Significant Developments in Health Care Fraud

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ABA HEALTH LAW SECTION MEMBER BENEFIT
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TOP 5 TOPICS

1. Major Government Enforcement Initiatives: What to Anticipate?

2. Government Enforcement Trends
   • Managed Care
   • Medicare D
   • Improper Sales and Marketing
   • Medical Necessity and Prosecutions of Individual Physicians

3. Anti Kickback Statute in Criminal and Civil Prosecutions

4. Defense Strategies and/or Mitigation Strategies
Universe of Government Actors

- **Department of Justice**
  - HEAT Task Force – Collected over 8 billion dollars since its formation.
  - **Fraud Section** – 40 attorneys devoted purely to enforcement of HC Fraud cases; travel nationwide. Divided primarily amongst Detroit, Miami, Tampa, Los Angeles, Houston, New York, and Louisiana.
  - Line Assistants by District
  - **Civil Division**- False Claims Act; bloated budget for FYE 2014

- FBI
- Medicaid Fraud Control Units (MCFU’s)
- Zone Program Integrity Contractors (ZPICs)
- Professional Relators
- DEA Office of Diversion
- FDA Office of Criminal Investigations (FDA-OCI)
- Office of Inspector General Department of Health and Human Services (OIG-HHS)
Potential Consequences for Bad Actors

- **Criminal**
  - Jail
  - Restitution
  - Asset forfeiture
  - Exclusion from government programs

- **Civil**
  - Civil Monetary Penalties
  - Treble Damages

- **Administrative**
  - Suspension of Payments
  - Collection of Overpayments
  - Civil Monetary Penalties
  - Exclusion from government programs
  - Suspension of license to practice medicine
  - Prepayment review
  - Debarment
Major Enforcement Initiatives

1. Prosecutions of C-Suite and Executives
2. Enhanced Sharing Between Civil and Criminal Division; New Qui Tam Policy
3. Send Industry Wide Messages
C Suites and Executives

Corporations do not act, but for the actions of individuals. In all but a few cases, an individual or group of individuals is responsible for the corporation’s criminal conduct. The prosecution of culpable individuals – including corporate executives – for their criminal wrongdoing continues to be a high priority for the department.

For a company to receive full cooperation credit following a self-report, it must root out the misconduct and identify the individuals responsible, even if they are senior executives.

We are not asking that you become surrogate FBI agents or prosecutors, or that you use law enforcement tactics like body wires. And we do not need to hear you say that executive A violated a particular criminal law. All we are saying is that we expect you to provide us with facts. We will take it from there.”

Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the 22nd Annual Ethics and Compliance Conference Atlanta, GA United States Wednesday, October 1, 2014
New Qui Tam Policy

“We in the Criminal Division have recently implemented a procedure so that all new qui tam complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed. Experienced prosecutors in the Fraud Section are immediately reviewing the qui tam cases when we receive them to determine whether to open a parallel criminal investigation.

Those prosecutors then coordinate swiftly with the Civil Division and U.S. Attorney’s Offices about the best ways to proceed in the parallel investigations. If a case raises potential criminal issues and needs investigative support, we have ready access to experienced fraud investigators from the FBI, HHS-OIG, the Postal Inspection Service and numerous other law enforcement agencies.

And we have a wealth of experience in successfully bringing parallel investigations. We do this in many contexts, not only with the Civil Fraud section and U.S. Attorney’s Offices, but with the SEC and other regulatory agencies, here and abroad. We know how to make it work…”

Assistant Attorney General, Leslie Caldwell, September 17, 2014; see http://www.justice.gov/criminal/pr/speeches/2014/crm-speech-140917.html
## CIVIL VS. CRIMINAL

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<td><strong>1.</strong> <em>U.S. ex rel. Guthrie v. A Plus Home Health Care, Inc.</em>, 12 CV 60629 (S.D. Fla.) Two doctors, including Dr. Alan Buhler and Dr. Craig Prokos agreed to pay $1.3 million as a settlement based on allegations that they paid improper marketing salaries to their spouses in exchange for referrals of patients to home health care organization.</td>
<td><strong>1.</strong> Dr. Angela Barrow and Dr. Robert Barrow (E.D. Ark. 2014) husband and wife doctors indicted based on splitting proceeds of referrals to local massage therapist and billing for services as physical therapy.</td>
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<td><strong>1.</strong> Paramjit Singh Ajrawat and his wife Sukhveen Kaur Ajrawat (D MD. 2014). Dr. Ajrawat was a licensed physician in Maryland who specialized in interventional pain management. S. Ajrawat was a licensed psychiatrist in Maryland. The Ajrawats owned and operated Washington Pain Management Center (WPMC) located in Greenbelt. Indictment alleges billing for services never performed and “upcoding” related to more invasive epidural procedures than provided.</td>
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Impact of this Policy

1. Shift in policy

2. How closely are Civil Division and Criminal Division working together?

3. Civil Investigative Demand Statute (31 USC Section 3733) specifically authorizes sharing information with Criminal Division

“To be parallel, by definition, the separate investigations should be like the side-by-side train tracks that never intersect.” – Federal District Judge Karon O. Bowdre, Chief Judge of the Northern District of Alabama.
CIVIL INVESTIGATIVE DEMAND STATUTE

• 31 U.S.C. Section 3733 delegates substantial authority to individual AUSA’s to send Civil Investigative Demands (CID’s) to investigate whistleblower claims before deciding whether or not to intervene in a lawsuit filed under seal.

• 31 U.S.C. Section 3733(i)(3) specifically authorizes sharing information with criminal division

   “Whenever any attorney of the Department of Justice has been designated to appear before any court, grand jury, or federal agency in any case or proceeding, the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony received under this section may deliver such attorney such material, answers, or transcripts for official use in connection with any case or proceeding as such attorney determines to be required.”
CHALLENGES TO CID’S

• CID requests testimonial communications
  • See United States v. Aria Sabit, No. 14-MC-50155 (E.D. Mich. April 1, 2014) (finding that government’s request for “any emails between defendant and organization would require defendant to make testimonial communications by forcing him to use the contents of his mind to identify those emails)

• CID is overly broad.
  • See 31 U.S.C. Section 3733(a)(2)(D)(iv)
  • See 31 U.S.C. Section 3733(h)(7)(A): Note though that during an oral examination the statute specifically states that a person may not refuse to object to a question for any reason other than asserting the Fifth Amendment right against self-incrimination. In practice, however, if the questions veer off into areas outside “primary areas of concern,” counsel should be able to object to those questions.

• CID requests privileged or confidential materials
  • United States v. Aurora Health Care, No. 14-MC-77 (E.D. Wisc. March 20, 2015). (rejecting claim that CID requested privileged materials based on Wisconsin’s peer review privilege)

• CID was served after the government decided to intervene
  • United States v. Kernan Hospital, Civil Action No. RDB- 11-2961 (D. Md. Nov. 20, 2012) (denying motion to enforce CID served by government after government made its intervention decision and noting that a CID is intended to be used responsibly “only in those instances where it is absolutely necessary to determine whether a fraud action under the [False Claims Act] is appropriate.”)
Government Enforcement Trends

1. MANAGED CARE – PART C

2. MEDICARE PART D – PHARMACIES AND DRUGS
   ◦ USE OF MISBRANDING STATUTE- OFF LABEL AND FOREIGN MEDICATIONS
   ◦ COMPOUNDING

3. IMPROPER SALES AND MARKETING
   ◦ MEDICAL DEVICES
   ◦ LABS
   ◦ PHARMA

4. INDIVIDUAL DOCTORS
MANAGED CARE

- Major area of enforcement for government in 2015
- No centralized Part C data depository which hinders ability to ID fraud
- No current mandatory reporting system where plan reports to CMS.
Foreign Beneficiary Managed Care Case


- The government filed an indictment alleging that more than a dozen individuals, including Dr. Santiago Montoya, participated in a conspiracy to commit health care fraud based on a scheme to defraud managed care plans in Florida.

- The scheme to defraud involved the false enrollment of beneficiaries who did not qualify for the particular plan based on their residency. Beneficiaries instead lived in Nicaragua and the Dominican Republic. Government has alleged a loss of at least $25M.

- Interesting issues:
  - Is enrollment a condition of payment in Medicare Advantage context or just condition of participation (or both)?
  - Is a beneficiary’s “residency” per a Medicare Advantage plan a legal question subject to reasonable interpretation which might therefore negate any intent to defraud?

- *See United States v. Whiteside*, 285 F.3d 1345 (11th Cir. 2002) (finding that false statement which classified debt interest as 100% capital related on cost reports submitted to the government for Medicare/Medicaid reimbursement was a case where the truth or falsity of a statement centers on an interpretive question of law and therefore defendant could not have made the statement knowingly and willfully)
SALES RETALIATION CASE


• Relator sales person reported violations of Medicare marketing rules to superiors and was eventually fired. Filed claim for retaliation under 31 USC Section 3730(h).

• Improper upselling, use of unauthorized marketing materials, and unsolicited contact with beneficiaries

• Court held that relator had stated a claim for retaliation under FCA retaliation provision

• Court noted that even though relator had not stated that HMO made any claims for payment to Medicare but found that its participation in an MA plan was conditioned on compliance with Medicare’s marketing regulations. See 42 C.F.R. Section 42.510(4)(viii).

• Court further found that “The Congressional Record specifically clarifies that ‘[s]ubmitting a claim for payment even though the defendant was violating the Government funded program’s conditions of participation or payment’ constitutes conduct that ‘clearly violates the False Claims Act.’” *Arthurs v. Global TPA, LLC*, at *5, citing 155 Cong. Rec. E129503
MEDICARE PART D
COMPOUNDING IN NE


- Multi-count indictment accusing 14 defendants including owners of New England Compounding Center and owners and sales representatives from company providing administrative and sales services to NECC, of engaging in a racketeering enterprise based on their distribution of compounded medications to purchasers without properly complying with proper health and safety regulations governing compounding pharmacies, including sterility and environmental monitoring.

- Allegations also describe a scheme to distribute compounded medications with fake patient prescriptions, false labels, or without prescriptions in violation of the Food Drug and Cosmetics Act.

- One of the fake patients was named “Hugh Jazz” others were Superman and Wonder Woman.
• Pharmerica paid $31.5 Million for dispensing controlled substances without a valid prescription and violated False Claims Act for dispensing drugs in violation of Controlled Substances Act.

• Attacked on Fed. R. Civ. P. 9(b) grounds but court found that claims were submitted by Pharmerica which were false because they provided false data to plan D sponsor knowing it was false and knowing it would be submitted to CMS. See United States ex rel. Jeniffer Denk v. Pharmerica Corporation, No. 09-CV-00720- (E.D. Wisc. Sept. 3, 2014) (DE-71) (Order Denying Pharmerica Corporation Motion to Dismiss)
GIFT CARDS AND WAIVERS

- *Physician Pharmacy Alliance* provided gift cards and routinely waived copayments to induce referrals or enrollments of Medicare patients.

- Settlement of $5 Million.
SALES AND MARKETING

1. MEDICAL DEVICES
2. LABORATORIES
3. PHARMA
PROCESS AND HANDLING FEES


• Multiple qui tam actions filed against Health Diagnostics Laboratories, Berkeley Labs, and Singulex. All labs provided expensive and advanced cardiovascular disease testing.

• Several of the labs hired a consultant, BlueWave Healthcare Consultants.

• Labs paid doctors a process and handling fee to store, maintain, and process blood specimens of patients. Process and handling fee was $10-$17.

• Qui tam alleged that fees were kickbacks in violation of AKS and Stark.

• Settlement resulted in $48M

• Complaints included CEOs of 3 of the companies as individual defendants.
FALSE MARKETING OF UNAPPROVED DEVICES

• *United States v Vascular Solutions, Inc and Howard Root, No. 14-cr-00926 (W.D. Tex. Nov. 13, 2014)*

• Untruthful marketing of medical devices used to treat varicose veins

• BROKE THE GOLDEN POST-CORONIA RULE

• Risk of patient harm and medical device intended for elderly population.
SPEAKER FEES


• Daichii Sankyo – global pharmaceutical manufacturer paid for lavish dinners and padded physicians with speaker fees to promote certain drugs

• Takeaway-CMS Open Payments – review your speaker programs
INDIVIDUAL PHYSICIANS

• CASH KICKBACKS
• ONCOLOGISTS
• UNNECESSARY SERVICES AND/OR UPCODING
• DR. BARRY KAPLOWITZ TRIAL
• MEDICAL NECESSITY
  • CARDIOLOGISTS
  • DERMATOLOGISTS
  • SPINAL SURGEONS
  • OPHTHALMOLOGISTS
CASH KICKBACKS

1. *United States v. Brett Halper*, No. 15-CR- (D. N.J. April 2, 2015). Dr. Brett Halper was one of several physicians in New Jersey charged by information with a violation of the Travel Act for referring blood specimens to a local diagnostic testing facility in return for cash payments. Government charged several other physicians in the same scheme with a violation of the Travel Act (Section 1952) instead of a violation of the Anti-Kickback Statute. Some of the other prior cases included *United States v. Dennis Aponte, M.D.* who received a two year sentence for accepting bribes.

2. Dr. Kutub Mesiwala (E.D. Mich. 2015). Dr. Mesiwala plead guilty to referring patients to several home health care organizations in exchange for cash kickbacks.
1. Robert Carter, MD (W.D. Mo. March 30, 2015); plead guilty to prescribing “misbranded” drugs he purchased from Canada for less money and was using to treat cancer patients.

2. Prabhjit S. Purewal, M.D., a Manteca based oncologist, agreed to pay the United States $550,000 to settle allegations that he defrauded Medicare, Tricare and Medicaid by billing these public insurers for chemotherapy drugs the US Food and Drug Administration had not approved for use in the United States. Dr. Purewal has paid the United States $400,000 to date.

3. Dr. Farid Fata (E.D. Mich. 2014). Dr. Fata, a hematologist-oncologist pleaded guilty for his role in a health care fraud scheme, admitting that he administered unnecessary chemotherapy to fraudulently bill the Medicare program and private insurance companies.
Unnecessary or “Upcoding”

1. Dr. Roman Johnson (N.D.N.Y. 2015) plead guilty to referring patients for unnecessary treatments and tests. According to his plea, Dr. Johnson submitted approximately $14.2 million in false and fraudulent claims to Medicare for medically unnecessary vitamin infusions, physical therapy, and occupational therapy that did not qualify for reimbursement by Medicare.

2. Dr. Carlos Mego and Dr. Subarrao Yarra, (S.D.TX 2014): entered into a civil settlement based on allegations that they billed Medicare for nuclear stress tests and physical examinations which were allegedly substandard, and that the nuclear medicine used in the tests was injected by personnel who lacked the requisite license. Many of the nuclear stress tests were allegedly unnecessary, as well as many of the coronary angiographies, echocardiograms and carotid doppler studies which the defendants billed to Medicare.

3. Dr. James F. Pruchniewsk (iM.D. Fla. 2014) podiatrist who owned and operated the North Lakeland Foot Clinic, in the Middle District of Florida. Dr. Pruchniewski did not employ a physical therapists licensed nurse or any physician other than himself. His clinic treated patients with something called “micro-vas therapy.” Micro-vas, also known as MVT, involved rendering electrical impulses to patients’ muscles, primarily in their legs, to supposedly stimulate circulation and healing and then illegally billed for the Micro-Vas services as physical therapy.

4. “Doctor at Home” Fraud (N.D. Ill. 2014). Doctor At Home registered nurse indicted for falsely certifying patients as being confined to their homes and requiring home health services; falsely increasing, or “upcoding,” claims for services; overscheduling and double-billing patient visits, submitting false claims for providing extensive oversight of patients’ home health services, and billing for tests that were not medically necessary.
Dr Barry Kaplowitz worked as a part-time medical director for Hollywood Pavilion, a clinic specializing in providing mental health and psychotherapy services. The allegations against Dr. Kaplowitz centered on his authorization for treatment of many patients whom either never received or never required treatments. His signature appeared on all documentation.

Prior to Dr. Kaplowitz’ trial, several patient recruiters whom had bilked millions of dollars for recruiting and referring patients to Hollywood Pavilion were convicted at trial and, in some cases, received sentences of more than 20 years.

Dr. Kaplowitz was convicted of one count (there were 9 counts) in the indictment, for conspiring to violate the Anti-Kickback Statute. He is awaiting sentencing.

A key component of Mr. Kaplowitz’ defense was that evil people had duped him and that they had used his robo signature to authorize thousands of patient treatments and procedures without his consent or authorization sometimes when Dr. Kaplowitz was on vacation.
MEDICAL NECESSITY

1. Cardiologists
2. Ophthalmologists
3. Spinal surgeons
4. Dermatologists
CARDIOLOGISTS AND STENTS

United States v. John Mitchell, 14-CR-00306-MEF-WC (M.D. Ala. May 21, 2014) (DE-1). Dr. John Mitchell for performing unnecessary stent procedures while falsifying the percentage of “stenosis” or blockage recorded in patient medical records. There are two (2) health care fraud counts and the government has elected to focus more aggressively on Dr. Mitchell’s alleged false entries concerning the level percentage of stenosis for seven (7) different patients in violation of Section 1035. United States v. John Mitchell, 14-CR-00306-MEF-WC (M.D. Ala. May 21, 2014) (DE-1 at 13-14).

United States v. Harold Persaud, 14-CR-00276-PAG (N.D. Ohio Aug. 20, 2014) (DE-1). The U.S. Attorney’s Office for the Northern District of Ohio indicted cardiologist Harold Persaud for health care fraud and violations of Section 1035. The health care fraud allegations against Dr. Persaud relate to a pattern of false stenting and a wide array of other conduct, including unnecessary follow up tests and procedures (e.g. nuclear stress tests, echocardiograms, and electrocardiograms), unnecessary and invasive imaging procedures used to determine the level of blockage in the arteries (e.g. cardiac catheterization, intra-vascular ultra sound, and aortograms), and referrals for unnecessary coronary artery bypass surgeries. Id. at DE-1 at 8-10. Importantly, the additional Thirteen Section 1035 counts also describe how Dr. Persaud repeatedly falsified “Cardiac Catheterization” reports by lying about the percentage of blockage appearing in patient arteries and how Dr. Persaud falsely documented symptoms of chest pain in patient files. Id. at DE-1 at 11-22.
DR JOSE KATZ- CARDIOLOGIST


In November 2013, Dr. Katz was sentenced to six-and-a-half years in prison and ordered to pay $19 million in restitution.

Dr. Katz enticed patients to visit his clinics. The New Jersey and New York clinics, Cardio Med Services LLC (Cardio-Med) and Comprehensive Health care & Medical Services LLC (Comprehensive), purported to provide cardiology, internal medicine, and other medical services to Medicare and Medicaid beneficiaries.

Dr. Katz ordered and performed essentially the same diagnostic tests for nearly all the patients he treated, regardless of their symptoms and he instructed his non-physician employees to order and perform diagnostic tests for patients of other doctors working at his companies, even though he had not examined those patients and the other physicians had not ordered the unnecessary tests. He admitted that he falsified patient charts and falsely diagnosed a majority of his patients with coronary artery disease and debilitating and inoperable angina to justify prescribing and administering unnecessary treatment, therefore subjecting them to serious risk of injury or death.
CONVICTIONS UPHELD

*United States v. McLean*, 715 F.3d 129 (4th Cir. 2013). On post trial motion court found that specific intent to defraud private and government payors may be inferred by the totality of the circumstances which included, among other things: a pattern of overstating blockage by a wide margin and placing unnecessary stents in a large number of patients, the stark disparity between what Dr. McLean recorded and what the angiograms revealed, McLean’s admission that he placed a stent in one patient because it was “easy,” and McLean’s undeniable financial motive.

*United States v. Mehmoud Patel*, No. 09-30490 (5th Cir. Aug. 13, 2012). On post trial motion, court found that the evidence illustrated that Dr. Patel falsified the level of blockage in patient records to justify unnecessary stenting procedures. Patient records also showed complaints relating to chest pain while those patients testified that no such complaints were ever made which was probative of fraud. *Patel*, at *9. And, once the investigation began, Dr. Patel “changed course” ordering fewer procedures which suggested “consciousness of guilt.
• The government alleged 53 separate counts of health care fraud relating to fraudulent billing for Mohs surgeries against Dr. Bajoghli. *Id.* at DE-1.

• Of importance, here, are the allegations (Counts 1-17) specifically related to. *Id.* at DE-1 at 7-8, 10-11. *Dr. Bajoghli’s intentional misdiagnoses of benign tissue as skin cancer in order to submit fraudulent claims to Medicare*

• The government also alleged that Dr. Bajoghli committed health care fraud when:
  • Dr. Bajoghli entered into a side agreement wherein he paid an out of state dermapathologist a per slide to analyze slides of patient skin tissue and then billed for that work under his National Provider ID; and
  • When Dr. Bajoghli delegated wound closure and suturing responsibilities to “unlicensed” and “unqualified” medical assistants when such procedures were not performed under his “immediate personal supervision.”
SPINAL SURGERY AND POD’S


- Indictment accuses Dr. Sabit of violating the health care fraud statute on more than a dozen occasions when he performed unnecessary spinal surgeries and subsequently falsified the CPT codes corresponding to those surgeries.

- According to the indictment Dr. Sabit performed spinal surgeries *without* implanting a spinal device into the patient and then authored reports containing false statements concerning the procedure performed, the device used, and the patients’ diagnoses which resulted in the submission of incorrect CPT codes to Medicaid for services that were medically unnecessary or *never rendered*. *Id.* at 9


- Dr. Sabit entered into a long standing joint venture agreement whereby Dr. Sabit was an investor in a medical technology company (Apex) distributing spinal implants.

- Apex targeted physicians, (e.g. Dr. Sabit) capable of performing a high volume of spinal surgeries involving their implants. Physicians were then compensated in part based on the profits they generated for Apex by performing spinal surgeries on Medicare patients.

- An integral part of the government’s theory of falsity is that payments to Dr. Sabit would cause him to perform spinal surgeries using implants that were not medically necessary.
OPHTHALMOLOGY AND LUCENTIS


• Unnecessary Lucentis injections and invasive procedures used to treat macular degeneration.

• The indictment is replete with diagnosis codes and CPT codes which is becoming the norm in these medical necessity prosecutions.

• Indictment also includes summaries of more than 30 patients and the treatments they received.

• Compare Civil - Dr. John Arthur Kiely (Ophthalmologist). United States v. John Arthur Kiely, M.D., Civil No. MJG-11-668, (settling alllegations that Dr. Kiely, a general ophthalmologist, submitted claims to Medicare and Medicaid for laser eye procedures that fell outside the medical standard of care. The government alleged that because the procedures did not meet the medical standard of care, they were not reasonable and necessary as required for reimbursement by Medicare and Medicaid. The claims covered by the settlement agreement included Argon Laser Trabeculoplasties (ALTs); Lysis of Adhesions procedures; and Laser Peripheral Iridotomies (LPIs)).
Anti Kickback Statute Developments

1. WILLFULLY AND 2009 AMENDMENTS
2. PER SE VIOLATION OF FCA
3. WHAT IS A REFERRAL?
4. EMPLOYEE EXCEPTION AND OTHER SAFE HARBORS
5. 2 PROVISIONS
WILLFULLY

- *United States v. Earnest Gibson III, et al.*, No. CR-12-600 (S.D. Texas October 13, 2014) (Jury Instructions). The AKS’ “willfully” requirement does not require the government to prove that a defendant knew that he violated the AKS, but it demands proof of a defendant’s knowledge that his conduct violated some law.

- *PPACA* removed specific intent requirement but still requirement that conduct committed “willfully.” *See 42 U.S.C. Section 1320a-7b(h)* (“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.”).

- Should this requirement extend to qui tam actions using AKS violation as predicate violation to allege violation of FCA? Should a relator be required to allege “willfully” to survive a motion for summary judgment?
PER SE VIOLATION

42 U.S.C. § 1320a-7b(g): “In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31.”

United States ex rel. Ruscher v. Omnicare, Inc., No. 4:08-cv-3396 (S.D. Tex. June 12, 2014) (DE-147 at 12-13) “Thanks to one of the lesser known provisions of the Patient Protection Affordable Care Act (PPACA) ... ‘a claim for payment that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes’ of the FCA regardless of whether other criteria, like certification, are satisfied.”
“REFERRAL” - UNITED STATES V PATEL


• Expansion of definition of “Referral” for purposes of AKS

• HOLDING - CERTIFYING AND RECERTIFYING A PATIENT IN A FORM 485 FOR HOME HEALTH SERVICES, EVEN WHEN THE PATIENT NEEDS THOSE SERVICES AND THE PHYSICIAN DOES NOT RECOMMEND THAT A PATIENT SEEK CARE FROM A PARTICULAR PROVIDER, IS A “REFERRAL” FOR PURPOSES OF THE AKS

• Court persuaded by Stark definition of “referral” which includes request by physician for, or ordering of, or the certifying or recertifying the need for any designated health care service. See 42 CFR Section 411.351

• NOTE - All of the patients “referred” to home health care provider actually needed home health services, i.e. services were medically necessary.
EMPLOYEE EXCEPTION AND OTHER SAFE HARBORS

• See United States v. Novak, Case No. 13-CR-00312 (June 30, 2014) (noting that defendant’s invocation of the employee exception as an affirmative defense to the AKS in a pre-trial motion to dismiss the indictment was premature because “for better or for worse there is no such thing as a motion for summary judgment in a criminal case.”).

• United States v. Turner, No. 12-20707 (5th Cir. April 2, 2014) at page 5 (finding that defendant was not entitled to an employee safe harbor instruction since she had not adduced any facts which would entitle her to such a defense)

• United States v. Robinson, 505 F. App’x 385, 387-88 (5th Cir. 2013) (the defendants were not entitled to safe harbor defense where, among other things, they were paid a fee or commission for Medicare beneficiary referrals; they did not receive regular paychecks, only referral payments; they received no training or direction from the alleged employer; they obtained their own leads and sources for referrals; and they were not required to keep regular office hours.)

• United States v. Chris Vernon, No. 11-CR-00012 (S.D. Ala. February 9, 2012) (DE-543 at 5-6), citing Hosp. Res. Pers. v. United States, 68 F.3d 421, 427 (11th Cir. 1995) (government objected to defendant’s request for a bona fide employee instruction, but also argued that, if the court were to grant such an instruction, the jurors should be entitled to consider all 20 factors outlined by the Internal Revenue Service in its Revenue Ruling regarding determination of who is a bona fide employee).

• United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F. 3d 88 (3d. Cir. 2009) (finding that the hospital failed to carry its burden of showing that the personal service exception applied because there was no written contract governing the services provided and there was no written agreement specifying compensation terms).

• United States v. Carroll, 320 F. Supp. 2d 748, 755-56 (S.D. Ill. 2004) (denying defendants’ motion to dismiss indictment alleging a violation of 42 U.S.C. §1320a-7b(b)(2)(B) when defendants offered free medical supplies to distributor of durable medical equipment to induce the distributor to purchase, lease, or order additional medical supplies from defendants and rejecting defendants’ argument that the discount safe-harbor of the AKS protected the subject marketing arrangement).
UNITED STATES V. LUIS SILAS

*United States v. Luis Silas*, 966 F.Supp.2d 1321 (S.D. Fla. 2013) – Anti Fraud Injunction Statute Case requiring restraint of assets pre trial based on finding of probable cause that defendants violated the law.

**Limitation of Employee Safe Harbor:** Key part of the holding concerning violation of law was that defendants did not satisfy safe harbor or exception for employees under AKS because they were not *furnishing covered services* or being paid for the *provision of covered services*. In other words, they could not meet the employee safe-harbor because they were getting paid, even as employees, for referrals of patients.

“The emphasized language in both of these provisions makes clear that the safe-harbor provisions will only apply when payments made to an employee compensate the employee for furnishing or providing covered items or services or items or services payable by Medicare, not simply for referring patients.”
TEXT OF FEDERAL AKS
42 USC 1320a-7b(()(A)-(B)

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program
DEFENSES AND MITIGATION

1. COMPLIANCE

2. VOLUNTARY DISCLOSURE

3. EXPERTS – DAUBERT AND/OR RELEVANCE; IMPROPER 704(b) TESTIMONY

4. INTENT TO DEFRAUD; GOOD FAITH DEFENSE; GOOD FAITH LACKING WHEN DOCUMENTATION FALSIFIED

5. NO LOSS FOR MEDICALLY NECESSARY SERVICES UNDER FEDERAL SENTENCING GUIDELINES
COMPLIANCE PROGRAMS

1. Roles of, and relationships between, the organization’s audit, compliance, and legal departments;
2. Mechanism and process for issue-reporting within an organization;
3. Approach to identifying regulatory risk; and
4. Methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.
VOLUNTARY DISCLOSURE BENEFITS

• **Release from False Claims Act**: DOJ Civil settlement releasing organization from liability under the False Claims Act.

• **FCA Statute of Limitations (SOL)**: SOL begins running on any potential *qui tam* action pursuant to the False Claims Act once disclosure is made to OIG.

• **Avoid Exclusion**.

• **Integrity Agreement**: Potentially avoid the requirement of an Integrity or Corporate Integrity Agreement.

• **1.5 Multiplier**: Presumption of a 1.5 multiplier for damages opposed to treble damages pursuant to a *qui tam* action.

• **Suspension of Overpayment Reporting Obligation**: Participation in SDP suspends a disclosing party’s obligation to report an overpayment to Medicare or Medicaid.

• **Factor Considered by DOJ Criminal Division and Federal Sentencing Guidelines**: Disclosure and cooperation are factors which directly influence prosecutorial decision making with respect to the criminal prosecution of individuals and business organizations. See Federal Sentencing Guidelines, 8C2.5(g); see Department of Justice Principles of Federal Prosecution, Section 9-27.620; see Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-28.700.
EXPERTS

• Extrapolation and statistical sampling both acceptable forms of analyzing claims data

• Federal Rule of Evidence 702, 703, and 704

• Experts permitted to testify about whether or not a procedure was medically necessary

• Experts permitted to opine that certain data or information is *probative* of fraud

• Use experts pre-trial and at trial to get theme across to jury or to government
EXPERT TESTIMONY


• United States v. Feingold, 454 F.3d 1001, 1007 (9th Cir. 2006) (permitting government expert to testify about the standard of care with which medical professionals generally must comply, and that Dr. Feingold's conduct fell far short of applicable professional standard).

• United States v. Schneider, No. 10-3281 (10th Cir. Jan. 16, 2013) (permitting experts to testify that defendant physician engaged in conduct outside the ordinary course of medical practice and permitting expert to testify that documents indicate a dishonest practice).

• United States v. Reddy, No.11-16146 (11th Cir. Aug. 16, 2013) (finding that it was harmful error to exclude defense expert testimony using extrapolation regarding radiologists review of slides).

• United States ex rel. et. al. v. Aseracare Inc., No. 2:12-CV-245-KOB (N.D. Ala. Dec. 4, 2014) (granting defendants’ motion to exclude the government’s marketing expert whose proffered testimony included explaining how defendant’s marketing practices show defendants’ knowledge of its false claims reasoning that such testimony does not satisfy Daubert reliability standards and it would not be helpful to the jury).

• United States v. Mehmoud Patel, No. 09-30490 (5th Cir. Aug. 13, 2012) (permitting the expert to opine that Dr. Patel drastically deviated from the standard medical procedures in performing cardiac stents and further noted that such deviation should be “probative of criminal liability.”).
GOOD FAITH DEFENSE

• In a health care fraud case, a defendant may raise good faith as a complete defense. The idea is to demonstrate that defendant did not intend to cheat or deceive anyone and the conduct amounted to an honest mistake even if that mistake was careless.

• See United States v. Cunningham, 554 F. App’x 126, 127 (4th Cir. 2014); United States v. Perry, No. 1:12-CR-173 (D. Md. 2012) (Dkt. No. 63)
QUESTIONS