Fraud & Abuse

SCOTT R. GRUBMAN, ESQ.

CCLB CHILIVIS COCHRAN LARKINS & BEVER LLP

The Statutes:
A Brief Overview

The False Claims Act ("FCA")

- Prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval.
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.

The False Claims Act ("FCA")

- Consequences of violating: Treble damages, per-claim penalties, exclusion.
  - Recently increased per-claim penalties: $10,957 to $21,916
- "Knowing" and "knowingly" includes actual knowledge, deliberate ignorance, or reckless disregard; **No proof of specific intent to defraud required**.

The False Claims Act ("FCA")

- Common examples of FCA violations:
  - Billing for medically unnecessary services
  - Violating Stark or AKS
  - Submitting claims for services provided by excluded persons
  - Improper retention of overpayment for more than 60 days
  - Lack of appropriate physician supervision

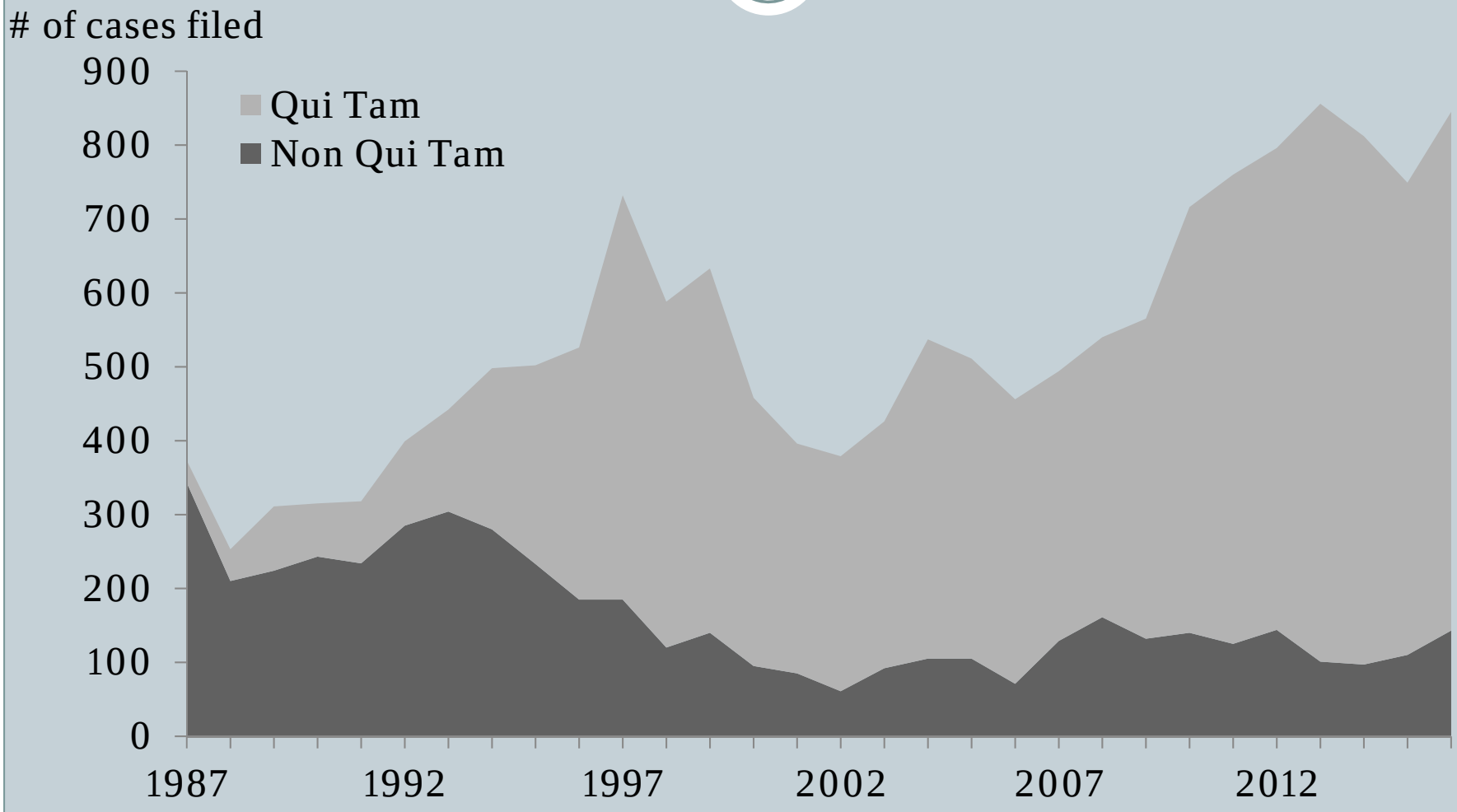
False Claims Act Trends

Healthcare-specific statistics:

FY	NEW MATTERS[2]		SETTLEMENTS AND JUDGMENTS[3]					RELATOR SHARE AWARDS[4]		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2008	60	231	162,972,022	962,461,088	6,852,571	969,313,659	1,132,285,682	185,933,162	1,522,164	187,455,327
2009	34	279	238,061,424	1,364,911,522	30,283,452	1,395,194,974	1,633,256,398	155,440,550	8,669,822	164,110,372
2010	42	385	546,963,733	1,955,805,336	15,478,518	1,971,283,854	2,518,247,587	335,084,132	4,373,489	339,457,621
2011	38	417	178,287,545	2,182,785,375	88,291,393	2,271,076,768	2,449,364,313	446,646,645	24,055,563	470,702,208
2012	25	414	557,273,967	2,504,096,869	37,563,668	2,541,660,538	3,098,934,505	280,816,748	10,527,293	291,344,041
2013	27	504	61,354,329	2,523,689,075	119,260,369	2,642,949,443	2,704,303,773	465,027,975	28,526,451	493,554,426
2014	32	470	88,054,490	2,271,159,011	66,322,326	2,337,481,337	2,425,535,827	382,745,316	10,877,186	393,622,502
2015	26	426	154,658,714	1,472,783,885	472,604,555	1,945,388,440	2,100,047,154	258,821,659	132,218,688	391,040,347
2016	69	501	97,579,302	2,427,980,533	71,931,554	2,499,912,087	2,597,491,389	431,263,484	19,254,883	450,518,367
TOTAL	907	6,683	6,127,157,067	26,639,454,777	1,139,519,880	27,778,974,658	33,906,131,725	4,371,321,550	260,253,992	4,631,575,542

Source: DOJ Civil Division Fraud Statistics

False Claims Act Trends



Recent FCA Settlements

- **Aug. 2017:** Navicent Health (Macon) agrees to $2.5M FCA settlement regarding allegations that it submitted ambulance bills that were either inflated or medically unnecessary. Two alleged schemes:
  - Non-emergency ambulance transports b/t hospitals billed at an inflated rate by claiming the trips were emergency trips.
  - Non-emergency ambulance transports of patients released from hospital to their residences, SNFs, etc., billed as emergency transports in violation of ambulance billing rules.

Recent FCA Settlements

- **July 2017:** Vanderbilt Univ. Medical Ctr. pays $6.5M to settle FCA *qui tam*. Allegations related to Vanderbilt's surgery scheduling practices. Complaint alleged that Vanderbilt used scheduling practices that forced surgeons to overbook schedules and rely on residents to perform the critical portions of their work in ICUs and drug anesthesia services.

The Anti-Kickback Statute

- Prohibits **knowingly & willfully** paying, offering, soliciting or receiving remuneration in return for referral.
- **Criminal**, civil & administrative remedies (including damages + penalties + exclusion).
- Predicate to FCA liability.

The Anti-Kickback Statute

- Applies to **all** federal healthcare programs except for the FEHBP.
- "One Purpose" rule.
- Safe harbors.

The Stark Law

- **The Rule:** If physician (or immediate family member) has financial relationship with entity (e.g. hospital), physician may **not** make referral to entity for designated health service ("DHS") and entity may **not** submit claims for such services.
  - "DHS" includes inpatient & outpatient hospital services.
  - "Financial Relationship" includes any compensation arrangement.
- Applies to Medicare and Medicaid.
- Strict liability (no intent required).
- Can lead to FCA liability, CMPs, exclusion.

CCLB CHILIVIS COCHRAN LARKINS & BEVER LLP

Trends in Govt. Enforcement Related to Hospital-Physician Relationships

I. **Physician Practice Acquisitions**

I. **Medical Directorships**

I. **Productivity Bonuses**

II. **Reestablished Per-Click Ban**

Physician Practice Acquisitions

Physician Practice Acquisitions

- Two common areas of concern related to hospital acquisition of physician practice:

  (1) The sale transaction itself; and

  (2) The terms of subsequent employment of practice's physicians.

Physician Practice Acquisitions

- When acquiring physician practice, hospital must be sure to fit squarely under Stark exception.
  - **Isolated Transaction Exception:** Remuneration must be:
    - Consistent with **FMV**;
    - Not determined in manner that takes into account (directly or indirectly) **volume or value of referrals by referring physician or other business generated between the parties**;
    - Remuneration would be commercially reasonable **even if physician made no referrals to the entity**.

Physician Practice Acquisitions

- Subsequent employment of physicians must meet requirements of Stark's **bona fide employment** exception. Should also meet requirements of AKS Safe Harbor.

Physician Practice Acquisitions

- **Lexington Medical Center Settlement (2016)**
  - Former employed physician files *qui tam* alleging that LMC violated Stark & AKS by acquiring physician practices for amounts that were not commercially reasonable or consistent with FMV in order to buy "access to [practice's] patients."
  - Relator alleges that hospital acquired his practice for more than FMV and that hospital then employed physicians and paid them in excess of FMV and with "unreasonably long" employment contracts.
  - Relator alleges that included in purchase of practice was the practice's "lucrative imaging devices which would generate ancillary service revenue for LMC."

Physician Practice Acquisitions

- **Lexington Medical Center Settlement (2016)**
  - Relator alleges that post-sale, hospital administration called meeting in which doctors were showed report generated by hospitals "internal referral-tracking system" which reported decline in ancillary referrals to hospitals. Relator alleges that purpose of meeting was "to make clear . . . that the premium LMC was paying in the form of compensation was in exchange for referrals to LMC."
  - Hospital executive allegedly told Relator that acquisition "was predicated on acquisition of [practice]'s in-house imaging equipment, which was expected to generate revenue for LMC."
  - Relator alleges that he was criticized for referring MRIs to another entity and was then terminated.

Physician Practice Acquisitions

- **Lexington Medical Center Settlement (2016)**
  - July 2016: LMC pays $17M to settle case. Enters into CIA.

Medical Directorships

Medical Directorships

- Common issues related to medical directorships:
  - Compensation in excess of FMV
  - Compensation for services that are not reasonably necessary
  - Lack of time-keeping records

Medical Directorships

- Medical directorships must meet applicable Stark exception.
  - **Personal Services Arrangements**:
    - In **writing, signed** by the parties, specifies services;
    - Covers all services furnished (can be separate agreements if incorporate each other by reference or cross-reference master list of contracts).
    - Aggregate services do not exceed those that are **reasonable & necessary for legitimate business purposes** of the arrangement
    - Duration of each arrangement is **at least 1 year** (if terminated, cannot enter into same or substantially same arrangement during first year of original agreement)
    - Compensation **set in advance, does not exceed FMV, does not take into account volume/value of referrals or other business generated b/t parties**.

Medical Directorships

- Medical directorships should also be structured to fall into AKS safe harbor for personal services and management contracts:
  - In **writing, signed** by parties;
  - Covers **all services** provided by agent to principal for term of agreement and specifies such services;
  - If periodic, sporadic, or part-time, specifies the exact schedule and length of, and charges for, intervals;
  - Not less than **1 year**;
  - Aggregate comp. set in advance, consistent with **FMV**, does not take into account **volume/value of referrals** or other business generated
  - Otherwise legal arrangement
  - Aggregate services do not exceed those which are **reasonably necessary** to accomplish commercially reasonable business purposes.

Medical Directorships

- **South Miami Hospital Settlement (2016)**
  - South Miami Hospital agrees to pay $12M to resolve *qui tam* alleging, among other things, that hospital knowingly allowed and billed for unnecessary medical procedures by one of its cardiovascular surgeons, and overcompensated surgeon by appointing him medical director of hospital's heart center and paying him above-FMV salary for these services:
    - Relator alleges that physician failed to maintain any logs or time records in order to document his time devoted to heart center.
    - Relator alleges that FMV for this position was b/t $20K and $50K. Physician at issue received $250K.

Productivity Bonuses

Productivity Bonuses

- Employed physician may receive productivity bonus so long as such bonus is based on services performed personally by the physician (i.e., work RVUs).

Productivity Bonuses

- **Halifax Settlement (2014)**
  - Halifax pays $85M to settle *qui tam* alleging, among other things, illegal productivity bonuses to six employed medical oncologists:
    - Bonus provisions of employment contracts provided that each physician would receive a portion of a total bonus pool that was equal to 15% of the "operating margin" of the overall medical oncology program.
    - Portion of the pool received by each physician determined by dividing total billings of all 6 physicians by each physician's individual billings.
    - Hospital argued that compensation fell under Stark's employment exception and provision permitting productivity bonuses.
    - Denying MSJ, court says that although each physician's proportional share of bonus pool was determined by personal services, the amount of the total pool included revenue from services referred but not personally performed by the physicians. Accordingly, did not fall under Stark exception.

Newly Reestablished Per-Click Ban

CMS Reestablishes Per-Click Ban

- **Stark rental/lease exceptions:** Must be in writing, signed, at least 1 year, reasonable and necessary, charges set in advance and consistent with FMV, and commercially reasonable. Charges cannot be determined in manner that takes into account volume/value referrals.

CMS Reestablishes Per-Click Ban

- **Background:**
  - **1998:** CMS proposes ban on per-use or per-click lease arrangements.
  - **2001:** CMS reverses position in final rule and permits such arrangements.
  - **2008**: CMS once again reverses and prohibits such arrangements.
  - **2015:** D.C. Circuit holds that although Stark statute is silent or ambiguous on this issue, CMS's interpretation of statute was not a "permissible and reasonable" review of Congress's intent for purposes of *Chevron* deference. *Council for Urological Interests v. Burwell.*

CMS Reestablishes Per-Click Ban

- **Nov. 2016:** CMS reestablishes per-click ban effective 1/1/17
  - 42 CFR 411.357(a)(5)(ii)(B) (space rentals), and 411.357(b)(4)(ii)(B) (equipment rentals).
  - CMS says prohibition is not absolute, but extends only to per-unit rental charges "where lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rental equipment."

Opioid Fraud & Abuse

Opioid Fraud & Abuse

- **July 2017**: DOJ announces largest healthcare fraud takedown in history. Nearly 1/3 of the 400+ defendants charged were charged in schemes related to prescribing and dispensing opioid and other narcotic drugs.

Opioid Fraud & Abuse

- **August 2017:** AG Sessions announces formation of DOJ's Opioid Fraud & Abuse Detection Unit.
  - Unit will utilize data to combat fraud & abuse related to opioids.
  - DOJ will fund 12 experienced prosecutors for 3-year term to focus exclusively on investigating and prosecuting fraud related to prescription opioids, including pill mills & pharmacies that unlawfully divert or dispense prescription opioids for unlawful purposes.

Questions?

404-262-6505

sgrubman@cclblaw.com

CCLB CHILIVIS COCHRAN LARKINS & BEVER LLP