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Health Care Fraud and Abuse (2011)

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Overview of Certain Federal Health Care Laws

- Physician Self-Referral Law (Stark)
- Anti-Kickback Statute (AKS)
- False Claims Act (FCA)
- Qui Tam ("Whistleblower") Suits

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Physician Self-Referral Law (Stark)

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Overview of Stark (42 U.S.C. § 1395nn)

- Stark is a Federal statute governing relationships between physicians and entities such as hospitals, health care facilities, and physician practices
- Stark is a strict liability statute - a party need not intend to violate the law to be in violation of Stark
- Stark Analysis:
 - Does Stark apply? Check definitions
 - If so, what Stark exception applies?

Stark Prohibition

IF: A physician (or immediate family member of a physician) has a financial relationship, *direct or indirect*, with an entity that furnishes designated health services



THEN: The physician may not refer Medicare or Medicaid patients to the entity for those services and the entity may not bill for such services

UNLESS: A Stark exception applies and is met

Physician

- Doctor of medicine or osteopathy
- Doctor of dental surgery or dental medicine
- Doctor of podiatric medicine
- Doctor of optometry
- Chiropractor



Note: a physician and the professional corporation ("PC") which he or she solely owns are treated the same under Stark

Designated Health Services (“DHS”)

- **Inpatient and outpatient hospital services**
- Clinical laboratory services
- Physical therapy, occupational therapy, & outpatient speech-language pathology services
- Radiology & certain other imaging services
- Radiation therapy services & supplies
- Durable medical equipment & supplies
- Parenteral and enteral nutrients, equipment & supplies
- Prosthetics, orthotics, prosthetic devices & supplies
- Home health services
- Outpatient prescription drugs

EXCLUDING services where DHS is bundled with non-DHS for payment (e.g., ASC, ESRD); certain items related to bundled services (e.g., implants in ASC, EPO in ESRD); certain services where DHS is used only to guide invasive non-DHS procedures (e.g., imaging used during cardiac cath)

Stark Definitions: “Immediate Family Member”

- Husband or wife
- Birth or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

Stark Definitions: “Entity”

- **Remember:** A physician cannot refer patients to an entity with which the physician has a financial relationship for designated health services (**DHS**)
 - Prior to October 1, 2009, an “entity” was the person or organization that actually dropped the bill for the services
 - As of October 1, 2009, the definition of “entity” was expanded to include any person or organization who performs services that are billed as DHS
- **Why we care:** physician ownership of organizations providing services “under arrangement” to a hospital now must fit into an ownership Stark exception

Stark Definitions: "Perform"

- CMS states in commentary that a service has been performed if the physician/physician organization "does the medical work for the service and could bill for the service" but an entity does not "perform" DHS if it only:
 - leases or sells space/equipment,
 - furnishes supplies not separately billable,
 - provides management or billing services, or
 - provides personnel
- No definitive guidance as to what combination rises to the level of "perform"
 - CMS asked for industry comment on its definition, but has decided that no further guidance is necessary at this time – only received 9 comments

Stark Definitions: "Referral"

- Does NOT include personally performed services
- Does NOT include a request by a pathologist for clinical diagnostic lab tests and pathological exam services, by a radiologist for diagnostic radiology services, or by a radiation oncologist for radiation therapy if:
 - The request results from a consultation initiated by another physician; and
 - The tests or services are furnished by or under the supervision of that pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist in the same practice as the requesting practitioner

Financial Relationships

- Ownership or Compensation
- Direct or Indirect
 - Important to determine classification because different exceptions apply to direct and indirect relationships
 - Indirect exception contains some additional flexibility
 - **Note:** The financial relationship does not need to relate to DHS or clinical or medical services for Stark to be triggered!



Financial Relationships Based Exclusively on Ownership

- Most applicable Stark exceptions for physician ownership are those for rural providers and for whole hospitals
 - After PPACA, physician-owned hospitals are only permitted if arrangement is in place by Dec. 31, 2010, and only limited future expansion is allowed; ownership relationship must be disclosed to patients and to HHS, which will publish it online

Stark *Direct Compensation Relationship*

- Remuneration passes between the referring physician and the DHS entity without any intervening entities
 - Example: Hospital contracts with a professional corporation for cardiology services. P.C. employs Dr. Smith
 - Seems simple enough...BUT must also determine whether physician "stands in the shoes" of his or her physician organization – if so, also a direct relationship

Physician "Stand In The Shoes"



- Is the physician a non-titular owner of a physician organization?
 - "Titular owner": a physician without the ability or right to receive any financial benefits of ownership or investment, including without limitation, profit distributions, dividends, sale proceeds or similar investment returns
 - "Physician organization": a physician, a physician practice, or a group practice
- If yes, then physician must SITS and has a direct relationship with DHS entity
 - Example: Dr. Smith works for Cardiology Associates, which operates as a group practice and shares profits. Cardiology Associates contracts with Hospital. This is considered a direct relationship between Hospital and Dr. Smith in need of a direct exception

SITS: Indirect vs. Direct

If physician is (1) employee, (2) independent contractor, or (3) titular owner (unless the sole owner of a PC*), does not have to SITS



If physician is non-titular owner, must SITS

If titular owner*, employee or independent contractor, may SITS



*If physician is the sole owner of his or her PC, even if ownership is titular, physician is considered the same as the PC and the relationship is direct

Stand in the Shoes: Important Dates

- When reviewing a particular arrangement, it is important to remember that:
 - The concept of “stand in the shoes” was effective as of December 4, 2007
 - Prior to this date, certain arrangements were treated as indirect
 - Arrangements compliant with the indirect compensation exception as of September 5, 2007 were grandfathered as indirect through the end of the then-current term
 - Between Dec 4, 2007 and Oct 1, 2008, ALL physicians, whether owners or not, stood in the shoes of their physician organizations – more direct relationships in need of direct exceptions
 - Effective October 1, 2008, converted to mandatory and permissible rule

Frequently Used Stark Exceptions for Direct Compensation Relationships

- **Employment Exception:** FMV; not determined in a manner that takes into account volume or value of referrals; commercially reasonable even if no referrals are made; bonus based on services **personally performed** by physician; cannot include “incident to” services or profit sharing of DHS services
- **Other Service Exceptions:** (Personal Services and FMV) for independent contractor relationships; adds requirements that compensation be **set in advance** and that agreement be in writing; PSA requires a term of **no less than 12 months**, but has a 6 month holdover provision; FMV exception requires that compensation not change and prohibits **no per click or percentage-based payments** in certain circumstances
- **Space and Equipment Rentals:** Adds certain **exclusivity** and other requirements as well as requirements that compensation be **set in advance** and that agreement be in writing for a term of no less than 12 months; 6 month holdover on same terms and conditions OK; **no per click or percentage-based payments** in certain circumstances
- **Isolated Transaction Exception:** For one-time sale of property or practice; amount of remuneration must be FMV and not determined in a manner that takes into account the volume or value of referrals; remuneration would be commercially reasonable even if physician made no referrals; no additional transactions between the parties for 6 months except under certain circumstances

Per-click and Percentage-based Prohibited Payments

- **Per-click payments:** Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee
- **Percentage-based payments:** A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space

“Set in Advance” Requirement

- Compensation is considered “set in advance” if the aggregate compensation, a time-based or per-unit of service-based amount, or a specific formula for calculating the compensation is set in an agreement between the parties **before** the furnishing of the items or services for which the compensation is to be paid
- Note: the formula for determining the compensation must be set forth in **sufficient detail** so that it can be **objectively verified**, and the formula **may not be changed or modified during the course of the agreement in any manner that takes into account** the volume or value of referrals or other business generated by the referring physician
- **According to CMS, parties cannot back-date agreements**



Amendments to Compensation

- In the preamble to recent Stark regulations, CMS stated its position with respect to modifying compensation arrangements under “set in advance” rules
- Amendments are permissible provided the following requirements are met:
 - All other requirements of the applicable Stark exception are met;
 - The amended compensation (or formula for determining compensation) is determined **before** the amendment goes into effect; the amended formula must be sufficiently detailed and objectively verifiable;
 - The amended compensation (or formula) does not take into account the volume or value of referrals or other business generated by the physician; AND
 - The amended compensation remains in place for 1 year after the date of the amendment

If Not Direct, Must Determine Whether it is an Indirect Compensation Arrangement

- Three components:
 - Unbroken chain of any number of financial relationships
 - Referring physician receives **aggregate compensation** from the entity in the chain closest to the physician that **varies with, or takes into account**, the volume or value of referrals or other business generated by the referring physician for the DHS entity
 - Link analyzed is the closest non-ownership link
 - DHS entity has actual knowledge, or acts in reckless disregard or in deliberate ignorance of, this
- If second prong is met, CMS likely to find the third prong met in most circumstances

Proceed with Caution



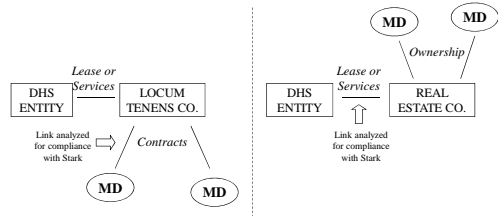
- Strongly recommend fitting any arrangement that could be indirect (i.e., that involves an unbroken chain) under the indirect compensation exception, and if possible, under a direct compensation exception
- CMS stated in recent commentary that:
 - The definition of "indirect compensation arrangement," particularly the second and third components is being interpreted too narrowly
 - Aggregate compensation can "vary" with referrals with **per-unit** compensation formulas
 - Aggregate compensation can "take into account" referrals in arrangements involving **inflated fixed payments** or **implicit** tying of compensation to referrals

Indirect Compensation Exception

- FMV compensation
- Not determined in any manner that **takes into account** the volume or value of referrals or other business generated by referring physician for DHS entity
- Not based on percentage of revenue or per-click (leases)
- In writing, signed, and specifies the services covered by the arrangement
- Commercially reasonable
- Does not violate the Anti-Kickback Statute

NO 'SET IN ADVANCE' REQUIREMENT

Indirect Exception: Links Analyzed for Compliance

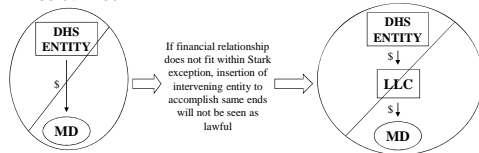


Proceed with Caution (II)

- Memorial Health: 2008 settlement for \$5.08M over “indirect” relationship allegedly created by fixed fee payment
 - Hospital paid affiliated physician group lump sum per year for teaching and indigent care services provided (\$600K for 2006)
 - Government alleges that payments were channeled to small number of high referring physicians and therefore indirect compensation arrangement created
 - Can’t avoid “indirect” arrangement by giving group a sum and saying “we don’t care how you distribute it”

Proceed With Caution (III)

- There is no entity “stand in the shoes” at this time (i.e., entities that are not physician organizations)
- BUT CMS HAS WARNED: arrangements that try to evade Stark by interposing shell entities will be closely scrutinized



Stark Ownership and Compensation Exception

- In-office Ancillary Services Exception is used by physician practices that are DHS entities
- One element of the exception is that the practice must be a Group Practice
- Group practices may share DHS profits, provided the group meets all of the requirements and special profit-sharing rules
 - Considerations
 - FMV and group practices
 - "Incident to" (not lab tests) included in productivity bonuses
 - Ability to share profits from DHS subsidiary
 - Hospitals may *not* utilize this exception for their employees – look to Employment Exception
- New PPACA disclosure requirement for in-office ancillary services
 - Must provide patients with notice and a list of at least 5 other local suppliers of MRI, PET, CT services within a 25-mile radius

Overview

- **Recent Activity: Definition of "Entity"**
- Consequences of Stark Violations
- Recent Case Law: Importance of FMV and Documentation

Case Law Challenge

Colorado Heart Institute, LLC et al v. Johnson, 609 F. Supp. 2d 30 (D.D.C. 2009):

- Arrangement at issue: cath labs provided personnel, equipment, drugs, and supplies; hospital billed for services under arrangement; hospital paid cath labs flat fee for each service provided
- Under new definition of "entity," physician ownership needed Stark exception (No Exception Available)
- So...three cardiac cath labs and their physician owners sought a declaratory judgment that CMS's new definition of "entity" exceeded statutory authority

Court dismissed the case for lack of jurisdiction because plaintiffs had access to administrative review (indirectly through the hospital)

Lithotripsy “Exception”

CMS has confirmed that lithotripsy is not DHS (see *American Lithotripsy Society*), even if provided under arrangement by a physician-owned entity to a hospital and billed by the hospital

- It therefore appears that CMS believes that lithotripsy can continue to be owned by referring physicians and billed by hospital as hospital services
- **Caution:** The arrangement must still be based on FMV in an arms-length transaction. See July 8, 2010 OIG settlement agreement with United Shockwave Services and two affiliated providers for \$7.3 million for “leveraging patient referrals to obtain contract business from hospitals”

Additional Considerations

- Although CMS does not consider lithotripsy to be DHS, the lease of such equipment by a hospital when the physician owners refer patients for other DHS is a compensation arrangement which must comply with Stark

Overview

- Recent Activity: Definition of “Entity”
- **Consequences of Stark Violations**
- Recent Case Law: Importance of FMV and Documentation

Consequences of a Stark Violation

- The entity may not bill Medicare for the claim
- Medicare cannot pay the claim
- Any Medicare payments for the claim during the period of disallowance must be **refunded**
- Knowing violations can result in civil monetary penalties of not more than \$15,000 for each service and exclusion from participation in Medicare
- Circumvention schemes can result in civil monetary penalties of not more than \$100,000 for each service and exclusion from participation in Medicare
 - *U.S. ex. rel. Barbera v. Tenet Healthcare Corporation* (SD FL, March 2004) (\$22.5 million settlement for alleged Stark violations relating to salaries paid to physicians in purchased practices)
- Probable False Claims Act exposure

Period of Disallowance

- Sets outer limits of the period of disallowance (i.e., period when physician cannot make DHS referrals and DHS entity cannot bill Medicare because financial relationships failed to meet a Stark exception)
 - Begins no sooner than the time the financial relationship fails to meet all requirements of an exception and
 - Ends not later than date relationship meets all requirements of exception **and** any excess compensation or underpayment has been paid
- Parties can argue on case by case basis that some other time period should apply

Period of Disallowance

- "This final rule does not purport to define when a financial relationship begins or ends. In every case, a financial relationship begins and ends according to the conduct of the parties and the specific facts of the case."
- All requirements of an exception must be met at the time the referral is made -- "[W]e believe that the statute does not contemplate that parties have the right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively."



Period of Disallowance

- CMS provides no assurance as to the period of disallowance if the reason for noncompliance is never corrected or in situations in which the excess compensation (or underpayment) can be construed as payment for referrals pre- or post-dating a noncompliant relationship

Burden of Proof

- In administrative appeals (42 CFR 405, Subpart I) of denials of payment for DHS made on the basis that the service was provided pursuant to a prohibited referral, the burden of proof or persuasion is **on the entity that submitted the claim** to prove it was not furnished pursuant to a prohibited referral
 - During the proceeding, burden of production may shift to CMS depending on the evidence
- Does not apply to appeals of CMP, exclusions or other remedies that involve knowing violations of Stark



Self-Referral Disclosure Protocol (SRDP)

- PPACA required Stark self-disclosure protocol
- SRDP enables health care providers of services and suppliers to disclose an actual or potential Stark violation to CMS
- The disclosing party's submission must include:
 - Disclosure
 - Description of Actual or Potential Violation(s)
 - Financial Analysis
 - Certification
- SRDP forms are available at:
https://www.cms.gov/physiciansselfreferral/65_self_referral_disclosure_protocol.asp

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SRDP

- The DHHS Secretary may reduce the amount owed for Stark violations, considering, without limitation:
 - The nature and extent of the violation
 - The timeliness of the self-disclosure
 - The cooperation of the disclosing party in supplying CMS with additional information
 - The litigation risk associated with the matter disclosed
 - The financial position of the disclosing party

Note: "A provider of services or supplier may not disclose an actual or potential violation(s) through the SRDP and request an advisory opinion for conduct underlying the same arrangement(s) concurrently." (Physician Self-Referral Disclosure Protocol)

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Overview

- Recent Activity: Definition of "Entity"
- Consequences of Stark Violations
- **Recent Case Law: Importance of FMV and Documentation**

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Case Law

U.S. ex rel. Drakeford v. Tuomey d/b/a Tuomey Healthcare System, Inc. (S.C. Mar. 29, 2010)

- Complaint alleged that part-time employment agreements with surgeons violated Stark, and therefore FCA, because they exceeded FMV
 - Physicians received 131% of net collections through salary and bonuses (industry averages are between 49% and 63%)
 - Non-competes prevented surgeons from using competing ASC
- Hospital had valuation from now-defunct consultant (also showing industry averages) and ignored warnings of counsel
- Jury found that physician employment agreements violated Stark but did not amount to FCA violations; court has granted motion for new trial on FCA claims

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Case Law

US ex. rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88 (3rd Cir. 2009)

- Exclusive contract for anesthesiology services did not fit into personal services exception to Stark
- Parties did not have a current written agreement, updated to reflect new services, new facilities, and change of ownership of hospital; and
- Inadequate documentation of updated fair market value of space, equipment, personnel. Negotiation of terms not enough to establish FMV

Case Law

U.S. v. Rogan, 517 F.3d 449 (7th Cir. 2008)

- Upheld \$64M fine against Peter Rogan, who owned and was the manager of Edgewater Medical Center, related to Stark and AKS violations
 - Improper payments to physicians via medical director agreements, physician recruiting agreements, teaching agreements, EKG agreements, and physician loans
 - Resulted in compensation above FMV for services not actually performed

Case Law

U.S. ex. rel. Singh v. Bradford Reg'l Med. Ctr., et al., Case No. 1:04-cv-00186-MBC. (W.D. Pa. Nov. 10, 2010)

- A camera sublease between a hospital and a physician practice created both indirect and direct compensation agreements
 - Indirect: Fixed payments considered the value of anticipated referrals by physicians
 - Direct: Individual physicians signed the lease, the hospital guaranteed payments for which the physicians were liable, and the hospital made payments on the physicians' behalf

Case Law

Bradford, (cont'd.)

- The sublease did not meet a Stark exception because:
 - The compensation was not FMV
 - An accountant's FMV analysis did not meet the Stark definition because the analysis considered the volume or value of anticipated referrals
 - The compensation arrangements were not set out in writing
 - A proposal letter and initialed invoices did not constitute a valid written agreement

Settlements

- Covenant Medical Center: \$4.5M to resolve allegations that it paid 5 employed physicians above FMV
 - Defendant alleged that formulas were based on personally performed services
 - Government appears to have looked at the end result – compensation actually received not FMV and not commercially reasonable

CONSIDER CAPPING MAXIMUM TOTAL COMP TO ENSURE FMV

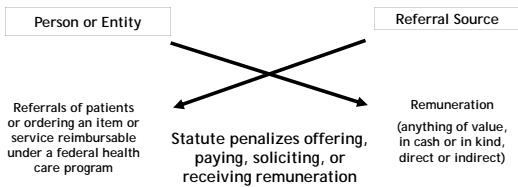
Anti-Kickback Statute (AKS)

Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7b(b))

Knowingly and willfully solicits or receives/offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- In return for referring/to induce to refer 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/to induce 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

Anti-Kickback Statute



Broad Prohibition

- Applies to any person or entity (not simply physicians)
- Applies to items or services reimbursable by any Federal health program
- Prohibits paying for referrals or receiving payment for referrals
- Prohibits paying or receiving payment for recommending or arranging for services ultimately reimbursable by Federal health programs
- Prohibits giving or receiving discounted or free items or services in exchange for access to Federal health program business
- "The Anti-Kickback Statute prohibits in the healthcare industry some practices that are common in other business sectors, such as offering gifts to reward past or potential new referrals"
(OIG Compliance Guide for Hospitals)

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AKS Definition: Intent

Because AKS is a criminal statute, the government must prove knowing, willful intent to violate AKS

- “One purpose” test: An act violates AKS if one purpose is to induce referrals, even if there are other, legitimate purposes for the agreement. *U.S. v. Greber*, 760 F.2d 68 (3rd Cir. 1985); *U.S. v. Borassi*, No. 09-4088 (7th Cir. May 4, 2011)

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Intent

- The Patient Protection and Affordable Care Act of 2010 addressed the level of intent required by AKS:
 - “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.” PPACA § 6402(f)(2)
- PPACA’s interpretation arguably preempts a previously prominent interpretation that AKS required proof of specific intent to violate the law. *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)

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Proving Intent

- Government will look for any evidence related to a defendant’s knowledge and purpose related to an arrangement
- Common pitfalls that could create unintended and unfortunate inferences (especially in emails)
 - Jokes about jail time
 - Compliance criticisms about others in general email (e.g., someone else acted improperly or with bad intent)
 - Discussions of referral source’s importance to the hospital/company in the context of any financial negotiation or decision
 - Calculations of the expected value or volume of referrals in connection with arrangement

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About Safe Harbors

- Under AKS, there are safe harbors
- Unlike Stark, parties don't have to meet all elements of a safe harbor. But if the party does meet the safe harbor elements, then the party will not be in violation of AKS
- Arrangements that fail to meet the elements of a safe harbor are evaluated based on their particular facts and circumstances
- "Set in advance" under AKS = annual fixed aggregate payment (unlike Stark)

Key Safe Harbors

- Small Entity Investment Interests
- Equipment and Space Lease
- Personal Services
- Discounts
- Bona fide Employment
- Practitioner Recruitment
- Group Practice
- Ambulatory Surgery Centers
- Electronic Health Records



Possible Penalties

- Substantial criminal felony penalties
 - Fines up to \$25,000 and/or up to 5 years imprisonment
- Exclusion from Medicare, Medicaid and other federal health care programs
- Civil monetary penalties up to \$50,000 per offense



False Claims Act: "In addition to the penalties provided for in this section or section 1128A, 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 Code." (PPACA § 6402(f)(1))

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Sanctions Focusing on Individual Accountability

- **Corporate Integrity Agreement (CIA)**
- **Divestiture**
- **Exclusion of Corporate Officers**

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Corporate Integrity Agreement

- Agreement an entity enters into instead of exclusion from Federal health care programs
- Executed when the OIG believes the entity continuing as a participant in Federal health care programs is in the public interest
- Generally last 5 years and include, for example, requirements that the entity develop written standards and procedures and establish compliance officers or a compliance board
- Frequently require certification by entity boards and management that the entity is in compliance with the CIA
- CIAs involving AKS violations have "Arrangements Procedures."
 - Database of existing and new contracts
 - Written review and approval process of all contracts
 - Compliance requirements for individuals

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Sanctions Focusing on Individual Accountability

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Divestiture

U.S. v. Norian Corp. Synthes, Inc., No. 09-CR-00403-LDD (E.D. Pa. Oct. 4, 2010)

- The OIG required a parent company to divest itself of a subsidiary to avoid exclusion from Federal health care programs
- Such a requirement was the first in a health care fraud case, though the OIG indicated this sanction may be used in future cases

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Sanctions Focusing on Individual Accountability

- Corporate Integrity Agreement (CIA)
- Divestiture
- **Exclusion of Corporate Officers**

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Exclusion of Corporate Officers

- The OIG has sanctioned individuals while allowing the entity to continue rather than excluding the entity from Medicare or Medicaid participation
- Two bases for exclusion:
 - Individuals with an ownership or control interest an entity, if the individual knew or should have known of the conduct leading to the sanction
 - Individuals who are officers and managing employees of an entity

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Common Arrangements Potentially Implicating the Anti-Kickback Statute

Joint Ventures – Potential High Risk Areas

- Selection of investors or size of investment opportunity based on anticipated level of referrals
- Tracking sources of referrals and distributing this information to investors
- Investment interests that are not transferable or that divest when the investor stops practicing medicine
- Disproportionate returns on physician investments
- Investment interests sold at nominal cost to physicians or pursuant to loans from the joint venture to the physician
- Joint ventures formed to provide services that one of the entities is already in the business of providing

(OIG Special Fraud Alert, Dec. 19, 1994)

Joint Ventures – Safe Harbors

- 40/40 Joint Ventures
 - No more than 40% of ownership held by persons who
 - Make/influence referrals or otherwise generate business for the entity
 - Furnish items or services
 - No more than 40% of gross revenues from investor referrals or business otherwise generated by investors
- Underserved Areas
 - No more than 50% of ownership held by persons who
 - Make/influence referrals or otherwise generate business for the entity
 - Furnish items or services
 - 75% of revenues derived from persons who reside in MUA or MUP
- Registered securities of company with \$50M in undepreciated net capital assets
- Group Practices: meets Stark definition of Group Practice and ancillary revenues meet Stark definition of "in office ancillary services"

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Ambulatory Surgery Centers – Safe Harbor

- Surgeon/Single Specialty
 - 1/3rd of physician investor’s medical practice income must come from ASC procedures
- Multi-Specialty
 - 1/3rd of physician investor’s medical practice income must come from ASC procedures
 - 1/3rd of physician investor’s ASC procedures must be performed at JV ASC
- Hospital/Physician
 - If JV ASC obtains space, equipment or services from hospital, must be via contract meeting safe harbor requirements
 - Hospital not in a position to make or influence referrals to investors or the JV ASC
- ASC may not provide ancillary services unrelated to ASC procedures that are separately billable

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Marketing Arrangements

- “Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals”
- Suspect Arrangements
 - Independent contractor arrangements
 - Compensation based on percentage of sales, volumes, or per referral
 - Marketing arrangements related to separately reimbursable items or services
 - Direct contact between the sales agent and physicians
 - Direct contact between the sales agent and beneficiaries
 - “White Coat” marketing - sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients
- Key Safe Harbor: Bona Fide Employment (no FMV provision)

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AKS Resources – Where to Look

- **OIG Website:** <http://oig.hhs.gov/fraud.asp>
 - Advisory Opinions
 - Industry Sector Specific Compliance Guidance
 - Fraud Alerts, Bulletins, and Other Guidance
 - Safe Harbor Commentary
- Case Law/Pleadings
- Publicly Reported Settlements

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False Claims Act (FCA)

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Civil False Claims Act (FCA) (31 U.S.C. § 3729 et seq.)

- Prohibits knowingly presenting a claim (or causing a claim to be presented) that is false or fraudulent, or using false statements or records to obtain payments on such claims
- Pre-PPACA, government argued implied or express false certification (e.g. on cost report) of compliance with AKS in conjunction with claims = FCA violation

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FCA Definitions: “Knowingly”

- A person acts knowingly when the person:
 - Has actual knowledge of the information;
 - Acts in deliberate ignorance of the truth or falsity of the information; OR
 - Acts in reckless disregard of the truth or falsity of the information
- **NOTE:** The FCA requires no proof of specific intent to find a person in violation of the FCA

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FCA Definitions: "Claim"

- Any request or demand for money or property that:
 - Is presented to an officer, employee, or agent of the U.S.
 - Is made to another recipient, if the money is to be spent on the Government's behalf, and if the Government:
 - Provides any portion of the money or property requested, OR
 - Will reimburse the recipient for any portion of the money or property requested or demanded

Recent FCA Developments

- 2009 FERA Amendments
- Changes under PPACA (2010)

2009 FERA Amendments

- Addressed the previously undecided issue of "reverse false claim" when a person fraudulently evades an obligation to pay or transmit money to the Government
- Amendments make an entity liable if the entity does not return overpayment made by the Government
- Result: A person can be in violation of the FCA without having submitted a false claim or statement to the Government

Changes under PPACA: Stark or AKS violations also FCA violations

False Claims Act: *“In addition to the penalties provided for in this section or section 1128A, 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 Code.”* (PPACA § 6402(f)(1))

Changes under PPACA: The 60-Day Rule

- Entities now have an obligation to report and refund overpayment made by federal healthcare programs
- This report or refund must be made 60 days after the overpayment is “identified” (“60-Day Rule”)
- Failure to follow the 60-Day Rule permits the government to assess civil monetary penalties and exclude violators from Medicaid participation

60-Day Rule

Biggest challenge for entities: When does the 60-Day Rule clock start running? “Identified” is not defined in the law or regulations to date

60-Day Rule: Possible Implications

- New York State Office of the Medicaid Inspector General (OMIG) has attempted to interpret and apply
 - Interpreted “indentify” to mean when “the fact of an overpayment, not the amount of the overpayment has been identified”
 - Can a thorough investigation into a possible overpayment be conducted in 60 days?
- Danger of incorrect and premature refunds by entities just to ensure the clock stops running

Civil Penalties

- Civil monetary penalty of no less than \$5,000 and no more than \$10,000 for each claim.
 - E.g. One claim form constitutes a single claim as recognized by the FCA; providers submit many claim forms each year
- Treble damages on amount paid
 - Damages can be reduced to double if a violation is disclosed by the person or entity violating the FCA

Self-Disclosure Requirements

- Damages may be reduced from treble to double damages if:
- The person in violation furnished the Government with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
 - Such person fully cooperated with any government investigation of such violation; AND
 - At the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation

The Aggregate Cost of FCA Violations

- The U.S. Department of Justice reported recovering **\$3 billion** in settlements and judgments in cases involving fraud against the government arising in FY 2010
 - Of that sum, **\$2.5 billion** represented health care fraud recoveries
 - Since 1986, the government has recovered over **\$27 billion** under the FCA

Pennsylvania False Claims Act (PA FCA)(62 P.S. § § 1407-08)

- Prohibits acts including, without limitation:
 - Knowingly or intentionally presenting a false or fraudulent claim for furnishing medical services or merchandise
 - Knowingly presenting a claim for furnishing medically unnecessary services or merchandise
 - Knowingly submitting false information to obtain greater compensation for medical services or merchandise
 - Knowingly submitting false information for obtaining authorization to furnish medical services or merchandise

PA FCA Criminal and Civil Penalties

- A person in violation is guilty of a third-degree felony for each violation
 - Up to \$15,000 penalties
 - Up to 7 years imprisonment
 - Must repay the amount of excess benefits or payments plus interest, up to 3 times the amount of excess benefits or payments
 - 5-year exclusion from Medicaid
- The department may immediately terminate Medicaid provider agreements for violations by providers
 - The department may begin a civil suit to collect up to double damages plus interest
 - Terminated providers are prohibited from owning, arranging for, rendering, or ordering any service for Medicaid recipients during the period of termination

Qui Tam “Whistleblower” Suits

Whistleblower (31 U.S.C. § 3730)

- A person may bring a civil action for a violation of the FCA for the person and for the Government
- The action is brought in the name of the Government
- The action may be dismissed only if the court and the Attorney General consent to and give reasons for dismissal

Procedures: Government Intervention

- If the Government proceeds with the action, then it will prosecute the action and not be bound by the relator, though the relator has the right to continue as a party to the action
- The Government may:
 - Dismiss the action
 - Settle the action
- If the Government elects not to proceed with the action, then the relator has the right to conduct the action
- A court may permit the Government to intervene at a later date upon a showing of good cause

Whistleblower Awards

- If the Government successfully pursues the action, then the relator receives 15 to 25% of the proceeds of the action or settlement of the claim
- If the relator successfully pursues the action after the Government declines to proceed, then the relator receives 25 to 30% of the proceeds, plus reasonable expenses and attorneys' fees

Protection for Relators

- Protections to employees, contractors, and agents discriminated against because of their actions as relators
- Relief includes:
 - Reinstatement with the same seniority status the relator would have had but for the discrimination
 - Two times the amount of back pay
 - Interest on the back pay
 - Compensation for any special damages sustained, including litigation costs and attorneys' fees

Barred Whistleblower Actions

- Actions based on allegations or transactions which are the subject of a suit or an administrative proceeding in which the Government already is a party
- Actions based on allegations or transactions that have been publicly disclosed in a Federal hearing or report, or in the news media
 - Unless the action is brought by the Attorney General or the person bringing the action is the original source of the information

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Whistleblower Definitions: “Original Source”

- An “original source” is an individual who:
 - Prior to public disclosure, has voluntarily disclosed to the Government the information on which the claim is based; OR
 - Has knowledge that is independent of and materially adds to the publicly disclosed allegations and have voluntarily provided the information to the Government before filing an action

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Deficit Reduction Act of 2005 Requirements

- Entities receiving \$5 million or more in Medicaid reimbursement must:
 - Establish written policies for employees providing detailed information about the FCA, state false claims laws, and whistleblower protections under the laws;
 - Include in written policies provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; AND
 - Include in any employee handbook a specific discussion of federal and state false claims laws, the right of an employee to be protected as a whistleblower, and the entity's policies for detecting and preventing fraud

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Pennsylvania Whistleblower Law (43 P.S. § 1421 et. seq.)

- No employer may discharge, threaten, or otherwise discriminate or retaliate against an employee because the employee or a person acting on behalf of the employee makes a good faith report or is about to report, verbally or in writing, to the employer or appropriate authority an instance of wrongdoing
- Nor because the employee is requested by an appropriate authority to participate in an investigation, hearing, inquiry, or court action

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PA Whistleblower Definitions

- “Employer”: A person supervising one or more employees, including the employee in question, a superior of that supervisor, or an agent of a public body
- “Employee”: A person who performs a service for wages or other remuneration under a contract of hire, written or oral, express or implied, for a public body
- “Appropriate authority”: A Federal, State or local government body, agency or organization having jurisdiction over criminal law enforcement, regulatory violations, professional conduct or ethics, or waste

Protection for PA Whistleblowers

- A person alleging a violation of the PA Whistleblower Law may bring a civil action for a injunctive relief, damages, or both, within 180 days after the occurrence of the alleged violation
 - If successful, a court may award:
 - Back wages
 - Full reinstatement of fringe benefits and seniority rights
 - Actual damages
 - All or a portion of the costs of litigation, including attorneys’ fees
- An employer may be fined up to \$500 for a violation
