  
**BROAD AND CASSEL**  
 ATTORNEYS AT LAW

**Compliance and Enforcement  
Hot Topics**

Health Care Compliance Association  
 San Juan Regional Conference  
 May 18 - 19, 2017

---

**Lester J. Perling, Esq., CHC**  
 Board Certified Health Care Lawyer

---

---

---

---

---

---

---


---

---

---

**Roadmap**

- ▶ Applicable Law
- ▶ Enforcement Trends
- ▶ Enforcement Theories
- ▶ Recent Legal Developments
- ▶ Questions


Copyright Broad and Caspel LLP 2017

---

---

---

---

---

---

---


---

---

---

**Applicable Law**

- ▶ The False Claims Act (FCA)
- ▶ The Anti-Kickback Statute (AKS)
- ▶ Physician Self-Referral Law (Stark Law)


Copyright Broad and Caspel LLP 2017

---

---

---

---

---

---

---


---

---

---

## The False Claims Act (FCA)

- ▶ The FCA is the federal government’s primary method of addressing fraud against government agencies and programs.
- ▶ The FCA provides for recovery of civil penalties and treble damages from *any person who knowingly submits or causes the submission of false or fraudulent claims* to the United States for money or property.
- ▶ The Attorney General, through DOJ attorneys, investigates and pursues FCA cases (except in declined qui tam cases).



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---


---

## Key Provisions in the FCA

Prohibition:

- ▶ Knowingly presents, or causes to be presented, a false or fraudulent claim for payment
- ▶ Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim
- ▶ Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government
- ▶ Conspiring to violate a liability provision of the FCA

31 U.S.C. § 3729(a)(1)



Copyright Broad and Cassel LLP 2017

---

---

---

---

---


---

---

---

## FCA Enforcement Theories

- ▶ Factual Falsity
  - False billing and overbilling
- ▶ Promissory Fraud/ Fraud in the Inducement
  - Obtaining contracts/services through fraudulent conduct
- ▶ Legal Falsity/False Certification
  - Certification of compliance with legal requirements
- ▶ Reverse False Claims
  - Retaining identified overpayments



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---


---

---

## Parties Enforcing the FCA

- ▶ Attorney General, through DOJ attorneys
- ▶ "Relators"
  - Private individuals suing in the name of the government to receive a portion of the recovery
  - The government may elect to intervene
- ▶ FCA Whistleblower Protections
  - Applies to employees and others (such as contract workers)
  - Relief may include double back pay, interest, reinstatement, and attorneys' fees and costs

31 U.S.C. § 3730(h)



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---


---

---

---

## FCA Damages and Penalties

- ▶ Simple Damages Calculation
  - Treble damages are traditionally calculated by multiplying the government's loss by three (*e.g.*, if defendant charged government \$100 for goods not received, treble damages are \$300).
- ▶ Complex, Contested Damages Calculation
  - Calculations are more complicated (and less certain) when the government receives goods or services it considers deficient or when there is a "false certification" or "promissory fraud."
- ▶ Civil Per Claim Penalty
  - Previously \$5,500 to \$11,000
  - Increased effective August 1, 2016 to between \$10,781 and \$21,563



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---


---

---

## The Anti-Kickback Statute (AKS)

- ▶ The AKS criminalizes
  - knowing and willful
  - payment (or offers) of remuneration
  - to induce patient referrals, reward a referral source, or generate business
  - involving any item or service payable by federal health care programs.
- ▶ The AKS covers those who provide (or offer) remuneration **and** those who receive (or solicit) remuneration.
- ▶ DOJ and HHS OIG are the dual enforcers of the AKS and CMP equivalent

42 U.S.C. § 1320a-7b(b)



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Anti-Kickback Statute, cont'd

- ▶ Remuneration includes anything of value, such as:
  - Cash, gifts, hospitality
  - Free or discounted rent
  - Compensation for medical directorships
  
- ▶ Under the "one purpose" test, remuneration violates the AKS so long as part of the purpose of the offer or payment to a referral source is an inducement for past or future referrals. *United States v. Borras*, 639 F.3d 774 (7th Cir. 2011).



Copyright Broad and Cassel LLP 2017

10

---

---

---

---

---

---

---

---

---

---

### AKS Penalties

- ▶ Potential consequences for AKS violation:
  - Jail terms of up to five years
  - Fines of up to \$25,000 per violation or twice the alleged gain or loss
  - Exclusion from participation in federal health care programs
  - Civil penalties of up to \$50,000 per kickback plus treble damages (three times the amount of remuneration)



Copyright Broad and Cassel LLP 2017

11

---

---

---

---

---

---

---

---

---

---

### AKS Safe Harbors

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>▶ Investment Interests</li> <li>▶ Space Rental</li> <li>▶ Equipment Rental</li> <li>▶ Personal Services and Management Contracts</li> <li>▶ Sale of Practice</li> <li>▶ Referral Services</li> <li>▶ Warranties</li> <li>▶ Discounts</li> <li>▶ Employees</li> <li>▶ Group Purchasing</li> <li>▶ Waiver of Beneficiary Coinsurance and Deductible Amounts</li> <li>▶ Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans</li> <li>▶ Price Reductions Offered to Health Plans</li> <li>▶ Practitioner Recruitment</li> <li>▶ Obstetrical Malpractice Insurance Subsidies</li> <li>▶ Investments in Group Practices</li> </ul> | <ul style="list-style-type: none"> <li>▶ Cooperative Hospital Service Organizations</li> <li>▶ Ambulatory Surgical Centers</li> <li>▶ Referral Agreements for Specialty Services</li> <li>▶ Price Reductions Offered to Eligible Managed Care Organizations</li> <li>▶ Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations</li> <li>▶ Ambulance replenishing</li> <li>▶ Federally Qualified Health Centers</li> <li>▶ Electronic health records items and services</li> <li>▶ <i>Cost-sharing waivers by pharmacies</i></li> <li>▶ <i>Cost-sharing waivers by emergency ambulance services</i></li> <li>▶ <i>Federally qualified health centers and Medicare advantage organizations</i></li> <li>▶ <i>Medicare gap discount program</i></li> <li>▶ <i>Local transportation</i></li> <li>▶ <i>[New in 2017]</i></li> </ul> |
|---|--|



Copyright Broad and Cassel LLP 2017

12

---

---

---

---

---

---

---

---

---

---

### Physician Self-Referral Law (Stark Law)

- ▶ The Stark Law prohibits physicians with financial relationship with a health care entity from referring patients to that entity to receive "designated health services" reimbursed by federal health care programs; and,
- ▶ The health care entity from submitting claims to federal health care programs for those services resulting from a prohibited referral.
- ▶ DOJ and HHS OIG are the dual enforcers of the Stark Law.



42 U.S.C. § 1395nn

13

---

---

---

---

---

---

---

---

---

---

### Stark Law, cont'd

- ▶ Designated health services include:
  - Clinical laboratory services
  - Physical / occupational therapy
  - Radiology / radiation services
  - DME / prosthetics / orthotics
  - Parenteral / enteral nutrients, equipment and supplies
  - Home health services
  - Inpatient and outpatient hospital services



14

---

---

---

---

---

---

---

---

---

---

### Stark Law Penalties

- ▶ Potential consequences of Stark Law violations:
  - Denial of payments
  - Refund of payments
  - Civil penalties of \$15,000 per service
  - Civil assessments of as much as three times the amount claimed



15

---

---

---

---

---

---

---

---


---

---

### Stark Law Exceptions

- ▶ Rental of office space
- ▶ Rental of equipment
- ▶ Bona fide employment relationships
- ▶ Personal service arrangements
- ▶ Physician recruitment
- ▶ Isolated transactions
- ▶ Certain arrangements with hospitals
- ▶ Group practice arrangements with a hospital
- ▶ Charitable donations by a physician
- ▶ Nonmonetary compensation
- ▶ Fair market value compensation
- ▶ Medical staff incidental benefits
- ▶ Risk-sharing arrangements
- ▶ Compliance training
- ▶ Indirect compensation arrangements
- ▶ Referral services
- ▶ Professional courtesies
- ▶ Obstetrical malpractice insurance subsidies
- ▶ Retention payments in underserved areas
- ▶ Community-wide health information systems
- ▶ Electronic prescribing items and services
- ▶ Electronic health records items and services
- ▶ Assistance to compensate a nonphysician practitioner
- ▶ Timeshare arrangements

42 CFR 411.357



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---


---

---

---

### AKS and Stark

- ▶ The government and relators often pursue alleged AKS and Stark violations in tandem in FCA cases involving providers.
- ▶ Since PPACA, claims “resulting from” violations of the AKS are false for purposes of the FCA. 42 U.S.C. § 1320a-7b(g).
  - See, e.g., *U.S. ex rel. Kester v. Novartis Pharms. Corp.*, 41 F. Supp. 3d 323, 331-33 (S.D.N.Y. 2014)
- ▶ Claims resulting from Stark Law violations also may be false for FCA purposes.
  - See, e.g., *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 792 F.3d 364, 382 (4th Cir. 2015)



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---


---

---

---

### Enforcement Trend- Increased Fraud Resources

- ▶ DOJ is devoting more and more resources to pursuing FCA cases
- ▶ New HHS OIG litigation team will focus on CMPs and exclusions in FCA-related cases DOJ opts not to pursue and in response to other referrals



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

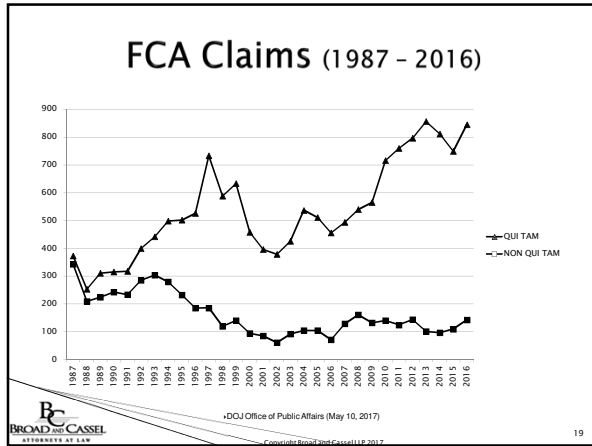
---

---

---

---

---



---

---

---

---

---

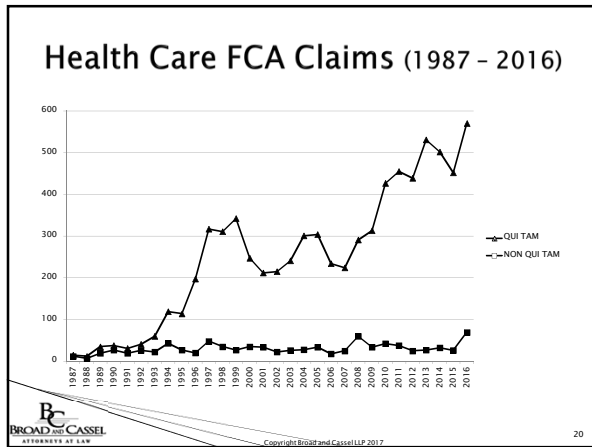
---

---

---

---

---



---

---

---

---

---

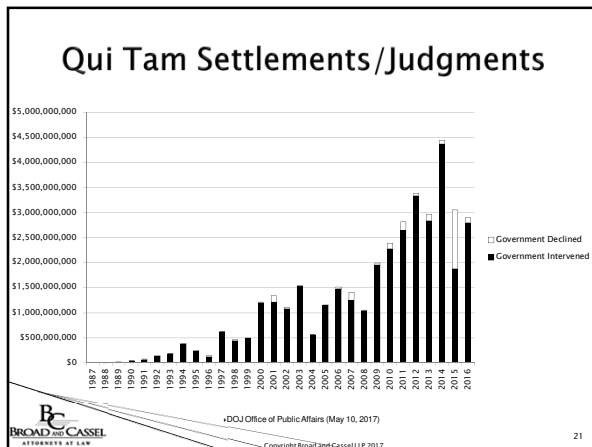
---

---

---

---

---



---

---

---

---

---

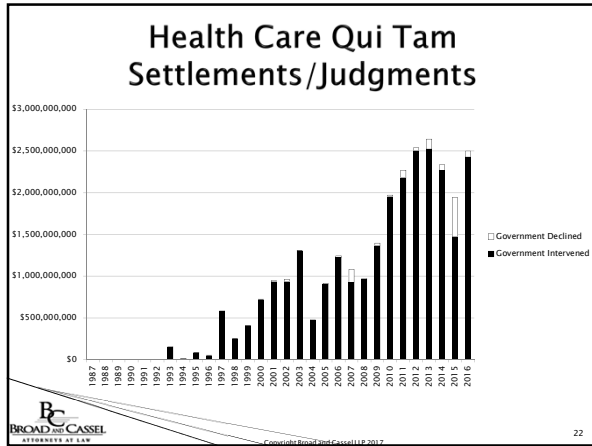
---

---

---

---

---




---

---

---

---

---

---

---

---

---

---

---

---

### 2016 DOJ FCA Recoveries

- ▶ \$4.7 billion recovered
  - \$2.5 billion came from the health care industry, including drug companies, medical device companies, hospitals, nursing homes, laboratories, and physicians.
  - The \$2.5 billion recovered in fiscal year 2016 reflects only federal losses. The DOJ also recovered millions of dollars for state Medicaid programs.
  - **This is the seventh consecutive year the Department's civil health care fraud recoveries have exceeded \$2 billion.**

**BROAD AND CASSEL**  
ATTORNEYS AT LAW

DOJ Office of Public Affairs (May 10, 2017)

Copyright Broad and Cassel LLP 2017

23

---

---

---

---

---

---

---

---

---

---

---

---

### 2016 Health Care Fraud and Abuse Expenditures

Mandatory Resources <sup>1</sup>	Fiscal Year 2016
Office of Inspector General	\$187,616,623
Health and Human Services Wedge <sup>2</sup>	35,883,926
Medicare Integrity Program <sup>3</sup>	866,475,413
MIP/Medicare (non-add)	799,823,463
Medi-Medi (non-add)	66,651,955
Department of Justice Wedge <sup>4</sup>	58,579,074
Federal Bureau of Investigation <sup>4</sup>	130,303,282
Subtotal, Mandatory HCFAC	\$1,278,858,324
Discretionary Resources	
Office of Inspector General	\$67,200,000
CMS Program Integrity	\$53,320,000
Medicare Program Integrity (Non-Add)	468,120,000
Medicaid Program Integrity (Non-Add) <sup>5</sup>	67,200,000
Senior Medicare Patrols (ACL Non-Add) <sup>6</sup>	18,000,000
Department of Justice	60,480,000
Subtotal, Discretionary HCFAC	\$681,000,000
Grand Total, HCFAC	<b>\$1,959,858,324</b>

**BROAD AND CASSEL**  
ATTORNEYS AT LAW

DOJ/DHHS – 2016 Annual Report Health Care Fraud and Abuse Control Program, pg. 87

Copyright Broad and Cassel LLP 2017

24

---

---

---

---

---

---

---

---

---

---

---

---



### Enforcement Trend 2– Parallel Criminal & Civil Investigations

- ▶ In September 2014, DOJ announced that all *qui tam* complaints would be reviewed by criminal prosecutors for potential parallel criminal actions.
- ▶ As a result, more companies now face simultaneous investigations by civil and criminal investigators.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### DOJ Health Care Fraud Actions

- ▶ Criminal Prosecutions
  - In FY 2016, the USAOs opened 975 new criminal health care fraud investigations and filed criminal charges in 480 cases involving 802 defendants. During that same time period, 658 defendants were convicted of health care fraud-related crimes during the year.
- ▶ Civil Matters
  - In FY 2016, the USAOs opened 930 new civil health care fraud investigations and had 1,422 civil health care fraud matters pending at the end of the fiscal year.



DOJ OIG HHS – 2016 Annual Report: Health Care Fraud and Abuse Control Program, pg. 71

Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 3– Individual Accountability and Liability

- ▶ Corporate cooperation credit hinges on disclosure of all relevant facts about the individuals involved in corporate misconduct.
- ▶ DOJ attorneys should focus on individuals from the inception of the criminal or civil investigation.
- ▶ Criminal and civil attorneys handling corporate investigations should communicate routinely.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Individual Accountability and Liability, Cont'd

- ▶ Absent extraordinary circumstances, no corporate resolution will provide individual immunity.
- ▶ Corporate cases should not be resolved without a plan to timely resolve related individual cases. Declinations as to individuals must be memorialized.
- ▶ Civil attorneys should evaluate whether to bring suit based on considerations beyond the individual's ability to pay.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Individual Liability Results

- ▶ *Miami Facilities* (July 22, 2016)
  - The owner of more than 30 Miami-area skilled nursing and assisted living facilities, a hospital administrator, and a physician's assistant were charged with conspiracy, obstruction, money laundering, and health care fraud in connection with a \$1 billion scheme involving numerous Miami-based health care providers.
- ▶ *Prime Healthcare Services Inc.* (May 25, 2016)
  - DOJ intervened in FCA suit against Prime and its CEO and founder, who allegedly pressured emergency department doctors to raise inpatient admission rates (regardless of medical necessity) and thereby caused the submission of false claims to federal health care programs.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 4- Continued *Qui Tam* Litigation

- ▶ In 2015, 38% of total qui tam suit recoveries from cases where the government did not intervene.
- ▶ Bigger, more sophisticated firms representing relators, applying firm resources to investigations allows relators to drive up fees.
- ▶ DOJ attorneys often use relators' counsel to advance pre-election investigations more quickly and efficiently, which results in more access to investigative findings for relators' counsel.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 5- Efforts to Erode the Scienter Standard

- ▶ Increasing number of cases that lack the fundamental elements of fraud previously required for liability, including cases targeting technical violations of:
  - Contractual requirements
  - Agency rules and regulations
  - Policies and procedures
- ▶ Result of increase in cases brought by relators' counsel who are incented to lower the scienter threshold and the difficulty of defining and providing culpable scienter
- ▶ Efforts to impose corporate liability based on subsidiary conduct (despite scienter requirement)



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 6- Corporate Integrity Agreements

- ▶ HHS OIG insisting on CIAs as a condition for settling administrative actions.
- ▶ CIA requirements are demanding and expensive, possibly requiring a provider to:
  - establish a compliance program with board and executive oversight
  - provide periodic reports regarding compliance
  - retain independent monitors to oversee and audit compensation agreements
  - train board members, executives, employees, and third parties
  - retain independent advisors to assess effectiveness of compliance programs



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Corporate Integrity Agreements

- ▶ CIAs contain stipulated penalties for violations of its provisions
- ▶ Actions to enforce terms of CIAs
  - In 2016, a hospice and home health provider paid a record \$3 million for violations of its CIA.
  - In 2015, a renal dialysis provider agreed to pay \$450,000 for alleged violations of its CIA.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 7 – Data Mining

- ▶ Use of data mining and quantitative analysis to develop leads and expand existing cases.
- ▶ DOJ may use early data analysis to probe whether and how allegations should be investigated further.
- ▶ DOJ and HHS have
  - expanded data sharing;
  - improved information-sharing procedures; and
  - used advanced data analysis techniques to identify aberrant billing levels in health care fraud “hot spots”-areas with high levels of billing fraud-and target suspicious billing patterns.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Trend 8 – RICO Lawsuits

- ▶ Private companies and competitors are increasingly turning to RICO lawsuits to address private sector false claims.
- ▶ The Racketeering Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961 et seq., takes aim at racketeering and organized crime.
- ▶ RICO prohibits conducting the affairs of an enterprise through a “pattern of racketeering activity” (or conspiring to do so). “Racketeering activity” defined by reference to a series of federal and state crimes.
- ▶ Under the statute, “[a]ny person injured in his business or property by reason of a violation” of RICO may sue in federal district court and recover treble damages, costs and attorneys’ fees.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### RICO/FCA-Like Provider Suits

- ▶ *Aetna Life Ins. Co. v. Behar* (S.D. Tex.)
  - Aetna sued Houston-based hospital based on alleged kickbacks to providers.
  - Aetna seeks up to \$120 million.
- ▶ GEICO goes on the offensive, suing (among others):
  - Massachusetts chiropractic / sports injury clinic, alleging that it overbilled for services provided by unlicensed staff and provided kickbacks to patients (D. Mass. Oct. 2015).
  - New York medical companies, alleging that they fraudulently billed for medical / physical therapy (E.D.N.Y. Aug. 2015; E.D.N.Y. Feb. 2015).
  - New Jersey physician and his practice, alleging that they paid referring providers kickbacks and billed for tests that were unnecessary (or were never provided) (D.N.J. Nov. 2012).
- ▶ *Liberty Mut. Fire Ins. Co. v. Acute Care Chiropractic Clinic, P.A.* (D. Minn.)
  - Denied providers’ motion to dismiss claim that they fraudulently billed while violating state corporate practice of medicine doctrine.
  - Akin to implied certification theory.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---


---

---

---

## Enforcement Theories

- ▶ Improper Financial Relationships
- ▶ Billing / Coding / Coverage
- ▶ Medical Necessity
- ▶ Quality of Care
- ▶ Overpayments
- ▶ Nexus of “reverse FCA” and the ACA 60-Day Rule



BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

37

---

---

---

---

---


---

---

---

## Enforcement Theory 1 – Improper Financial Relationships

- ▶ Approximately 14 settlements under the AKS with providers and drug and device companies in 2016 so far, resulting in recoveries ranging from \$245,000 to \$513.8 million.
- ▶ The government and relators take an extremely broad view of what counts as remuneration.
  - The obvious: cash payments, paid vacations
  - The less obvious: speaker fees, physician compensation, joint venture investments
  - The even less obvious: targeted advertising, electronic health record integrations, urine testing cups



BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

38

---

---

---

---

---


---

---

---

## Improper Financial Relationships

- ▶ The potential for criminal AKS liability and civil FCA penalties increases risk to companies facing AKS allegations.
  - In August 2016, Tenet Healthcare announced an agreement to pay almost \$514 million, comprised of a civil monetary payment of \$368,000,000 and a criminal monetary payment of \$145,788,345 to resolve kickback allegations.
  - Two subsidiaries also agreed to plead guilty to criminal offenses.



BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

39

---

---

---

---

---

---

---

---

### Improper Financial Relationships, Cont'd

- ▶ Millennium Health, a large laboratory, agreed to pay \$256 million to resolve allegations that it violated the AKS, the Stark Law, and the FCA by paying doctors in return for referrals of lab testing business and billing federal health care programs for excessive drug testing (purportedly caused by promoting physicians to adopt standing orders for drug testing).
- ▶ Millennium allegedly provided free urine drug test cups to physicians on the condition that the physicians would return those cups to Millennium for testing.
- ▶ As part of the settlement, Millennium entered into a CIA with HHS OIG.



Copyright Broad and Cassel LLP 2017

40

---

---

---

---

---

---

---

---

---

---

### Improper Financial Relationships, Cont'd

- ▶ In October 2015, Tuomey Healthcare System settled FCA claims relating to alleged violations of the Stark Law for \$72.4 million
  - To avoid losing lucrative outpatient procedure referrals to a new surgery center, Tuomey contracted with 19 specialists, requiring the physicians to refer their outpatient procedures to Tuomey in exchange for compensation exceeding FMV.
  - Tuomey ignored its attorneys' warnings that the physician contracts were "risky" and raised "red flags."



Copyright Broad and Cassel LLP 2017

41

---

---

---

---

---

---

---

---

---

---

### Improper Financial Relationships, Cont'd

- ▶ The government is just as actively pursuing AKS-based FCA cases against pharma and device manufacturers as well:
  - March 2016: Record DOJ AKS/FCA settlement with Olympus Corporation, a manufacturer and distributor of endoscopes, for \$623.2 million (plus \$22.8 million to settle alleged FCPA violations).
  - November 2015: \$390 million resolution of claims against Novartis Pharmaceuticals Corp. relating to its allegedly improper financial relationships with specialty pharmacies.



Copyright Broad and Cassel LLP 2017

42

---

---

---

---

---

---

---

---

---

---

**Enforcement Theory 2 –  
Billing / Coding / Coverage**

- ▶ These cases involve a wide range of legal theories, but tend to involve facts that include:
  - Billing for services not provided; or
  - “Upcoding” services that were provided.

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

**Billing / Coding / Coverage**

- ▶ In January 2016, Kindred Healthcare Inc. and its subsidiary, RehabCare, agreed to pay \$125 million to resolve allegations that they violated the FCA by causing SNFs to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary and skilled, or that never occurred.
- ▶ Kindred’s alleged policies and practices (e.g., setting unrealistic financial goals and scheduling therapy to achieve the highest reimbursement level regardless of patients’ clinical needs) allegedly resulted in unreasonable and unnecessary services.

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

**SNF Billing/Coding/Coverage**

- ▶ SavaSeniorCare LLC
  - The government has alleged that SavaSeniorCare improperly maximized reimbursement rates by delaying patient discharges and pressuring staff to meet unrealistic financial goals.
- ▶ HCR ManorCare
  - The government has alleged that ManorCare inappropriately maximized reimbursement rates by pressuring staff to provide unnecessary treatment, keeping patients longer than necessary, and setting unrealistic financial goals.
- ▶ Life Care Centers of America
  - The government alleged that Life Care improperly maximized reimbursement rates for patient stays by encouraging staff to keep patients for the maximum length of time and pressuring therapists to provide therapy to patients regardless of whether they needed it.
  - Claims resolved with \$145 million settlement and CIA

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Billing/Coding/Coverage, Cont'd

- ▶ In December 2015, Dynasplint Systems, Inc. and owner George Hepburn agreed to pay \$10.3 million to resolve allegations of false claims.
  - The government alleged that the defendants knowingly, and improperly, charged Medicare for splints provided to patients in skilled nursing facilities. Patients in skilled nursing facilities should have received the splints as part of their bundled services.
  - To submit these claims, the defendants allegedly represented that the patients were located outside of skilled nursing facilities.



Copyright Broad and Cassel LLP 2017

46

---

---

---

---

---

---

---

---

---

---

### Billing/Coding/Coverage, Cont'd

- ▶ In June 2015, hospice care provider Covenant Hospice, Inc. agreed to pay more than \$10.1 million to settle false claims allegations.
  - The government alleged that Covenant Hospice, Inc. submitted claims to Medicare, Tricare, and Medicaid for general inpatient care that should have instead been submitted as routine home care.
  - The federal government will receive \$9.6 million of the settlement and Alabama and Florida will receive more than \$552,000.



Copyright Broad and Cassel LLP 2017

47

---

---

---

---

---

---

---

---

---

---

### Billing/Coding/Coverage, Cont'd

- ▶ In June 2015, Community Health Network, an Indiana-based non-profit health system, agreed to pay more than \$20 million to resolve allegations that it submitted false claims to the Medicare and Medicaid programs.
  - CHN contracted with ASCs to provide outpatient surgical services to CHN patients. CHN allegedly represented that the surgeries were performed in the outpatient department of CHN's hospitals, rather than in an ASC, thereby resulting in higher reimbursement



Copyright Broad and Cassel LLP 2017

48

---

---

---

---

---

---

---

---

---

---



**Enforcement Theory 3 –  
Medical Necessity**

- ▶ Primary Theories
  - Unnecessary Procedures: Large-scale, complex approach to medical necessity cases
  - Inpatient vs. Outpatient: Cases indicate broader scrutiny of this issue
  - Long-term Care Facilities: Current DOJ sweep looking for unnecessary lengths of stay
- ▶ These theories demonstrate DOJ’s skepticism of hospitals’ pursuit of profit and potential abuse of federal health care programs.

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

**Medical Necessity**

- ▶ In March 2016, 21st Century Oncology and its subsidiary, South Florida Radiation Oncology LLC, agreed to pay \$34.7 million to resolve false claim allegations.
  - The government alleged that the providers performed and billed for procedures that were not medically necessary.
  - The government alleged that Gamma function procedures, intended to measure the radiation emitted by a patient following radiation treatment, were
    - (1) performed and billed by physicians and physicists not trained to review and utilize the results,
    - (2) billed even when results were not read for a week following a patient’s last treatment, and
    - (3) billed even when technical failures prevented a result from being obtained.

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

**Medical Necessity, Cont'd**

- ▶ Since October 2015, DOJ has reached 81 settlements involving more than 450 hospitals nationwide for more than \$250 million related to cardiac devices that were implanted in Medicare patients in violation of coverage requirements.
- ▶ The NCD for ICDs provides that ICDs generally should not be implanted in patients who recently suffered a heart attack or had heart bypass surgery or angioplasty and generally prohibited implantation of ICDs during specified waiting periods
- ▶ The DOJ alleged that from 2003 to 2010, each settling hospital implanted ICDs during the prohibited periods in violation of the NCD

BROAD AND CASSEL  
ATTORNEYS AT LAW  
Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Theory 4 – Quality of Care

- ▶ Claims for reimbursement of inpatient care are false if the services are "grossly" deficient or substandard, such as to make them essentially "worthless."
- ▶ Quality-of-care allegations are sometimes used as a vehicle to plead theories not actionable in themselves, such as:
  - Regulatory violations, e.g. violations of Medicare conditions of participation or state licensure rules
  - Failure to meet the "standard of care" in the field
  - Pursuit of profit goals by management and/or corporate parent
- ▶ Investigations focus on management pressure to sacrifice patient care in favor of the bottom line.
- ▶ FCA theories based on deficient quality of care have faced resistance in the courts.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Quality of Care

- ▶ In October 2014, Extendicare and its subsidiary agreed to pay \$38 million to resolve allegations that Extendicare billed Medicare and Medicaid for nursing services that the government contended were "so deficient that they were effectively worthless."
- ▶ The government alleged, inter alia, that Extendicare failed to:
  - (1) have a sufficient number of skilled nurses to adequately care for its skilled nursing residents;
  - (2) provide adequate catheter care to some residents; and
  - (3) follow the appropriate protocols to prevent pressure ulcers or falls.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Quality of Care, Cont'd

- ▶ A September 7, 2016 DOJ civil complaint against Vanguard Healthcare LLC, six of its subsidiary facilities, and its Director of Operations, alleging false claims based on "nonexistent, grossly substandard, and/or worthless nursing home services."
- ▶ DOJ is pursuing the corporate parent based on:
  - "Alter ego" theory;
  - Alleged corporate knowledge (based on termination of employees); and
  - Theory that the parent caused the facilities to be materially deficient by failing to provide adequate resources.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Enforcement Theory 5 – Overpayments

- ▶ Amendments to the FCA in 2009 created liability for the retention of any “overpayment” by federal health programs. 31 U.S.C. § 3729(a)(1)(G), (b)(3).
- ▶ Knowing—including reckless—violations of the PPACA’s “60-day Rule” can violate this “reverse False Claims Act.”
- ▶ Subjects providers to fraud liability in a broad context, including where they lacked the requisite knowledge when originally submitting the claim.
- ▶ Overpayment cases under the FCA emphasize the importance of robust compliance programs.



Copyright Broad and Casseal LLP 2017

---

---

---

---

---

---

---

---

---

---

### Overpayments

- ▶ The 60-day Rule requires that a provider who received an overpayment must repay it within 60 days of the time it is “identified.” On February 12, 2016, CMS issued final guidance on the 60-Day Rule:
  - ▶ *When the 60-day period begins to run*
    - The clock begins when a provider “has or should have, through the exercise of reasonable diligence, determined” that it has received an overpayment.
  - ▶ *Required diligence*
    - Providers must use “reasonable diligence,” which includes proactive compliance activities and reactive investigations.
    - Timely, good-faith investigations should generally be completed within six months of receiving credible information regarding an overpayment.
  - ▶ *Look-back period*
    - A provider must look back and investigate all similar payments received in the six years prior to the overpayment.



81 FR 7653 (Feb. 14, 2016)

Copyright Broad and Casseal LLP 2017

---

---

---

---

---

---

---

---

---

---

### Overpayments, Cont'd

- ▶ In August 2015, Pediatric Services of America, Inc., Pediatric Healthcare Inc., Pediatric Home Nursing Services, and Portfolio Logic LLC agreed to pay \$6.88 million to settle allegations of false claim in a “precedent-setting” FCA settlement.
  - DOJ alleged that the defendants violated the FCA by maintaining or writing off credit balances on their books without investigating whether those credit balances were the result of government overpayments.



Copyright Broad and Casseal LLP 2017

---

---

---

---

---

---

---

---

---

---

## Overpayments, Cont'd

- ▶ In August 2016, Continuum Health Partners, Inc. agreed to pay \$2.95 million to the federal government and New York State to resolve False Claims Act allegations.
  - The alleged that defendants identified hundreds of overpayments from Medicaid as a secondary payer, but failed to timely repay them even after state auditors identified the issue.
  - Prior to settlement, the District Court had recognized the viability of this FCA theory in denying defendants' motion to dismiss. See *U.S. ex rel. Kane v. Healthfirst et al.*



Copyright Broad and Cassel LLP 2017

58

---

---

---

---

---

---

---

---

---

---

## Recent Legal Developments

- ▶ Implied Certification
- ▶ Materiality
- ▶ Post-*Escobar*
- ▶ Statistical Sampling



Copyright Broad and Cassel LLP 2017

59

---

---

---

---

---

---

---

---

---

---

## Development 1 - Implied Certification

- ▶ *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). Relator brought FCA suit against leading nationwide provider of mental health services, alleging that hospital provided inadequate care to a teenage patient by using underqualified personnel to deliver counseling services.
- ▶ The Court held that the implied certification theory can provide a basis for FCA liability where:
  - "the claim does not merely request payment, but also makes specific representations about the goods or services provided," and
  - "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."
- ▶ The Court declined to decide "whether all claims for payment implicitly represent that the billing party is legally entitled to payment."



Copyright Broad and Cassel LLP 2017

60

---

---

---

---

---

---

---

---

---

---

## Development 2 – Materiality

- ▶ *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). The Court concluded that “[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision.”
- ▶ The Court characterized the materiality requirement as “rigorous” and “demanding,” and confirmed that materiality can be a basis for dismissing a case on a MTD.
- ▶ The relevant question is not whether the alleged underlying legal violation was “capable” of affecting payment, but whether the government actually “would not have reimbursed the claims had it known that it was billed for . . . services that were performed [in violation of the statute or regulation at issue].”
- ▶ Government knowledge of violations paired with continued payment can be “very strong evidence” that requirements are not material.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

## Development 3 – Post-Escobar

- ▶ *U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC*, No. 14–2804 (7th Cir. Sept. 1, 2016). Relator premised FCA claim on alleged “upcoding” and provision of unnecessary medical procedures.
- ▶ Allegations that mental health clinic told employees to use code for “full psychological assessment by a therapist” to bill for assessments by receptionists and nurse practitioners was “even more specific than those” presented in Escobar, and thus satisfied Rule 9(b). The clinic “allegedly billed Medicaid for a completely different treatment,” and thus the relator’s claim “involves an express false statement.”
- ▶ But, Relator’s medical necessity allegations “provide[d] no medical, technical, or scientific context [that would explain] why Acacia’s alleged actions amount to unnecessary care.”
- ▶ “Without additional context providing reason to question the appropriateness of [Acacia’s] policies, the complaint does not present allegations of fraud with sufficient particularity.”



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

## Post-Escobar

- ▶ *U.S. ex rel. Dresser v. Qualium Corp.*, No. 5:12–cv–01745 (N.D. Cal. July 18, 2016). Relator and DOJ brought FCA suit against owner of diagnostic sleep clinics, which treated sleep disorders and dispensed DME, for conducting tests in unapproved locations, using unqualified personnel, and dispensing DME based on improper tests.
- ▶ Defendants relied on Escobar, but the court held several claims were sufficiently pled under “literally false,” express false certification, or fraudulent inducement theories. But, as to implied false certification, an alternative theory, the court rejected the United States’ materiality allegations as insufficient under Escobar.
- ▶ Defendants had certified generally that they would “abide by Medicare laws, regulations, and program instructions.” The government “allege[d] in several places that [it] would not have paid Defendants’ claims had they known of Defendants’ fraudulent conduct,” but did “not explain why.”



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Post-*Escobar*, Cont'd

- ▶ *U.S. ex rel. Paradies v. AseraCare Inc.*, No. 2:12-CV-245, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016).
- ▶ The government cannot prove a claim was objectively false when medical experts disagree about whether care was medically necessary and there is no other evidence of falsity.
- ▶ “[C]ontradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law.” *Id.* at \*4.
- ▶ Similar arguments may be gaining traction in other courts around the country.



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Post-*Escobar*, Cont'd *AseraCare Inc.*, Cont'd

- ▶ The government has appealed the decision:
  - “At the heart of the district court’s rulings lies a fundamentally flawed interpretation of what it means for a claim to be ‘false’ under the False Claims Act.”
- ▶ The government contends that conflicting medical opinion is irrelevant because claims are not “reimbursable” – and thus “false” – if they are not supported by adequate documentation.
  - “In a False Claims Act suit concerning eligibility for payment under Medicare, a claim is false if it is not reimbursable under Medicare. And a hospice claim is only reimbursable under Medicare if the hospice provider has sufficient clinical documentation to support a patient’s prognosis of a terminal illness. The jury therefore properly relied upon the relevant patients’ medical records— as elucidated by the competing medical experts—to determine whether AseraCare was entitled to reimbursement under Medicare.”



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

### Development 4 – Statistical Sampling

- ▶ FCA plaintiffs in recent years have attempted to use statistical methods to seek liability for thousands of claims without establishing each claim’s falsity.
- ▶ Federal district courts have been divided on whether statistical sampling can be used to prove liability in FCA cases, but several in recent years have approved of sampling.
  - *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, No. 1:08-cv-251, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014)
- ▶ No federal court of appeals has directly addressed this issue yet in the FCA context.
- ▶ Although the Fourth Circuit agreed to hear a case certifying this issue, it ultimately declined to address this issue.
  - *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330, 341 (4th Cir. 2017).



Copyright Broad and Cassel LLP 2017

---

---

---

---

---

---

---

---

---

---

## Statistical Sampling

- ▶ The Supreme Court recently approved use of statistical sampling to prove liability in a labor and employment class action suit.
  - *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016). "Whether and when statistical evidence can be used to establish [] liability will depend on the purpose for which the evidence is being introduced and on 'the elements of the underlying cause of action.'"
  - The government and relators may argue that the Supreme Court's decision in *Tyson Foods* supports use of sampling in FCA suits.
  - But some courts have interpreted *Tyson Food's* purpose-specific test to reject statistical sampling in FCA cases. See, e.g., *U.S. ex rel. Wall v. Vista Hospice Care Inc.*, No. 3:07-CV-00604, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

---

---

---

---

---

---

---

---

---

---

## Statistical Sampling, Cont'd

- ▶ Defendants may obtain discovery from government to counter statistical sampling (or to explore other issues).
- ▶ If courts continue to endorse sampling approach, how the parties construct their samples will be critical, especially as nationwide multi-site cases proliferate.
  - *Deane v. Dynasplint Sys., Inc.*, No. CIV.A. 10-2085, 2015 WL 1638022, at \*1 (E.D. La. Apr. 13, 2015). Defendants sought more than 17,000 annual cost reports for more than 7,000 nursing homes from the government. The government protested on burden / expense grounds, but the court rejected the government's argument and compelled production:
    - The government "cannot be permitted to restrict defendant from receiving information its expert believes is necessary to mount an adequate defense."
    - "In light of the broad scope of this litigation, as framed by the government itself, the government must commit all resources necessary to comply. . . ."

---

---

---

---

---

---

---

---

---

---

## Key Takeaways

- ▶ Record numbers of *Qui Tam* actions continue to be filed against health care entities
- ▶ The Government continues to devote significant resources to health care fraud and abuse
- ▶ Novel legal theories (implied certification) as well as classic theories (RICO) continue to find footholds in health care fraud litigation

---

---

---

---

---

---

---

---

---

---

## Questions?

Lester J. Perling, Esq., CHC  
Broad and Cassel LLP  
100 SE 3rd Avenue, Suite 2700  
Fort Lauderdale, Florida 33394  
Telephone: (954) 745-5261  
Fax: (954) 713-0968  
lperling@broadandcassel.com



Copyright Broad and Cassel LLP 2017

70

---

---

---

---

---

---

---

---