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**COZEN
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PRESENTATION

PENNSYLVANIA BAR INSTITUTE
Fundamentals of Health Law
Fraud and Abuse Fundamentals

Presented by
Mark H. Gallant, Esquire
Cozen O'Connor
1900 Market Street
Philadelphia, PA 19103
215-665-4136
mgallant@cozen.com

*The confidence to
proceed.*

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INTRODUCTION

- "Fraud" or "Abuse"?
- Medicare/Medicaid Program Concerns
 - Overutilization
 - Increased program costs
 - Corruption of medical decision-making
 - Unfair competition
 - Systemic corruption
- In June 15, 2010 testimony before the House Common on Ways and Means, Subcomm. On Health and Oversight, OIG Chief Counsel estimated that "7.8 percent of the Medicare fee-for-service claims . . . Paid (\$24.1 B)" in FY 2009 "did not meet program requirements"

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THE PLAYERS



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COZEN O'CONNOR CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

- Medicare administration
 - Central, regional offices
 - CMS Administrative Contractors
 - Intermediaries and Carriers
 - RACS
- Stark regulatory authority
- Stark advisory opinions

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COZEN O'CONNOR HHS OFFICE OF INSPECTOR GENERAL (OIG)

- Audits, investigations, special studies
- Enforcement via exclusions, CMPs
- Regulatory authority for AKS
- Advisory Opinions
- Investigates/refers FCA cases
- Self-disclosures

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COZEN O'CONNOR DEPARTMENT OF JUSTICE (DOJ)

- “Main Justice” and AUSAs
- Criminal and civil FCA Prosecutions
- Collaborations with OIG, CMS

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COZEN O'CONNOR OTHER PLAYERS

- FBI
- IRS
- State AG
- State MFCUs
- State regulatory agencies
- Private Health Insurance Carriers

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COZEN O'CONNOR OVERVIEW OF FEDERAL FRAUD AND ABUSE LAWS

- Anti-Kickback Statute
- Stark Law
- Exclusions, CMP Law
- False Claims Act
- Miscellaneous (Healthcare) Fraud Laws



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COZEN O'CONNOR ANTI-KICKBACK STATUTE (AKS)

- Criminal Statute – 42 USC §1320a-7b(b)
 - Anyone – individuals or entities
 - Knowingly and willfully
 - Soliciting or receiving
 - Remuneration, directly or indirectly, overtly or covertly, in cash or in kind
 - In return for referring any item or service reimbursable under federal health program (e.g. Medicare/Medicaid)
- One Purpose Test – Greber

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COZEN O'CONNOR ANTI-KICKBACK STATUTE

- ACA Amendments: Under ACA §6401(f)(1), claims for items resulting from a kickback constitute false claims under FCA
- INTENT: Under ACA Amendments, proof of actual knowledge of or specific intent to violate the statute is not required

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COZEN O'CONNOR ANTI-KICKBACK STATUTE

- Statutory Exceptions
 - Discounts
 - Payments to Employees
 - Waivers of Certain Co-Insurance by FQHCs
 - Qualifying Group Purchasing Vendor Agreements
 - Certain Risk-Sharing Arrangements
 - Part D Drug Manufacturer Discounts
 - “Safe Harbored” Practices

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COZEN O'CONNOR ANTI-KICKBACK STATUTE

- Safe Harbors
 - Criteria – If an arrangement meets all elements, it is exempt from prosecution
 - Multiple Purpose – Must satisfy multiple safe harbors
 - Failures to fully satisfy safe harbor
 - Not per se illegal
 - Violations will turn on subjective intent

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COZEN O'CONNOR ANTI-KICKBACK STATUTE

- Safe Harbors (Cont.'d)
 - Investment Interests
 - Large and Small
 - Solo and Group Practices
 - Space and Equipment Rentals
 - Personal Services Contracts and Employment
 - Sale of Practice Physician
 - Physician Recruitment
 - Discounts and Rebates

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COZEN O'CONNOR ANTI-KICKBACK STATUTE

- Safe Harbors (Cont.'d)
 - Warranties
 - Patient Referral Services
 - Waiver of Beneficiary Cost-Sharing
 - Ambulatory Surgery Center Ownership
 - Group Purchasing Organizations
 - Electronic Health Records

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COZEN O'CONNOR PRACTICE TIP

OIG website is a great resource

<http://oig.hhs.gov/index.asp>

- Kickback advisory opinions
- Fraud alerts, advisory bulletins
- Compliance Program Guidance (CPG)
- Preambles to safe harbor regulations
- Self-disclosure program information
- Exclusions database
- Work plan, semi-annual and OEI reports

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COZEN O'CONNOR THE STARK (PHYSICIAN ANTI-REFERRAL) STATUTE

- If physician (or immediate family member) has a *financial relationship* with a *DHS entity*, then the physician *cannot refer* Medicare patients to the entity, and the entity cannot bill Medicare for the DHS *unless* an exception applies
- Applicable to Medicaid
- World's "dullest" bright line
 - Three phases of regulations

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COZEN O'CONNOR STARK SANCTIONS

- Nonpayment of claims
- Refund amounts received for claims
- CMPs for knowing violations
 - \$15k per referral, \$100k for "circumvention" schemes
- Program exclusions
- FCA liability for violations
- Reverse FCA liability for unreported overpayments

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COZEN O'CONNOR THREE QUESTIONS

- Is there a referral by a physician for a designated health service payable by Medicare?
If so
- Does physician (or "immediate family member") have a financial relationship with entity furnishing DHS?
If so
- Does financial relationship fit within an exception?
If not, there's a per se violation

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KEY STARK CONCEPTS

- Physician referral
- Designated health services (DHS)
- Entity
- Financial relationship
- Exceptions
- Self Reporting Requirements

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PHYSICIAN "REFERRAL"

- Oral, written, other
- Directed (imputed) referrals and services after "consults"
- Excludes personally performed services
- Exceptions for specified self referrals by pathologists, radiologists, and radiation oncologists

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DHS CATEGORIES

- Clinical laboratory services
- PT/OT
- Radiology & imaging services
- Radiation therapy services
- DME
- Home health services
- Parenteral and enteral nutrients, etc.
- Prosthetics and orthotics
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

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THE DHS "ENTITY"

- Old Rule: Entity "furnishing DHS" is the entity to which CMS makes payment for the DHS
- Amended Rule (10/1/2009): Person/entity furnishes DHS if it has –
 - "Performed services " billed as DHS, or
 - Presents a claim to Medicare for the DHS

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"PERFORMING" DHS

- Entity does not "perform" DHS if it only:
 - Leases or sells space/equipment
 - Furnishes supplies
 - Provides management or billing services; or
 - Provides personnel

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IMPACT OF AMENDMENT

- Expanded definition applies to referral by physician owner to entity that performs DHS services "under arrangements" (e.g., mobile lithotripsy or MRI obtained under contract and billed by hospital)
- Separate Stark analysis required for referrals to each DHS entity

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FINANCIAL RELATIONSHIP

- Ownership or Investment Interests
- Compensation Arrangements
 - Direct
 - Indirect
 - In cash or in kind

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INDIRECT COMPENSATION

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graph LR; Doctor[DOCTOR] <--> Company[COMPANY]; Company <--> DHS[DHS ENTITY];
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"Stand in the Shoes" (SITS)

- Direct versus Indirect referral concept
- Current Rule (since 10/1/08):
 - Physician SITS if he has an ownership/investment interest in the Physician Organization (PO)
 - Non-owners and "titular" owners may elect to SITS
 - Payment to PO creates financial relation with individual physicians

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STAND IN THE SHOES (SITS)

Employees, Indep. Ks & Titular Owners

"Indirect" comp becomes direct

Group and Its Owner Docs

DHS ENTITY

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PRACTICE TIP

Analyze arrangements under the law in effect at the relevant time

Variations can make the difference between compliance and noncompliance

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STARK EXCEPTIONS

1. Exceptions for ownership/investment
2. Exceptions for ownership/investment and compensation
 - "Service-based exceptions"
3. Exceptions for compensation

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OWNERSHIP EXCEPTIONS

- Publicly-traded securities/mutual funds
- Rural provider exception
- “Whole hospital” exception
 - Modified under ACA to limit physician ownership in new hospitals and to limit expansion of facility capacity at existing physician-owned hospitals

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SERVICE-BASED EXCEPTIONS

- Physician services
 - Performed personally or under personal supervisory
- Group practice rules
- In-office ancillary services
 - Supervision (availability)
 - Location (same building)
 - Billing
 - ACA disclosure requirements (MRI/CT/PET)
- Academic Medical Center (AMC) services
- Services for prepaid health plans (e.g., risk sharing bonuses and penalties)

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PERMITTED OWNERSHIP

- Non-DHS entities
- Rural area providers
- Whole Hospitals (subject to ACA)
- ASCs (unless ancillary DHS)
- Mutual funds and public securities
- In-office ancillary services
 - Supervision, location, billing rules
- Radiologists, radiation oncologists, and pathologists can own their own facilities

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COZEN O'CONNOR COMPENSATION EXCEPTIONS

- Rental of Office Space & Equipment
- Employment
- Personal Service Arrangements
- Physician Recruitment
- Isolated Transactions
- Remuneration Unrelated to DHS
- Non-Monetary Compensation

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COZEN O'CONNOR COMPENSATION EXCEPTIONS

- FMV Compensation
- Medical Staff Incidental Benefits
- Risk Sharing Arrangements
- Indirect Compensation
- Physician Retention Payments in Underserved Areas
- Health Information Technology exceptions

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COZEN O'CONNOR COMPENSATION EXCEPTIONS

- Rule of thumb: FMV is key
 - Set in advance
 - Volume or value of referrals
 - Commercial reasonableness
- Many exceptions are one directional
- Beware percentage comp and “per click” fees in leases

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PRACTICE TIP

Read the preambles

- Detail agency's current and interpretations and approaches on particular issues
- Analyze issues with preambles at hand
 - Word search pdf versions of preambles
 - Mark table of contents with page numbers
- Preambles do not have force of law but may garner "Jefferson deference"

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PRACTICE TIP

Be alert for warning signs of prohibited compensation

- Windfalls to physicians
- Inflated or distorted compensation
- Compensation reflecting referrals
- Commercially unreasonable deals
- Undocumented deals
- Kickbacks

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PRACTICE TIP

Be alert for warning signs of prohibited compensation

- Part-time, off-site rentals of DHS
- Joint recruiting that confers a benefit on an existing physician practice
- Deals that don't match the paperwork

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PRACTICE TIP

Stark in a Nutshell

- Restricted physician ownership of DHS entities
- Any compensation must be FMV
- Have written agreements (safest if evergreen)
- Many formulaic requirements, and all must be satisfied
- Arrangements permitted under Stark may still implicate the anti-kickback statute
- *Advise clients what NOT to do*

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PRACTICE TIP

Know the differences between Stark and AKS

- What types of referrals count
- Who can be liable
- Necessary intent
- Nature of exceptions and sanctions
- Who enforces

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STARK vs. AKS REFERRALS

<u>Stark</u>	<u>Kickback</u>
Referrals by physician only	Referrals by any person or entity
Referrals for DHS only	Referrals for any items or services reimbursable by federal health care program

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WHO CAN BE LIABLE?

<u>Stark</u>	<u>Kickback</u>
Billing DHS entities	Any person/entity
Referring physicians (for CMP if knowing violation)	

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NECESSARY INTENT

<u>Stark</u>	<u>Kickback</u>
Civil statute: No mens rea; strict liability	Criminal statute; "knowing and willful" standard applies
"Knows or should know" standard applies for CMPs	

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EXCEPTIONS & SANCTIONS

<u>Stark</u>	<u>Kickback</u>
Mandatory exceptions	Voluntary safe harbors
Nonpayment, CMPs, exclusion, FCA liability	Jail, criminal fines, CMPs, exclusion, FCA liability

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ENFORCEMENT

<u>Stark</u>	<u>Kickback</u>
CMS as to nonpayment	OIG and DOJ
OIG as to CMPs, exclusion	
DOJ as to FCA	

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PRACTICE TIP

Stark Analysis Comes First

- All elements present?
- If yes, any exceptions applicable?
- If no, STOP! Illegal arrangement
- If yes, go to AKS analysis

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PRACTICE TIP

AKS Analysis Comes Second

- Is remuneration provided to induce referrals?
- If yes, do any exceptions apply?
- If no, do any safe harbors apply?
- If no, is remuneration FMV?
- If yes, is any one purpose to induce referrals?
- If yes, STOP! Illegal arrangement
- If no, GO!

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STARK DISCLOSURE

- March 24, 2009 Open Letter Regarding OIG Self-Disclosure Protocol:
 - Providers should use OIG’s SDP for potential Stark violations only if potential AKS violations exist
 - Minimum CMP of \$50,000 for non-compliance with the Stark Law and AKS reported under the SDP

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STARK DISCLOSURE

- Stark Self Disclosure Protocol (Sept. 23, 2010)
 - Required by ACA
 - Authorizes compromise of Stark debts
 - <http://www.cms.gov/PhysicianSelfReferral>
- Key elements
 - Detailed description of arrangement and parties
 - Notice of violations or potential violations: no advisory opinions
 - Estimate of liability during period of non-compliance
 - Description of compliance programs and how discovered
 - Criminal and civil liability exposure
- Relation to 60 day repayment rule

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STARK DISCLOSURE

- Sec. 6409(b) of PPACA “authorizes” Secretary to reduce the amounts owed under § 1877(g) for designated health services (“DHS”) billed in violation of Stark law, based on:
 - (1) Nature and extent of improper or illegal practice
 - (2) Timeliness of self-disclosure
 - (3) Cooperation in providing additional information
 - (4) Such other factors as Secretary deems appropriate
- No formal “pass” for “technical” violation in SRDP

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PRACTICE TIP

Don't forget applicable state laws

- Stark
- Kickback and "fee splitting"
- Licensure laws and rules
- Balance billing laws
- Physician ownership disclosures
- Medicaid reimbursement rules
- Corporate practice of medicine rules

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PRACTICE TIP

Consider whether your client is in the planning vs. implementation stage

- Clients in planning stages need more conservative advice
- Creative arguments may be needed by FCA defendants
- Getting too creative with advice in the planning stages can result in liability for both client and YOU
- Role of Advisory Opinions

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PRACTICE TIPS

Advise clients not just what to do, but what NOT TO DO!

- Be wary of slippery slopes and narrow borders

Understand reimbursement

- You can't spot fraud and abuse if you can't follow the money
- You can't follow the money if you don't know how services are reimbursed

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PRACTICE TIP

Communicate clearly with OIG, CMS

- Seek input from the agency
- Remember that most CMS staffers are not attorneys
- Describe your problem in detail, don't hide the ball
- Be mindful of what's in it for CMS? (e.g., better access to care, lower costs). See OIG Advisory Opinions
- Patience is a virtue!

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OTHER FEDERAL F&A STATUTES

- Program Exclusion Authority
- Civil Monetary Penalties Law (CMPL)
- Payment Suspensions
- False Claims Act
- Private Insurance Fraud
- Mail and Wire Fraud

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PROGRAM EXCLUSION

- 42 U.S.C. § 1320a-7
- Death knell
- Applies to all government health care programs (except FEHBP)
- Affirmative duty to check exclusion status
- Mandatory or permissive
- Administrative proceedings

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MANDATORY EXCLUSION

- Convictions for Medicare/Medicaid or patient abuse offenses
- Minimum 5 years
- Mitigating and aggravating circumstances
- ACA amendments and rules

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PERMISSIVE EXCLUSION

- Derivative
 - Misdemeanors (other than Medicare/Medicaid)
 - License revocations
 - Exclusion from another program
 - Loan defaults
- Non-Derivative
 - Substandard care
 - Kickbacks
- Mitigating and aggravating circumstances

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CMP LAW

- 42 USC §1320a-7a
- Prohibited Conduct
 - False or Fraudulent Claims
 - Violation of AKS
 - Violation of Stark
 - Violation of EMTALA
 - Offers of remuneration to Medicare/Medicaid beneficiary likely to influence to order or receive services or items payable under Federal Healthcare Program (co-pay and co-ins waivers)

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CMP LAW

- Prohibited Conduct (cont'd)
 - Arrangements with excluded persons
 - Payments by hospital to physician to reduce or limit services
 - Providing unnecessary items or services
- CMP Penalties
 - Various amounts
 - Program exclusion
 - Refer to OIG LEIE database

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PAYMENT SUSPENSIONS

- ACA imposes mandatory payment suspensions based on “credible allegations” of fraud absent “good cause”
- Also applies to Medicaid
- Final Rule with Comments published February 2, 2011

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CIVIL FALSE CLAIMS ACT (FCA)

- 31 USC §3729
- Prohibitions include knowingly –
 - Presenting or causing the presentment of a false claim to federal government
 - Making, using, or causing to be made or used a false statement material to an obligation to pay money to gov't
 - Concealing or improperly avoiding/decreasing an obligation to pay gov't
 - “Reverse false claims” for failures report and satisfy repayment obligations pursuant to §6402 of ACA

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CIVIL FALSE CLAIMS ACT

- “Knowingly” defined --
 - Actual knowledge,
 - Deliberate ignorance, or
 - Reckless disregard for truth or falsity of information
- Qui Tam (Whistleblower Provisions)
 - Relator can recover up to 30%
 - Whistleblower protection for employees, contractors and agents from employer retaliation

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CIVIL FALSE CLAIMS ACT

- Statute of limitations
 - 6 years after violation or
 - Within 3 years after material facts are known or should have been known, but not more than 10 years after violation
- Treble damages and civil penalties
 - Civil penalties \$5,500 – \$11,000 per claim

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CIVIL FALSE CLAIMS ACT

- FERA of 2009 Expansions
 - Claims presented to government contractors and agents
 - Modified/relaxed “intent” requirement
 - Whistleblower protections for contractor s and agents

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COZEN O'CONNOR FCA: "ORIGINAL SOURCE" EXPANDED UNDER ACA

- Original Source Before ACA:
 - has "direct and independent knowledge" and
 - "voluntarily provided the information to the government before filing an action"
- Original Source After ACA:
 - voluntarily discloses information to the government prior to a public disclosure;
 - has knowledge that is independent and materially adds to the publicly disclosed allegations, and voluntarily provided information to Government before filing suit

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COZEN O'CONNOR PUBLIC DISCLOSURE BAR TO FCA QUI TAM SUITS NARROWED BY ACA

- Original Source Before ACA:
 - jurisdictional issue
 - federal, state and local reports, investigations or administrative hearings all are possible sources of public disclosure. Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson (U.S.S. Ct. Mar. 30, 2010)
- Original Source After ACA:
 - no longer jurisdictional; government decides whether case may proceed
 - sources of public disclosure limited to Federal reports and/or investigations or administrative hearings which the government is a party

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COZEN O'CONNOR CIVIL FALSE CLAIMS ACT

- Reverse False Claims
 - PPACA §6402(a) added SSA§1128j(d)
 - Pertains to any overpayment retained by a "person"
 - Any overpayment must be reported in writing and returned to the Secretary, the State, an intermediary, a carrier, or a contractor, within 60 days after the date on which the overpayment was identified, or by date any corresponding cost report is due
 - Failure to refund overpayment by applicable deadline can result in a failure to satisfy an "obligation" and a false claim

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OTHER STATUTES

- Excessive charges and “supplementation” of Medicare/Medicaid rates – 42 U.S.C. §1320a-7b
- False claims to private healthcare insurers – 18 U.S.C. §1347
- Obstruction of Criminal Investigations of Healthcare Offenses – 18 USC §1518
- Mail and Wire Fraud – 18 USC §1341 and §1343

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CORPORATE COMPLIANCE PLANS

- Purpose – commitment to honest and responsible corporate conduct
- Benefits – increase likelihood of preventing, identifying and correcting unlawful and unethical behavior
- Sec. 6401(a)(8) of ACA modifies the conditions of participation under Medicare, Medicaid and Title XXI
 - Requires each provider or supplier to adopt a compliance program containing “core elements” established by Secretary in consultation with OIG for particular industry or category
 - Secretary shall determine implementation date
 - Separate requirements for nursing facilities

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CIA/DPAs

- Corporate Integrity Agreements
 - No admission of guilt or wrongdoing
 - Basic Elements
 - OIG website: <http://oig.hhs.gov/fraud/cias.asp>
- Deferred Prosecution Agreements
 - Confession of wrongdoing
 - Probationary period
 - DOJ will dismiss all charges if entity reforms by end of probationary period

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PRACTICE TIP

Keep up with a changing industry

- Legal publications
 - BNA & CCH products
 - ABA Health Lawyer
 - AHLA Health Lawyers Weekly
- Business publications
 - WSJ and other general news media
 - Modern Healthcare
 - Kaiser Foundation reports (kaisernetwork.org), etc.

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PRACTICE TIP

Join some Listserves

- OIG, CMS listserves
- AHLA listserves (20)

Compliance	In-house Counsel
Reimbursement	Stark Law
Tax	Part D
FDA	HMO, Hospital, etc.

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PRACTICE TIP

Resources

- CMS website – <http://www.cms.hhs.gov/default.asp>
 - Manuals
 - Medicare Coverage Database (NCDs, LCDs)
 - Contact info for CMS carriers, FIs, etc.
- OIG website
 - Fraud Alerts
 - Bulletins
 - Advisory Opinions

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PRACTICE TIP

Resources

- CMS Stark webpage – <http://www.cms.hhs.gov/PhysicianSelfReferral>
 - Statute, regs and preambles
 - Advisory opinions
 - DHS code updates
 - FAQs

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PRACTICE TIP

Resources

- AHLA – <http://www.healthlawyers.org>
 - Health Law Archive
 - Cross links to government and public websites

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PRACTICE TIP

Take advantage of training opportunities

- Conferences and teleconferences
- Webinars
- In-house training
- Write articles
- Know when the water is too deep!

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