False Claims Act and the Medicare Fraud Strike Force, How They Are Used and What Drives DOJ Decisions
- Discuss Specific Examples of How the FCA and Strike Force Can Impact Providers
- Provide Real-World Guidance on How Corporations and Individuals Can Mitigate/Prevent FCA and Strike Force Exposure
 - **Important Things To Remember**
- Analyze the Language, Scope and Requirements of the Yates Memorandum
- Answer Questions and Comments About Current Civil and Criminal Priorities, Trends and Actions By DOJ in the Healthcare Arena

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United States Attorney's Office

- U.S. Attorney is appointed by the President and reports to the U.S. Attorney General.
- U.S. Attorney serves as the chief federal law enforcement officer in the district.
- Louisiana has 3 federal districts: Western, Middle and Eastern.
- Middle District of Louisiana covers nine parishes (counties) in South Central Louisiana.

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United States Attorney's Office

- Leadership (USA and FAUSA)
- Criminal Division (Chief and Dep. Chiefs)
- Civil Division (Chief)
- Administrative Division (A.O.)

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United States Attorney's Office
Criminal Division

- **Major Crimes and Narcotics Priorities**
 - Human Trafficking
 - Civil Rights Violations
 - Sexual Exploitation of Children
 - Violent Offenders
 - Narcotics
 - Immigration Crimes

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United States Attorney's Office
Criminal Division

- **Fraud and White Collar Crime Priorities**
 - Health Care Fraud
 - Public Corruption
 - Computer Crimes
 - Identity Theft
 - Tax fraud
 - Environmental crimes

Civil Division

- Health Care Fraud

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HEALTH CARE FRAUD PREVENTION AND ENFORCEMENT ACTION TEAM (“HEAT”)

- Joint Initiative between HHS and DOJ.
- Strike Forces established in fraud “hot spot” locations.
- Use advanced data analysis to identify high-billing levels.
- Prevention/Deterrence.

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Medicare Fraud Strike Forces: United States Attorneys Offices

U.S. Dept. of Justice, Criminal Division
FBI
HHS, OIG
MFCU
Local and State Law Enforcement

<p>Baton Rouge Chicago Detroit Los Angeles</p>	<p>New York Dallas Houston Miami</p>	<p>Tampa</p>
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Baton Rouge Strike Force

- Established in Dec. 2009
- Prosecutors from U.S. Attorney’s Office and Criminal Fraud Section of DOJ
- Investigators from FBI, HHS-OIG, MFCUs, and other law enforcement agencies
- Target highest HCF areas
- Fast acting, real time prosecutions of ongoing billing schemes

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Strike Forces – Results (National)

- Strike Forces have charged almost 2,000 defendants who billed for almost \$6 billion.
- In FY 2013, strike forces charged 345 individuals, secured 234 guilty pleas, and obtained 46 jury trial convictions and an average prison sentence of 52 months.

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**Strike Forces – Results
(Baton Rouge)**

- 75 Different Defendants Charged
- Conviction Rate > 96%
- 7 Defendants Sentenced 84 Months or More
- Highest Sentence 180 Months (Multiple Cases)
- Highest Sentence 156 Months (Single Case)
- Total Judgments and Restitution Orders > \$100 million

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**Shifa Community Mental Health Centers
*United States v. Naz Jafri et al.***

- CMHCs in Baton Rouge and Houston, Texas
- 17 defendants convicted via plea or trial
 - August 2014:
 - Owner sentenced to 108 months in prison
 - Psychiatrist sentenced to 86 months in prison
 - Numerous others sentenced to prison terms
- At the time, believed to be largest mental health clinic fraud prosecution in U.S. history

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All-Star Medical Supply
United States v. Ahaoma Boniface Ohia et al.

- DME company in Baton Rouge and Houston
- Claims for PWCs, brace kits
- Fraudulent billings > \$2.5 million
- Lead patient recruiter/marketer pled guilty prior to trial
- Owner convicted of all counts at trial
 - Sentenced to 13 years in prison
 - 2015: 5th Circuit affirmed conviction and sentence
 - 2017: District court denies defendant's 2255 motion

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Other Health Care-Related Efforts

- Drug diversion
 - Prescription drugs diverted from lawful/legitimate use
 - Often investigated by DEA / FBI
 - May involve false claims to Medicare, Medicaid, private insurer
- Traditional fraud/embezzlement
 - Mail fraud/wire fraud/other crimes
 - Victim may be in the health care industry

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The False Claims Act:
31 U.S.C 3729 et seq.



- Originally enacted during the Civil War (1863)
- Redresses fraud involving federal government programs
- Prohibits false claims, records or statements involving U.S. money
- Most start with relators, though not required
- Investigating Agencies
 - OIG (various agencies), FBI, NCIS, DCIS among many others
- Limitations Period:
 - 6 years from date of claim, record or statement OR 3 years from date of discovery by an official with authority to act, but in no event more than 10 years after the submission of the claim
- Treble damages
- Penalties of \$5,500 to \$11,000 for each false claim or statement
 - NOTE: FCA PENALTY RANGE **RAISED** effective July 1, 2016 to \$10,781 - \$21,563 per proven false claim. This is an inflationary adjustment of 198% over the previous penalty range.
- Joint and several liability for defendants

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The False Claims Act:
31 U.S.C. 3729 et seq.

"Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval ... or knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States ... for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted ... plus 3 times the amount of damages which the Government sustains because of the act of that person"

The terms "knowing" and "knowingly" 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.

✓ No Specific Intent to Defraud is Required

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The False Claims Act Recoveries



- For Fiscal Year 2015:
 - Total Recoveries = **\$3.5 billion**
 - Total Health Care Recoveries = **\$1.9 billion**
 - Total Health Care Qui Tam Recoveries = **\$1.8 billion**
 - Total New Qui Tam Filings = **638**
 - Total New Qui Tam Health Care Filings = **423**
 - **DOJ intervenes in approximately 25% of the qui tam cases** in which it makes an intervention decision (some cases get dismissed pre-election)
 - Total relator (whistleblower) awards **\$597 million** (does not include costs/fees paid separately)
 - Since 2009, total **\$26.4 billion** recovered on **6,179 qui tams** and **837 non-qui tams** (all types)

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The False Claims Act:
Anatomy of a FCA Case

- Key Elements
 - Claims
 - Falsity (Stark/AKS)
 - Knowledge
 - Actual Knowledge
 - Deliberate Ignorance
 - Reckless Disregard
 - Materiality (See *Escobar* below)
 - Damages (actually not required but almost always present)
 - Causation
 - The FCA is directed not merely at those who submit false claims but also at those who "cause" false or fraudulent claims to be submitted. ("Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct . . . would ineluctably result in false Medicaid claims"). United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003)

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The False Claims Act:
31 U.S.C. 3729 et seq.

Universal Health Services v. U.S. ex rel. Escobar (136 S.Ct. 1989) (06-16-16)

Held: Implied False Certification can be a basis for FCA liability if defendant makes specific representations about the goods or services provided but fails to disclose non-compliance with **material** statutory, regulatory or contractual requirements that makes those representations misleading

Held: FCA liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. Rather, what matters is whether the defendant knowingly violated a requirement that the defendant knows is material to the payment decision.

- Gov't designation as "condition of payment" is relevant but not dispositive
- Gov't cannot deem materiality merely by designating compliance with the provision as a "condition of payment."
- Gov't option to deny payment if it knew of defendant's non-compliance also not sufficient for materiality finding
- Not material if non-compliance is "minor or insubstantial"
- Gov't payment in full, despite knowledge of non-compliance, is "very strong evidence" provision is not material

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The False Claims Act:
Intervention Decision

- After Its Investigation, the United States May Choose to Intervene and Take Over the Litigation. This is a Critical Juncture for Relators. Though Relators May Proceed Without the Government, 80-85% of Non-intervened Cases Do Not Go Forward. Also Critical Point for Defendant.
- **Key Drivers in Government's Decision:**
 - The strength of the case and the evidence
 - The magnitude of the associated damages
 - Non-monetary issues such as patient health or safety, and other quality of care concerns
 - Whether the conduct is part of a pervasive practice that the government wants to address
 - The potential for individual liability
 - The potential deterrent value of the case

NOT a key driver: Relator's personal baggage

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The False Claims Act:
Categories Potentially Affecting Providers

- Billing For Goods or Services Not Provided
 - Quality of Care Cases
- Billing for Ineligible Goods or Services
 - Medical Necessity Cases
- Inflated Billings
 - Hospitalist Cases
- False Certification Cases
 - Kickback and Stark Cases

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The False Claims Act:
Billing for Goods or Services Not Provided

- An Entity May Not Bill The Government For Non-Existent, Worthless or Substandard Products or Services
 - "...in a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent to no performance at all." U.S. ex rel. *Mikes v. Strauss*, 274 F.3d 687 (2d Cir. 2001).
 - U.S. Files Suit Against Georgia Medical Center and Physician; Allegedly Submitted Claims for Worthless Services to Federal Health Care Programs (July 27, 2010)
 - The United States alleged that operative procedures performed by a general surgeon and related hospital services were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were of no medical value and endangered the lives of federal health care program beneficiaries.
 - The physician was a general surgeon by training. The hospital allowed him to perform highly specialized endovascular procedures in the cath lab. The physician lacked specialized training to perform such procedures, was not qualified or competent to perform such procedures, had never performed such procedures before at any of the hospitals where he had been on staff, and did not even have privileges to perform the procedures.
 - Allegations of resulting patient harm included seriously injury and the death of one patient from hemorrhagic shock following an endovascular procedure during which the physician perforated a renal artery

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The False Claims Act:
Billing for Ineligible Goods or Services

Medical Necessity

Social Security Act
"Section 1862 (42 U.S.C. § 1395y) - (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services (1)(A) which, except for items and services described in a succeeding paragraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member...."

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The False Claims Act:
Billing For Ineligible Goods and Services (Medical Necessity)

- Kentucky Hospital Agrees to Pay Government \$16.5 Million to Settle Allegations of Unnecessary Cardiac Procedures (January 29, 2014):
 - The government alleged that doctors working at Saint Joseph Hospital performed numerous invasive cardiac procedures, including coronary stents, pacemakers, coronary artery bypass graft surgeries and diagnostic catheterizations, on Medicare and Medicaid patients who did not need them, and that the hospital was aware of these unnecessary procedures.
 - One cardiologist working at the hospital performed many of the medically unnecessary coronary stents. That doctor plead guilty to a federal health care fraud offense and has been sentenced to serve 30 months in prison.
 - The government also intervened in a separate lawsuit alleging False Claims Act violations by two other physicians who referred patients for and performed the unnecessary procedures and tests, and their practice group.
 - The government actions stem from a whistleblower complaint filed by three Lexington, Ky., cardiologists pursuant to the qui tam provisions of the False Claims Act.
 - The Relators, Drs. Michael Jones, Paula Hollingsworth and Michael Rukavina, received a total of \$2.46 million of the \$16.5 million settlement with the hospital.

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The False Claims Act:
False Certification Cases- Stark and AKS

- Illinois Physician Pleads Guilty to Taking Kickbacks from Pharmaceutical Company and Agrees to Pay \$3.79 Million to Settle Civil False Claims Act Case (Feb. 13, 2015)
 - ✓ Physician pleaded guilty to receiving illegal kickbacks totaling \$600,000 from pharmaceutical companies in exchange for regularly prescribing the company's anti-psychotic drug to his patients.
 - ✓ Physician also paid the United States and the state of Illinois \$3.79 million to settle a parallel FCA lawsuit alleging that, by prescribing the drug in exchange for kickbacks, the physician caused the submission of false claims to Medicare and Medicaid.
 - ✓ The scheme began in 2003 when the physician agreed to switch his patients to generic clozapine if the company paid him \$50,000 plus other benefits under a one-year "consulting agreement."
 - ✓ In addition to direct payments, the company also provided all-expenses paid trips to Miami for the physician and his wife and various employees. The physician quickly became the largest prescriber of generic clozapine in the country.

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Types of FCA Cases Recently Resolved

- U.S. ex rel. Vinca v. Advanced BioHealing, Inc., (M.D. FL)
 - \$350 million settlement . Allegations: Defendant paid kickbacks to induce clinics and physicians to use or overuse Dermagraft, a bioengineered human skin substitute approved by the FDA for treatment of diabetic foot ulcers.
 - Kickbacks: Lavish dinners, drinks, entertainment and travel; medical equipment and supplies; Payments for sham speaking engagements & bogus case studies; and cash, credits and rebates.
 - Resolved allegations defendant unlawfully marketed Dermagraft for unapproved uses, made false statements to inflate the price of Dermagraft, and caused improper coding of Dermagraft claims. (1/11/17)
- U.S. ex rel. Meehan v. Medstar Ambulance, Inc., (D. Mass.)
 - \$12.7 million settlement . Allegations: Medstar routinely billed for services that did not qualify for reimbursement because transports not medically reasonable and necessary, billed for higher levels of services than required by patients' conditions, and billed higher levels of services than were actually provided. (1/13/17)
- U.S. ex rel. Taylor v. Life Care Centers of America, Inc. (E.D. Tenn)
 - \$145 million settlement. Allegations that Life Care instituted corporate-wide practices designed to place and bill beneficiaries at the Ultra High reimbursement level for rehabilitation therapy irrespective of the clinical needs of the patients.

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QUESTIONS? COMMENTS? REFUNDS?

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