Anti-Kickback and Stark Update

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Outline of Presentation

- Anti-kickback statute
  - Basics
  - Recent developments
- Stark
  - Basics
  - Recent developments
- Voluntary disclosure
- Legislative developments

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Fraud and Abuse Authorities Focusing on Relationships With Referral Sources

- Anti-Kickback statute
- Stark self-referral prohibitions
  - State "Mini-Stark" statutes

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Areas of Governmental Concern

- Additional Cost
- Over, Under, and Mis-Utilization
- Quality of Care
- Access to Care
- Patients' Freedom of Choice
- Competition
- Exercise of Professional Judgment

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Medicare Anti-Kickback Statute

- Prohibited Conduct
  - Knowing & willful
  - Solicitation or receipt *or*
  - Offer or payment of
  - Remuneration

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Medicare Anti-Kickback Statute

- Prohibited Conduct *cont'd*
  - In return for referring a Program patient, *or*
  - To induce the purchasing, leasing , *or* arranging for or recommending purchasing or leasing items or services paid by the program

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Medicare Anti-Kickback Statute

- Penalties
  - Criminal fines & imprisonment
  - Civil money penalty of $50,000 *plus* 3X the amount of the remuneration
  - Exclusion

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Medicare Anti-Kickback Statute

- False Claims Act liability
  - Pre- PPACA of 2010
    - *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc, et al.* Case No. 04-14458 (11th Cir. 9/9/05)
  - PPACA of 2010
    - Section 6402 (f)(1) specifically makes Anti-Kickback violations actionable under the FCA

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Stark Vs Anti-Kickback Statute

- Intent standard
- Compliance with exception/safe harbor
- Definition of "referral"
- Stark applies only to DHS

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Intent: Pre-PPACA of 2010

- Intent to violate: 9th Circuit (*Hanlester– requires defendant have specific intent to violate the kickback statute*)
- Intent to commit act: 5th Circuit (*Davis*: "willfully" means the defendant must have specific intent merely to perform an "illegal act")
- Middle ground: 8th Circuit (*Jain*: "willfully" means "unjustifiably and wrongfully, known to be such by the defendant")

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Intent: PPACA of 2010

- Section 6402 (f) (2)
  - "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."
  - Legislatively overrules *Hanlester*

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Intent

- *Greber* "one purpose test" (majority of Circuits)
  - If just *one purpose* of a payment is to induce referrals, even if there are other legitimate purposes, it is illegal
- *Bay State Ambulance* "primary purpose" test (First Circuit)
  - Referrals must be the *primary* purpose of the remuneration; a minor purpose or incidental benefit is not enough

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Intent

- "[Defendants] can not be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law. There must be an offer or payment of remuneration [with intent, at least in part, to gain influence over the reason or judgment of a person making referral decisions.]"
  - Jury instruction No. 32

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Statutory Exceptions

- Statutory exceptions
  - Discounts
  - Employer/employee
  - Group purchasing
  - Part B co-insurance waivers
  - Managed care plans
  - Pharmacy waivers or Part D cost-sharing
  - FQHC and Medicare Advantage organization
  - FQHC and donor
  - E-prescribing

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Safe Harbors

- Warranties
- Space Rentals
- Equipment Rentals
- Personal services/management agreements
- Group purchasing
- Co insurance waivers
- Sale of professional practices

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Safe Harbors

- Additional safe harbors added through the years to address increasingly complex health care financial arrangements– ASCs, recruitment, shared risk arrangements
- Safe harbors adopted in 2006 permitting donations of e-prescribing (same as Stark) and EHR technology

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Other Policy Statements

- Advisory Opinions
- Policy Statements
  - Special Fraud Alerts
  - Advisory Bulletins
  - Model Compliance Plans
  - Selected Correspondence Posted on the OIG Website
    - www.hhs.gov/oig

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Key Issues Under the Anti-Kickback Statutes

- Joint Ventures
- Commissioned Sales Representatives
- Medical Director and other Service Agreements
- Leases
- Discounts

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Joint Ventures

- Background
  - *Hanlester*
- 1989 Special Fraud Alert on Joint Ventures
  - Manner in which investors selected/retained
  - Nature of business structure
  - Financing/business structure
- 2003 Special Advisory Bulletin on Contractual Joint Ventures
  - JVs between existing suppliers and health care entities to services that entities patients are "suspect"

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Joint Ventures

- Safe harbors
  - Large publicly traded entities
    - Net tangible assets >$50,000,000
  - Small entity safe harbor
    - <40% "tainted investors"
  - Ventures in medically underserved areas
    - <50% held by "tainted" investors
  - ASC safe harbor
    - Single specialty
    - Multi-specialty
    - Hospital/surgeon joint ventures

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Commissioned Sales Representatives

- W-2 Employment safe harbor
  - Bona fide employment under IRS rules
- Advisory Opinion 98-10 criteria for non-employee commissioned sales reps
  - Compensation based on % of sales
  - Direct program billing by seller
  - Direct contact between rep and physicians
  - Direct contact between rep and patients
  - Does rep have "undue influence"
  - Marketing of separately reimbursable items

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Medical Director and Other Service/Management Agreements

- Safe Harbor Requirements
  - Signed written agreement
  - Covers all services to be provided
  - If part-time, contains schedule of services
  - One year term
  - ***Aggregate*** compensation set in advance at fair market value
  - Services do not include promoting illegal activity
  - Services "commercially reasonable"

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Medical Director and Other Service/Management Agreements

- Application to hospital-based physicians
  - Management Advisory Report
- 1992 Special Fraud Alert: Hospital Incentives to Physicians

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Space and Equipment Leases

- OIG Special Fraud Alert: Rental of Space in Physicians Offices By Persons or Entities to which Physicians Refer (February, 2000)
- Targeted arrangements in physician offices
  - CORF's providing PT and OT
  - Mobile diagnostic services
  - DME "consignment closets"

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Space and Equipment Leases

- OIG Focus
  - Appropriateness of the rental agreement
  - Rental amounts
  - Time and space considerations

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Space and Equipment Leases

- Lease Safe Harbor
  - Signed written agreement
  - Covers all space/equipment leased
  - If part-time, contains schedule of use
  - One year term
  - ***Aggregate*** rental set in advance at fair market value
  - Lease "commercially reasonable"

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Discounts

- Discount safe harbor
  - 3 buyer categories
    - Cost-report
    - HMO/CMP
    - Other
  - Disclosure of discounts

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Discounts

- ***Not*** a discount
  - Cash or cash equivalents
  - Discounts on one item based on purchases of a different item
  - Reductions in price to one payer but not Medicare/Medicaid
  - Waivers of co-pay/deductible

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Discounts

- 1999 Safe Harbor Revisions
  - Permits charge-based providers to receive year-rebates
  - Created "offeror" concept
  - Eliminated requirement that charge-based providers report discounts on claims
  - Discounts on multiple items permitted when reimbursement methodology is the same
- "Prebates": 7/17/00 M. Thornton letter

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Discounts

- "Swapping"
  - Advisory Opinion 99-2
    - Discount arrangement between Ambulance Company and SNF for PPS and non-PPS transports
  - Advisory Opinion 99-13
    - Discount arrangement between Pathology Group and Hospitals or Physicians

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Discounts

- OIG Indicia of "Suspect" Discounts
  - Discounted prices below fully loaded (not marginal) costs
  - Discounted prices below those given to buyers with comparable "account" volume, but without potential Program referrals

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Discounts

- Subsequent Retreat
  - Discounts below fully loaded costs not *per se* unlawful
  - Must be a "linkage" between the discount and referrals of Program business

    Letter of Kevin G. McAnaney (April 26, 2000)
- Compliance Guidance for Clinical Laboratories
  - 63 Federal Register 45,076 (August 24,1998)

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Case Developments

- *United States ex rel. Thomas v. Bailey*, E.D. Ark.(11/06/08)
  - Qui tam suit alleging that medical device manufacturer violated the Anti-kickback statute via a sham consulting agreement with a physician to induce physician to use its products
  - Hospital was alleged to have submitted false claims by billing for devices ordered by the physician
  - Claims dismissed because Hospital made no false certifications

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Case Developments

- *United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, S.D. Ohio (Christ Hospital)
  - DOJ intervened in a qui tam suit alleging that Hospital gave cardiologists kickbacks in the from of favorable access to its cardiology unit based on revenues they generated for the hospital
  - Cardiologists allegedly rewarded for referrals to the hospital with favorable scheduling times for their own patients while physicians who were not good referrers were denied time.
  - Settlement in principle reportedly reached

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Recent Advisory Opinions

- Advisory Opinion 09-01 (Mar. 13, 2009)
  - SNF program offering complimentary local transportation to residents' families did not lead to CMPs
  - Benefit was uniformly offered to all patients, regardless of payer
  - Transportation resources in SNF's area were lacking
  - Costs not shifted to federal government

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Recent Advisory Opinions

- Advisory Opinion 09-05 (May 14, 2009)
  - Hospital compensation program for on-call services did not lead to administrative sanctions or CMPs
  - Hospital reimburses doctors who perform services for uninsured patients who benefit the hospital through the Medicaid DSH adjustment
  - All payment is on the basis of services performed, not referrals

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Recent Advisory Opinions

- Advisory Opinion 09-04 (May 20, 2009)
  - Charity grants supporting diagnostic tests, which were funded, in part, by drug manufacturers, pharmacies and suppliers, had sufficient safeguards to prevent beneficiary inducement
  - Assistance awards are based on charity's independent judgment, without regard to selection of donors' products
  - Financial assistance is based on uniform, verifiable criteria

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Recent Advisory Opinions

- Advisory Opinion 09-08 (July 21, 2009)
  - Institutional Patient Assistance Plan (IPAP), which provided drugs to hospitals for distribution to indigent patients, did not trigger administrative sanctions/CMPs
  - Hospitals screened based on size/DSH percentage, not utilization
  - IPAP not available to any patient with prescription drug coverage through federal program

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Recent Advisory Opinions

- Advisory Opinion 09-09 (July 29, 2009)
  - Ambulatory Surgery Center (ASC) joint venture between hospital and a physician group would not trigger administrative sanctions
  - Hospital employees will not refer patients to ASC, will not encourage or require medical staff to refer to ASC or physician group, and will not track referrals
  - Physicians' interest in ASC joint venture held through an LLC, but each physician would be independently qualified to own interest directly

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Recent Advisory Opinions

- Advisory Opinions 09-10, 10-01, 10-02, 10-03
  - Medigap "preferred hospital" networks did not lead to administrative sanctions or CMPs
  - Hospitals offered discounts to Medigap insurers, and were included in the preferred hospital network
  - Beneficiaries with qualifying inpatient admissions to network hospitals received discounts from insurers, including up to 100% reduction in deductible
  - While anti-kickback concerns were implicated, OIG found relatively low risk of overutilization

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Physician Self-Referral Statute

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Stark Self Referral Law

- **Physician may not refer:**
  - Medicare or Medicaid patients
  - For "designated health services"
  - to an entity with which the physician *or*
  - an immediate family member has
  - a "financial relationship"
  - Unless the relationship fits in an exception

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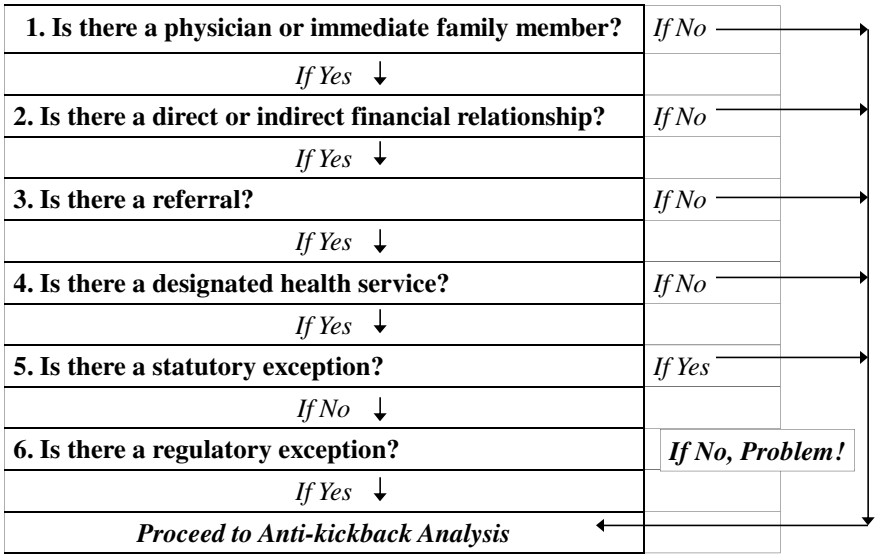
Stark Analysis Decision Tree



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Designated Health Services

- Clinical Lab
- Physical Therapy
- Occupational Therapy
- Radiology, including MRI, CAT, ultrasound, nuclear
- Radiation Therapy
- DME
- Parenteral and Enteral services and supplies
- Prosthetics and Orthotics
- Home Health
- Outpatient RX Drugs
- Inpatient and Outpatient Hospital services (except Litho)

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Stark Super Exceptions [42 CFR 411.355]

- Exceptions to both ownership and compensation
  - In-Office Ancillary Services
  - Physician Services
  - Services By Federally-Qualified HMO or Prepaid Health Plan with Medicare Contract
  - Academic Medical Centers
  - Misc. (ASC implants, Dialysis drugs, Preventive services, Eyeglasses after cataract surgery, Intra-family referrals)
  - N.B. – Be careful! Some exceptions only except services and not the financial arrangement

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Stark Ownership Exceptions [42 CFR 411.356]

- Ownership Exceptions
  - Publicly-Held Companies with Equity exceeding $75,000,000
  - Mutual funds
  - Rural Providers
  - Ownership of Hospital as a Whole
    - Admitting Privileges Required

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Stark Compensation Exceptions [42 CFR 411.357]

- Rental of Office Space
- Rental of Equipment
- Bona Fide Employment
- Personal Services
- Physician Recruitment
- Isolated Transactions
- Hospital Remuneration Unrelated to DHS
- Payments by Physicians
- Charitable Donations by Physicians
- Non-monetary compensation
- Fair market value compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- OB malpractice insurance subsidies
- Professional courtesy
- Retention Payments in underserved areas
- Community-wide EHR
- EHR donations

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Sanctions

- Denial of Payment
- Refund of Amounts Collected as a Result of Improper billing
- Civil Money Penalties of $15,000 per Item or Service Plus 2X the Amount Claimed
- Civil Money Penalties of $100,000 for "Circumvention Schemes"
  - Circumvention described very narrowly
  - Sanction is not what most people think
- Exclusion
- False Claims Act Liability

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Key Definition – "Referral"

Request/ordering or certifying medical necessity (including tests ordered pursuant to consult)

- ***Does not*** include personally performed services
- ***Does*** include "incident to" (comments sought)

- Referral imputed to physician if he/she "directs" or "controls" person making it
  - Preamble includes NPs and PAs in this category
- Special favorable rules for pathologists, radiologists and radiation oncologists

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Key Definition- Entity

- A person or entity is considered to be furnishing DHS if it is
  - The person or entity that has presented the claim to Medicare for the DHS, including pursuant to reassignment, and
  - <u>The person or entity that has performed the service that is billed as DHS</u>

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Key Definition- "Financial Relationship" [42 CFR 411.354]

- Ownership or investment
  - Direct
  - Indirect
- Compensation arrangement
  - Direct
  - Indirect

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Key Definitions – Ownership or Investment

- "Direct ownership/investment interests"
  - Includes secured debt
  - Does ***not*** include
    - Retirement plan
    - Stock options earned as compensation until exercised
    - Unsecured loans
    - "Under arrangements" contracts

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Key Definitions – Ownership or Investment

- Indirect ownership/investment interest
  - Unbroken chain of any number (>1) of persons or entities between physician and entity furnishing DHS
  - Entity has actual knowledge (or reckless disregard or deliberate ignorance) of interest
  - Need not know precise composition of chain

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Key Definition - Remuneration

- Statute - "The term 'remuneration' includes any remuneration, directly or indirectly, overtly or covertly, in cash or kind"
- Regulation – "any payment or benefit made directly or indirectly, overtly or covertly, in cash or in kind . . ."

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Key Definition- Direct Compensation [42 CFR 411.354(c)]

- Direct compensation arrangements
  - Any arrangement involving remuneration between a DHS entity and a physician (or family member)
  - No person or entity interposed between them
    - except a sole physician PC, or
    - A "physician organization" in which the physician has an ownership or investment interest
      - Physician organization means "a physician, a physician practice, or a group practice"
      - See also, CMS Stark FAQs
  - No "stand in shoes" for DHS entity and its parent, subsidiaries, or sister entities

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Key Definition- InDirect Compensation [42 CFR 411.354(c)(2)]

- "Unbroken Chain" of any number of entities between physician and entity
- Aggregate compensation to physician from closest link in chain varies with or takes into account the volume or value of referrals or other business generated to entity providing DHS
- Entity providing DHS has actual knowledge or acts in reckless disregard of existence of such relationship

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Space and Equipment Lease Exceptions

- The agreement is set out in writing, is signed by the parties, and specifies the premises it covers
- The term of the agreement is at least 1 year
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor other than common areas prorated on use)

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Space and Equipment Lease Exceptions

- The rental charges over the term of the agreement are set in advance and are consistent with fair market value
- The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties

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Space and Equipment Lease Exceptions

- Compensation for a space or equipment rental cannot be based on a formula using
  - a percentage of revenue earned, billed, collected or otherwise attributable to the services performed or business generated through the use of the equipment or in the space; or
  - a per-unit of service rental charge where the charges reflect services provided to patients referred by the lessor to the lessee.
- The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor

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Space and Equipment Lease Exceptions

- Arrangement is in writing, signed by the parties, specifies the services covered
- Arrangement covers all services to be provided by physician to entity
- Aggregate services contracted for may not exceed those reasonable and necessary for the legitimate business purposes
- Term must be at least one year (if terminated may not enter into the same arrangement during the first year of the original term)

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Personal Service Exception

- Compensation must be set in advance and except for physician incentive plans, does not take into account the volume or value of referrals or other business generated between the parties.
- Services may not involve the counseling of an unlawful business arrangement

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Personal Service Exception

- Requires agreement to cover all services provided by physician to entity
- Allows either incorporation by reference of all other agreements or cross reference to master list of contracts maintained centrally
- Permits physician incentive plan exception to include downstream payments

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Fair Market Value Exception

- Arrangement is in writing, signed by the parties, specifies the services covered
- Set timeframe of one year
- Arrangement covers all services to be provided by physician to entity

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Fair Market Value Exception

- Compensation must be set in advance and not take into account the volume or value of referrals or other business generated between the parties.
- Space or equipment leases cannot be based on
  - % of revenues, billings or collections on services provided in space or using equipment
  - Per click fees cannot be used if charges reflect services to patients referred by lessor to lessee

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Fair Market Value Exception

- Arrangement must be commercially reasonable
- Cannot violate other laws
- Services may not involve the counseling of an unlawful business arrangement

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Indirect Compensation Exception

- The compensation received by the referring physician from the entity with which he has a direct financial arrangement must FMV and not take into account the value or volume of referrals or other business generated by the physician for the DHS entity. Where the physician's direct financial arrangement is an ownership interest, such as an LLC investment, the compensation test is applied to the compensation arrangement closest to the physician.

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Indirect Compensation Exception

- The compensation arrangement must be set out in writing, signed by the parties, and specify the services covered by the arrangement.
- Compensation for space or equipment leases cannot be based on
  - % of revenues, billings or collections on services provided in space or using equipment
  - Per click fees cannot be used if charges reflect services to patients referred by lessor to lessee

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Indirect Compensation Exception

- The arrangement cannot violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission

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STARK III – 72 FR 51012 (9/5/2007)

- "Stand in the Shoes" Expansion
- FMV exception expansion & impact on Payments by Physician exception
- Percentage Compensation Methodologies
- Termination/amendment of contracts
- Shared ancillary services/exclusive use by space & equipment lessees
- Elimination of MD compensation FMV safe harbor

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STARK III.v (aka FY 2009 IPPS)

73 FR 48688 (8/19/2008)

- Stand in the Shoes
- Period of Disallowance
- Alternative Method of Compliance
- Percentage Compensation Methodologies
- Per Click Compensation Methodologies
- Under Arrangements a/k/a "entity" definition

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CURRENT ISSUES

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Elimination of MD Compensation Safe Harbor

- Phase II created a MD comp FMV safe harbor
  - Average of 4 physician comp surveys @ 50% level
- Phase III change – eliminated the compensation safe harbor
  - Reiterates that FMV is based on facts and circumstances
  - Observes that FMV for physician services "may differ" from FMV for administrative services
- Government has since become very aggressive on MD comp and FMV

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Percentage Compensation Methodologies

- In Phase III discussion of "set in advance," CMS clarifies that % comp arrangements are deemed to be "set in advance" but may still "take into account the value or volume of referrals or other business generated"
- In Phase III discussion of "indirect compensation" exception, CMS states that % of collections may not satisfy FMV test

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Percentage Compensation Methodologies

- In 2009 IPPS, CMS amends the compensation exceptions to exclude only % comp based on revenues billed or collected for services in leased space or equipment
  - Inference that % comp in other arrangements fits
- Query – Don't many % arrangements vary with value and volume of referrals or other business generated?

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Shared Services/Exclusive Use

- IOAS exception requires the MD/group to provide supervision & lease exceptions require the lessee to have "exclusive" use during lease
- CMS comment in Phase III discussion of IOAS that shared ancillary services don't comply unless block lease
- CMS comment in Phase III discussion of lease exceptions that non-exclusive shared facilities do not fit in exception
- CMS comment in 2009 IPPS that "on demand" leases are prohibited by new "per click" restrictions

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Modification of Agreements

- Phase III clarification that, for purposes of "set in advance" requirement, agreements between DHS entity and physicians can be modified during the term so long as the amendment is not related to volume or value of referrals or other business generated between the parties. Specific exceptions may have other requirements on amendments.

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Modification of Agreements

- Phase III clarifies that parties may amend leases multiple times during or after first year provided that the rental charges are not changed
- Phase III also said that if the rental charges are changed, parties must terminate the agreement and enter into new agreement

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IPPS Clarifies the Clarification

- Amendments to an agreement are ok during the term if:
  - All requirements of the applicable exception are satisfied
  - The modified compensation or formula is set in advance in sufficient detail to be verified
  - The formula does not take into account the volume or value of referrals or other business generated by the referring physician
  - The new compensation scheme stays in place for at least a year from the amendment
- Language can be read to allow modifications w/in the original one year term

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Payments by a Physician

- Phase III states that, in light of expansion of Fair Market Value exception to include remuneration from physician to DHS entity and limitation in payments by physician that no other exception applies, routine purchases must meet FMV standards
- Phase III changed exception language from "items or services . . . not specifically excepted" by another provision to "not specifically addressed"

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Payments by a Physician

- Following criticism, CMS "corrected" the reg text to restore the "not specifically excepted" language. 72 Fed. Reg. 68,075
- N.B. The operative phrase "that are not specifically excepted by another provision" modifies "items or services" and not the generic term "compensation."

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"Stand in the Shoes"

- Application of SITS rules makes indirect comp arrangements into direct comp
- In Phase I, SITS only applied to a physician and a sole physician professional corp.
- In Phase III, CMS extended SITS to any arrangement where the only intervening entity between the DHS and physician was a "physician organization"

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"Stand in the Shoes"

- In 2009 IPPS, CMS modified SITS so that it is only mandatory if the physician was an owner of the physician organization
- **N.B.** In 2009 IPPS, CMS declined to extend SITS to DHS entity's parent, sub, or sister entities

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SITS Squirms

- Phase III SITS provision was delayed but protected any arrangement that fit in the indirect compensation exception at the time of publication for the length of the current term
  - No protection if claim was the arrangement was not an indirect compensation arrangement
  - Those arrangements had to comply by 12/4/2007

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SITS Squirms

- 2009 IPPS only grandfathered if restructured to fit in Phase III
- Interim period of exposure from 12/4/2007 through 10/1/2008
  - For employed physicians in physician organizations where no intervening entity

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Per Click Leases

- Phase I & II deemed per click and per service payments not to vary with the value or volume of referrals even if the lessor could affect the # of procedures
- 2009 IPPS modifies space and equipment **lease**, FMV, & indirect comp exceptions to prohibit "per click" and per service comp if the charges reflect services provided to patients referred by the lessor to the lessee

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Per Click Leases

- N.B. The published text in 2009 IPPS reads "patients between the parties"
  - Corrected at 73 FR 57,543 to "patients referred by the lessor to the lessee."

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Definition of DHS Entity

- Phase I defined entity as the person or entity that has presented the claim to Medicare for the DHS, including pursuant to reassignment
- 2009 IPPS expanded definition to include any person or entity that performed the DHS service
- CMS refused to define "perform"

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CMS Guidance on "Perform"

"Physicians and other suppliers generally know when they have performed a service and are entitled to bill for it. . . We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS." 73 FR 48,726

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Entity Redux-The 2010 PFS Final Rule – 74 FR 61, 933 (11/25/2009)

- CMS solicits comments on the following, inter alia:
  - Whether CMS should define or clarify "perform"
  - Whether the analysis should be the same for inpatient and outpatient services provided under arrangements
  - Whether performance should be based on how many of the following elements are provided: (i) space; (ii) equipment; (iii) supplies not separately billable; (iv) management services; (v) billing services; (vi) technical personnel not otherwise billable

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Entity Redux-The 2010 PFS Final Rule – 74 FR 61,933 (11/25/2009)

- The degree to which the amount and nature of services provided by physician and nonphysician personnel should affect the determination
- The degree to which the ability to bill separately for the service should affect the determination
- Whether there are other alternatives that would protect against overutilization, while permitting legitimate arrangements

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The Negative Pregnants

- Temporary non-compliance [42 CFR 411.353(f)]
  - In compliance for 180 days preceding non-compliance
  - Fell out for reasons beyond control of entity & promptly corrected upon discovery
  - Within 90 days of non-compliance
- Missing Signature Rule [42 CFR 411.353(g)]
  - Only for failure of "signature" requirement
    - But "signed" does not require a signature!
  - 30 days for non-inadvertent; 90 days for inadvertent

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The Negative Pregnants

- Period of Disallowance [42 CFR 411.353(c)]
  - "begins at the time the financial relationship fails to satisfy the requirements of an applicable exception"
  - Ends "no later than" (i) date FR satisfies an exception; (ii) excess comp is returned and FR satisfies exception; or (iii) any below FMV payments are remedied and FR satisfies exception

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Cases

- The Good
- The Bad
- The Ugly

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U.S. ex rel. Villafane v. Sollinger et al., 453 F.Supp. 2d 678(W.D. KY 2008)

- Villifane, a physician & UL faculty member, filed FCA case alleging that Kosair Hospital's contribution to UL Research fund, which in turn partially funded UL Med School faculty salaries, created a compensation arrangement that took into account volume and value of referrals
  - "But for" UL referrals, Kosair would not contribute
  - "But for" Kosair contributions, UL could not fully fund faculty salaries

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U.S. ex rel. Villafane v. Sollinger et al., 453 F.Supp. 2d 678(W.D. KY 2008)

- Earlier ruling (457 F. Supp. 2d 743) in case found AMC exception applies even before regulatory exception
- States that in interpreting the regulation, Ct follows CMS admonition to interpret the exceptions broadly and prohibition narrowly

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U.S. ex rel. Villafane v. Sollinger et al., 453 F.Supp. 2d 678(W.D. KY 2008)

- Holds that "not taking into account the volume or value of referrals or other business generated" is an objective test
  - Measured by looking at compensation to the physician
  - If FMV, no further inquiry
  - Expressly rejects "but for" argument

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U.S. ex rel. Kosenske v. Carlisle HMA et al., 554 F.3d 88 (3d Cir. 2009)

- Physician formerly in BMA, an anesthesiology group, brought FCA alleging that Hospital's arrangement w/ BMA pursuant to which BMA provided exclusive anesthesiology and pain management services to freestanding Hospital Outpatient Clinic did not qualify for Stark exception.
- Agreement from 1992 for exclusive anesthesiology and pain management services for the Hospital but it predated the Clinic
- District Ct had granted summary judgment finding compliance with PSA exception

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U.S. ex rel. Kosenske v. Carlisle HMA et al.

- Negotiations between parties do not necessarily establish FMV b/c parties are in position to refer to each other
- Exclusivity is remuneration for Stark purposes
  - Contrary to decades of AKS guidance
  - Query why outpatient exclusivity is remuneration unless it is the Hospital that is referring?

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U.S. ex rel. Kosenske v. Carlisle HMA et al.

- Provision of space, supplies & staff is remuneration even if hospital is billing & receiving payment for facility fee
- Ignores the regulatory definitions of direct and indirect compensation
  - Under regulations, there is no indirect compensation arrangement since physician comp from BMA apparently did not vary based on referrals to Hospital
- Remanded to Dt. Ct and scheduled for trial

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U.S. ex rel. Drakeford v. Tuomey (D. S.C. 2010)

- Physician alleges Hospital entered into part-time employment arrangements with local physicians to perform outpatient procedures at Hospital outpatient surgery center that were not FMV and took into account the value or volume of referrals
- Hospital said Stark Law does not apply b/c the compensation was FMV and did not vary or take into account referrals
- Jury found Hospital violated Stark but not FCA

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Self Disclosure

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Legal Obligation to Disclose?

- Medicare statute
  - Felony for anyone "having knowledge of the occurrence of any event affecting his initial or continued right to any such benefit or payment, or the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment" from concealing or "failing to disclose" such an event with a "intent fraudulently to secure" payment which is excessive or unauthorized.
    - 42 U.S.C. § 1320a-7b(a)(3)

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Legal Obligation to Disclose?

- Medicare statute (cont.)
  - 2002 CMS proposed rule purporting to implement the statute "clarified" that providers must return excess payments within 60 days of "identifying or learning of the excess payment". (67 Fed. Reg. 3,662 (Jan. 25, 2002)). Regulation never finalized.
  - No known prosecutions.

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Legal Obligation to Disclose?

- False Claims Act – Changes to the FCA language made as part of Fraud Enforcement and Recovery Act of 2009 (FERA)
  - it is now illegal to "knowingly conceal…or knowingly and improperly avoid…or decrease…an obligation to pay or transmit money or property to the Government…"
    - 31 U.S.C. § 3729(a)(1)(G)
- Eliminated the old statutory language's need for a "false statement or record" – mere knowledge is apparently enough

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False Claims Act Penalty Reduction

- FCA violations result in treble damages plus a civil penalty of $5,000-$10,000, unless:
  - The "person committing the violation" furnishes U.S. officials with "all information known to such person" within 30 days of obtaining such information;
  - The person cooperates "fully" with the investigation; and
  - At the time of the disclosure, there was no action (civil, criminal, or administrative) underway with regard to the subject, and the discloser was not aware of any investigation
- In such case, a court may assess not less than double damages, plus the government's court costs. 31 U.S.C. § 3729(a)(7)

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Patient Protection and Affordable Health Care Act

- Section 6402
  - Requires reporting and repayment of overpayments within 60 day of ***identification*** (or due date of next cost report, if applicable)
  - Reports to be made to:
    - Secretary (OIG, CMS)
    - State, or
    - Carrier, intermediary or contractor
  - Violations actionable under the FCA

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Potential Benefits of Disclosure

- Potential to avoid criminal liability
- Potential to minimize civil exposure
- Potential to avoid Corporate Integrity Agreements
- Potential to neutralize *qui tam* suits

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What Does Disclosure Guarantee?

- While disclosure can minimize penalties, fines, and criminal liability, no reduction in penalties is guaranteed, and the OIG reserves the right to make criminal referrals
- Changes announced in OIG's most recent "open letter" mean that no self-disclosure can be settled in the self-disclosure program for less than $50,000
- May not eliminate vulnerability to Qui Tam suits
  - *U.S. ex rel. Rost v. Pfizer, Inc. and Pharmacia Corporation*

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Why Disclose?

- Self-disclosure unlikely to result in criminal investigations or prosecutions of the disclosing entity
- Fines and penalties are reduced more often than not, and may actually be eliminated
  - In 2007, OIG statistics indicated it had referred more than half of its Self-Disclosures to Medicare contractors for resolution, presumably without penalty

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Stark as Special Case

- OIG's recent "open letter" made it difficult to say where pure Stark disclosures could be made, if at all
- CMS had not yet released any guidance regarding self-disclosure of Stark violations
- Stark's disproportionate liability makes disclosure unpalatable
  - Failure to disclose raises at least the potential for devastating economic penalties later, as well as Qui Tams and potential criminal actions for a knowing failure to disclose or "active concealment"

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To Whom To Disclose?

- DOJ?
- OIG?
- The Medicare Contractors?
- CMS?

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To Whom To Disclose?

- To the OIG – only "potential fraud against the Federal health care programs, rather than merely an overpayment." "Potential fraud" does not include Stark violations only – there must be at least a "colorable" violation of the anti-kickback statute
- "Merely an overpayment" – disclose to the Contractor
- Stark Violation only - ?

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OIG's Self-Disclosure Protocol - Background

- First Displayed in the Federal Register in 1998. 63 Fed Reg. 58,399 (October 30, 1998)
- Created out of a pilot program operated by the HHS-OIG and the Department of Justice, but is now operated by OIG alone
- Open to all providers, from individual providers to large hospital systems
- Based on the belief that "providers must be willing to police themselves, correct underlying problems and work with the Government to resolve these matters"

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Open Letters

- Although the OIG has not changed its Self-Disclosure protocol from its inception, it has issued several open letters which have slightly changed Self-Disclosure procedures and parameters

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April 24, 2006 Open Letter

- In its first letter, the OIG noted:
  - It may be willing to waive its exclusion authority for providers with sufficient compliance programs who settle their monetary liability under the False Claims Act and the CMP law and enter Corporate Integrity Agreements (CIA)
  - Providers who remain non-compliant even under a CIA, may face contractually specified penalties, including exclusion
  - Corporate Compliance Agreements (CCAs) may be available to providers with existing compliance programs – CCAs last 3 years rather than 5, and do not require independent monitoring

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April 24, 2006 Open Letter

- OIG noted that the Self-Disclosure Protocol was an appropriate vehicle to resolve potential Stark liability when the Anti-kickback statute is also implicated
- Resolution of Stark and AKS issues would involve discussions with the DOJ to ensure that it is aware of each disclosure
- OIG noted that it continued to settle self-disclosed issues near the lower end of the spectrum of available penalties

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April 15, 2008 Open Letter

- OIG's second letter made substantive changes to what must be included in initial written disclosure, including:
  - A "complete" description of the disclosed conduct;
  - A description of the internal investigation or a commitment as to when it will be completed;
  - An estimate of damages and a description of the calculation method or a commitment as to when it will be completed; and
  - A statement of the laws potentially violated

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April 15, 2008 Open Letter

- The provider "must be in a position" to complete the investigation and damage assessment within 3 months of acceptance into the Protocol
- The OIG reaffirmed that the Protocol is for potential breaches of law only – billing errors should be submitted to the appropriate Medicare Contractor
- A "presumption" that providers who promptly cooperate will not be required to enter into CIAs or CCAs was also announced – a direct change from the last letter

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March 24, 2009 Open Letter

- "Narrowed the scope" of the protocol's application to Stark and Anti-Kickback
- Requires a "colorable" violation of AKS – no self-disclosure of Stark only violations
- AKS violations now require a minimum of $50,000 settlement (the statutory maximum penalty for each kickback, not including 3x assessment)
- Reaffirmed inclination to settle matters at "lower end" of damages "continuum"

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Current Status of Protocol

- Useful for substantial violations of law
- Requires relatively quick turnaround (on Provider's side) from initial submission to completed investigation
- Stand-alone Stark violations not covered
- Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
- Continuing focus on compliance programs, good faith cooperation, and prompt disclosure

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Patient Protection and Affordable Care Act- CMS Disclosures

- Creation of CMS Self-Referral Disclosure Protocol (Section 6409)
  - Requires CMS to establish a self-disclosure protocol within 6 months to enable providers to disclose actual and potential Stark law violations.
  - Authorizes CMS to compromise for amounts less than the overpayment for the prohibited claims
  - Factors for consideration
    - Nature and extent of the improper or illegal practice
    - Timeliness of disclosure
    - Cooperation in providing additional information
    - Such other factors as Secretary considers appropriate

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Disclosure to Contractors

- Disclosure to contractors (such as intermediaries or carriers) is only appropriate where the provider does not believe the overpayment is the result of fraud
- Each contractor may have their own specific protocols or procedures, but the Medicare manual system provides general guidance

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Recent Self-Disclosure Settlements

- St. John Health System (Tulsa, OK) 12/09
  - $13.2 million settlement for Stark technical violations
  - Violations involving 23 physicians found in internal audit were self-disclosed
  - Discount, if any, on Stark overpayment is unclear

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Recent Self-Disclosure Settlements

- Condell Medical Center (Liberty, IL) 12/08
  - $36 million Stark/Anti-Kickback settlement
  - Alleged below-market leases, forgiveness of loans, undocumented service agreements
  - Self-disclosure of violations found in the course of a due diligence in the course of a sale transaction
  - Discount?

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The Patient Protection and Affordable Care Act

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PPACA Provisions Affecting Stark

- Overpayments et al.
- Stark self-disclosure authority
- Stark in office ancillary disclosure requirement
- Restrictions on physician investments in hospitals

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PPACA Provisions Affecting AKS

- Rejection of Hanlester Specific Intent
- Provision that makes AKS tainted claims "false claims"

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Other PPACA Provisions Affecting Stark & AKS

- Gainsharing and other payment reforms
- Mandatory compliance programs for almost everyone
- Patient freebies are back!
- Increased Enforcement Agency Funding

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Overpayments

- FERA makes knowing retention of overpayment a false claim
- PPACA put nails in coffin
  - creates clear obligation to refund overpayments
  - creates Stark self-disclosure process
  - require compliance programs for virtually all providers/suppliers except physicians

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Implications

- Huge new FCA exposure for hospitals
- While self-disclosure may help with technical violations, still opens issues of Fair Market Value to challenge
  - Gov't taking increasingly aggressive view on FMV
- Mandatory compliance programs will be discovering more and more of these problems
- Smaller and less sophisticated hospitals will be disproportionately impacted

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Stark Self Disclosure

- requires HHS Secretary to establish self-disclosure protocol for Stark violations
- authorizes CMS to compromise for amounts less than the prohibited claims

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Stark Self Disclosure

- Factors for consideration
  - Nature and extent of the improper or illegal practice
  - Timeliness of disclosure
  - Cooperation in providing additional information
  - Such other factors as Secretary considers appropriate

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IOAS Disclosure

- Amendment to In-Office Ancillary Services Exception (Section 6003)
  - Referring physician must inform patient in writing that the patient may obtain the service from a person other than the referring physician or the physician's group practice.
  - Referring physician must provide list of suppliers who furnish such services in the area where the patient resides
  - Applies to: MRI, CT, PET and any other DHS the Secretary determines appropriate
  - Applies to services furnished on or after January 1, 2010

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Amendments to Rural Provider and Whole-Hospital Ownership Exceptions

- To qualify for the exceptions, a physician-owned hospital must have physician ownership or investment *and* effective Medicare provider agreement as of August 1, 2010
  - Reconciliation Bill, H.R. 4870, may extend to December 31, 2010
- Subject to a very limited exception process, hospitals cannot expand the number of operating rooms, procedure rooms, or licensed beds in place as of date of enactment.
- The aggregate percentage of the total value of ownership in the hospital, or an entity whose assets include the hospital, held by physician owners and investors cannot increase post-enactment
- Hospitals must meet other specified requirements regarding conflicts of interest, bona fide investments and patient safety issues

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Gainsharing and Payment Reforms

- PPACA extends gainsharing demonstration and push pilot programs for bundled payments, Post Acute Care (PAC) payments, Accountable Care Organizations (formerly known as PHOs)
- Need/encouragement of hospital & physician integration and coordination is fundamentally at odds with 30 years of anti-kickback and Stark

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Payment Pilot and Demos

- Post Acute Care Payment Reform
- Accountable Care Organization Pilot
- Medical Home Pilot
- Gainsharing Demonstration extension
- Preventable Hospital Readmissions
- Global Payment Demo
- Payment Bundling Pilot Program
- Hospital & SNF based Value Purchasing program
- Medicare Shared Savings Program

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Mandatory Compliance Programs for Almost Everyone

- PPACA requires mandatory compliance programs for everyone but physicians
- Special provision for SNFs and NFs, include quality improvement
- CMS can add providers to requirement

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Patient Freebies Are Back

- PPACA authorizes OIG to create exceptions to the beneficiary inducement CMP, including
  - Retail stores' loyalty programs
  - Copays for first fill of a generic drug
  - Items connected to a patient's medical care if there is financial need
  - Remuneration which promotes access to care and poses a low risk of harm to patients or federal programs

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Increased Enforcement $$

- PPACA provide additional $125 million to Health Care Fraud and Abuse Control Program over 10 years (approximately 4% increase)
- Increased access by DOJ and OIG to CMS databases
- RAC expansion

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QUESTIONS?

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