

Stark, Anti-kickback and Foreign Corrupt Practices Act Compliance

HCCA Board & Audit Committee Compliance Conference
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Overview

- ▶ The Foreign Corrupt Practices Act
- ▶ The Anti-kickback Statute
- ▶ The Stark Law and Regulations
- ▶ The OIG Perspective

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The Foreign Corrupt Practices Act

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U.S. FCPA Anti-Bribery Prohibition

- ▶ Any act in furtherance of
 - ▶ A payment, offer, promise or authorization of ...
 - ▶ Money or anything of value
 - ▶ To a “foreign public official,” political party, party official, or candidate
 - ▶ To promote an action in order to obtain an improper advantage (*quid pro quo*)
 - ▶ In order to assist in obtaining or retaining business

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FCPA Penalties and Consequences

- ▶ Individuals -up to 5yrs Prison/\$100,000 per violation
- ▶ Entities—criminal fines up to \$2 million per violation
- ▶ SEC Penalties Record Keeping Penalties: Entities --\$2.5 million per violation; Individuals \$1 million per violation/ 10yrs in prison
- ▶ Can be barred from federal contracts

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The Foreign Corruption Practices Act

- ▶ Board Members Have an Oversight Role
 - ▶ Top Level Commitment: Compliance Tone at the Top
 - ▶ Risk Assessment: Entities must objectively assess bribery risk exposure
 - ▶ Implement measures proportionate to the complexity of the entity's business activities.
 - ▶ Entity must show that its anti-bribery measures are clear, effectively implemented and enforced

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United Kingdom Anti-Bribery Act

- ▶ Creates Individual and Corporate Criminal Offenses
 - ▶ Failure of Commercial Organization to Prevent Bribery
 - ▶ Failure to Supervise
 - ▶ Strict Liability if any associated person gives bribe to obtain or retain an advantage in the conduct of business
 - ▶ Prohibits commercial bribery and bribery of government official
 - ▶ Convict of commercial organization faces an unlimited fines

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The Foreign Corruption Practices Act

- ▶ Board of directors and Top Management must demonstrate that:
 - ▶ A commitment to prevent bribery by persons associated with the entity
 - ▶ They foster a culture within the entity that all forms of bribery is never acceptable or condoned.
 - ▶ The entity communicate its commitment to zero tolerance to internal and external stakeholders.

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The Foreign Corrupt Practices Act

- ▶ Third Party Due Diligence:
 - ▶ Entities must be concerned about how their agents undertake any form of work on their behalf.
 - ▶ Entities must establish firm due diligence procedures that document real knowledge of their agents and third parties activities
 - ▶ Good Governance requires effective communication and continuous monitoring of this risk

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The Anti-Kickback Statute

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Federal Anti-Kickback Statute (“AKS”)

- ▶ AKS makes it illegal to offer or pay remuneration with the intent to induce referrals of government program business
- ▶ Prohibited Conduct
 - ▶ Knowing & willful
 - ▶ Solicitation or receipt *or*
 - ▶ Offer or payment
 - ▶ Of remuneration
 - ▶ In return for referring a Federal Health 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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AKS Safe Harbors

What are the AKS Safe Harbors and why do they matter?

- ▶ Statutory and regulatory “safe harbors” immunize from criminal and civil prosecution of certain payment and business practices implicated by the AKS
- ▶ Compliance voluntary, but all elements of safe harbor must be met to be protected
 - ▶ Specific safe harbor requirements apply to different types of arrangements
- ▶ Arrangements outside of safe harbor subject to examination of facts and circumstances
 - ▶ If improper intent, law is violated
 - ▶ If no improper intent, no violation

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Anti-kickback Statute

What is “Fair Market Value” and why does it matter?

- ▶ “FMV must reflect an arm’s-length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral between them.”
 - ▶ 1994 Special Fraud Alert
- ▶ Most AKS safe harbor regulations require FMV
- ▶ The government presumes that compensation outside of FMV is in exchange for referrals
- ▶ Some courts have held that a FMV payment is not “remuneration”

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AKS Penalties

- ▶ Violation is a felony
 - ▶ Criminal fines/imprisonment
 - ▶ Non-prosecution Agreements/DOJ Monitorships
- ▶ Government also enforces through civil FCA and administrative proceedings
 - ▶ Can result in monetary damages and penalties
 - ▶ Civil FCA - mandatory **treble damages** plus **per claim penalties** of \$11,665 to \$23,331 based on revenues received on claims resulting from the kickback
 - ▶ Administrative penalties -- \$50,000 per violation plus up to 3X amount of remuneration
 - ▶ Corporate Integrity Agreements

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The Stark Law and Regulations

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Stark Rule: Plain Language



If a ***Physician*** (or immediate family member) has a direct or indirect ***Financial Relationship*** with an ***Entity***, unless the ***Financial Relationship*** meets the requirements of an ***Exception***:

- the ***Physician*** may not ***Refer*** any ***Designated Health Services (“DHS”)*** to the ***Entity***,
- the ***Entity*** may not bill for any ***DHS Referred*** by the ***Physician***,
- no Medicare payments may be made for ***DHS Referred*** by the ***Physician***, and
- the ***Entity*** must refund all moneys collected for ***DHS Referred*** by the ***Physician*** (unless no actual knowledge or reckless disregard re: the ***Physician’s*** identity).

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Example: Rental of Office Space Exception

- ▶ Agreement in writing, signed by the parties, specifies the premises
- ▶ Term of at least one year
- ▶ Amount of space is reasonable and necessary for legitimate business purposes of lessee
- ▶ Space is used exclusively by lessee (except pro-rata share of common areas)
- ▶ Rent is set in advance and consistent with fair market value
- ▶ Rent is not determined in a manner that takes into account volume or value of referrals
- ▶ Arrangement is commercially reasonable even if there are no referrals
- ▶ Indefinite holdover as long as all other requirements of the exception are satisfied



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Stark Law and Regulations Overview

- ▶ Unlike the Anti-Kickback Statute (violations require proof of improper intent) Stark is strict-liability
- ▶ Managing to keep things within exceptions is a team sport
- ▶ Claims filed as a result of tainted referrals also implicate the False Claims Act (3x damages + per claim penalty)
- ▶ Stark is largely enforced when DOJ intervenes in a *qui tam* filed pursuant to the False Claims Act by an insider
- ▶ Timely self-disclosure to CMS or OIG (if there are also possible AKS implications) can significantly mitigate exposure resulting from non-compliance

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Stark/AKS: Questions Board Members Should Ask

- ▶ Who has/shares responsibility for managing arrangements that cause AKS or Stark risk?
- ▶ How are Referral Source Arrangements managed?
 - ▶ What process for identifying and assuring proper management?
 - ▶ What is the review and approval process? (legal review, FMV, business rationale)
 - ▶ What process for assuring that performance and payments adhere to contract terms?
- ▶ How are responsible personnel trained on risks and responsibilities?
- ▶ How and when are processes audited/monitored to confirm adherence to requirements?

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Stark/AKS Good Governance

- ▶ Where Governance Fails: High Risk Areas
 - ▶ Failure to ensure an effective review and approval process for new and renewing referral source arrangements
 - ▶ Failure to ensure an effective process to Audit and Monitor compliance with contract terms
 - ▶ Disregarding advice of counsel/Forum Shopping for legal advice
 - ▶ Considering ROI of referral source relationships in Business Planning documents
 - ▶ Consideration of downstream referrals in physician practice acquisitions
 - ▶ Entering into arrangements with referral sources in the face of documented evidence of intent to induce referrals

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Stark/AKS - What Can Go Wrong?

- ▶ Forest Park - seven guilty verdicts at trial for hospital kickbacks to referring physicians for non-government patients
- ▶ Tuomey Healthcare -- \$237M civil FCA verdict for Stark Law violations on part-time physician employment agreements (settled for \$72.4M)
- ▶ Blue Wave - civil FCA verdict of \$114 M against three executives for paying physicians for sham lab “process and handling fees”
- ▶ Multiple pharmaceutical companies in past two years paying more than \$850M in the aggregate for kickbacks to patients through “foundations” to cover co-pays
- ▶ Tenet -- \$513M criminal and civil FCA settlement for payments to indigent care OB clinic
- ▶ William Beaumont Hospital -- \$84.5M settlement for above FMV physician compensation and below FMV rent
- ▶ Vitas Health -- \$200K civil FCA settlement for kickbacks in the form of contributions to cancer charity established by referring physician in exchange for hospice referrals; referring physician pled guilty and sentenced to 45 years

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The OIG Perspective

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Corporate Integrity Agreements

- ▶ OIG enters into CIAs in connection with health care fraud settlements
 - ▶ False Claims Act (FCA)
 - ▶ Civil Monetary Penalties Law (CMPL)

- ▶ CIA in exchange for OIG exclusion release

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CIA Requirements

- ▶ Compliance Officer
- ▶ Compliance Committee
- ▶ Management and Board Obligations
- ▶ Written Standards
- ▶ Training and Education
- ▶ Review Procedures
 - ▶ Claims Review
 - ▶ Arrangements Review
- ▶ Risk Assessment
- ▶ Disclosure Program

- ▶ Ineligible Persons
- ▶ Notification of Government Investigations
- ▶ Overpayments
- ▶ Reportable Events
- ▶ Implementation Report/Annual Reports
- ▶ Breach and Default
 - ▶ Stipulated Penalties
 - ▶ Material Breach

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CIA - Arrangements and Focus Arrangements

- ▶ **“Arrangements”** :
 - ▶ ... actual *or potential* source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value
 - ▶ ...every financial relationship that implicates Stark Law

- ▶ **“Focus Arrangements”** ...every Arrangement:
 - ▶ ...with *actual* source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value
 - ▶ ...that implicates Stark Law

- ▶ “Focus Arrangements” carve outs

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CIA - Arrangements

- ▶ Train individuals involved with development, approval, management, or review of Arrangements (and those who handle Focus Arrangements)

- ▶ Risk assessment should assess and address risk associated with Arrangements (and Focus Arrangements)
 - ▶ identify and prioritize risks
 - ▶ develop internal audit work plans related to the identified risks
 - ▶ implement internal audit work plans
 - ▶ develop corrective action plans in response to internal audits results
 - ▶ track the implementation of the corrective action plans to assess effectiveness

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CIA - Focus Arrangements

Requirements include, for example...

- ▶ Create central tracking system
- ▶ Document names and position of those involved with negotiation, review, and approval
- ▶ Track remuneration
- ▶ Document fair market value and those involved with fair market value determination
- ▶ Track services and monitor leases
- ▶ Written review and approval process with legal review; specifying and documenting business need or rationale, and determining fair market value

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CIA - IRO Review

- ▶ Systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements (and Focus Arrangements)
- ▶ Review of (actual) Focus Arrangements to verify certain information

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Board Compliance Obligations

- Review and Oversight
- Submit Description of Materials Reviewed
- Training
- Compliance Expert
- Resolution

“The Board of Directors has made a reasonable inquiry into the operations of [the] Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, ... has implemented an effective Compliance Program to meet Federal health care program requirements and the requirements of this CIA.”

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Management Certification

- ▶ “I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [the] policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of ... is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

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CIA Enforcement

CIA enforcement actions posted on OIG's website

- ▶ Stipulated Penalties
- ▶ Material Breach

<https://oig.hhs.gov/fraud/enforcement/ciae/index.asp>

CMPL settlements of Reportable Event disclosures

- ▶ Employment of excluded individuals
- ▶ Kickbacks and self-referral violations
- ▶ Improper billing

<https://oig.hhs.gov/fraud/enforcement/cmp/reportable-events.asp>

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Reporting Conduct

▶ OIG Self Disclosure Protocol

- ▶ Benchmark 1.5 multiplier
- ▶ AKS remuneration-based
- ▶ Presumption of no CIA

▶ CMS Stark Self Disclosure Protocol

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OIG Compliance Resources

Resources Available at www.oig.hhs.gov:

- ▶ Safe Harbors (preambles)
- ▶ Compliance Program Guidance
- ▶ Advisory Opinions
- ▶ Special Fraud Alerts and Special Advisory Bulletins

Resources Available at www.oig.hhs.gov - Compliance Resource Portal:

- ▶ Toolkits
- ▶ Provider Compliance Resources and Training
- ▶ Resources for Health Care Boards

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Panel Contact Information

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Appendix

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Anti-kickback Statute Key Concepts

- ▶ Remuneration
 - ▶ Anything of value; Cash or in-kind; Direct or indirect; No “de minimus” exception
- ▶ Referral
 - ▶ Referring; Admitting; Ordering; Purchasing; Recommending; Arranging for
- ▶ Induce
 - ▶ To attempt to influence the other party’s judgment on referral decisions; no actual agreement or referrals required
- ▶ Knowingly and Willfully
 - ▶ Acting voluntarily with intent to violate the law
- ▶ One Purpose Test
 - ▶ If **any one purpose** of payment is to obtain referrals, government argues arrangement is illegal; legitimate purposes irrelevant

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Stark Definitions

“PHYSICIAN”

- ▶ Doctor of Medicine; Doctor of Osteopathy; Dentist; Dental Surgeon; Doctor of Podiatric Medicine; Doctor of Optometry and Chiropractor.
- ▶ **ALSO: Immediate Family Members** - husband or wife; birth or adoptive parent; child; sibling; step-child, -parent, or -sibling; in-law (mother, father, son, daughter, sister, brother); grandparent or grandchild or the spouse of either.

“FINANCIAL RELATIONSHIP”

- ▶ **Compensation** - any *Remuneration* between a physician (or immediate family member) and an Entity.
- ▶ **Ownership/Investment**
 - ▶ Equity, debt or other means
 - ▶ Stock, options, partnership, bonds, loans, etc.
 - ▶ NOT retirement plan interests
 - ▶ NOT options received as compensation (until exercised)
- ▶ **Indirect Financial Relationship** - An unbroken chain of either compensation or ownership/investment interests (or both) between a Physician and Entity



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Stark Definitions

“ENTITY”

- ▶ **Performs DHS:** The person or organization that performs DHS services billed to Medicare, or
- ▶ **Bills for DHS:** The person or organization that bills for the DHS service to Medicare.

May include a physician's solo practice, a practice of multiple physicians, any other person, sole proprietorship, public or private agency or trust, corporation, partnership, LLC, foundation, not-for profit corporation or unincorporated association.

“REFER”

- ▶ Request (any form—written, oral, electronic, other) by a physician for DHS
- ▶ Ordering of DHS
- ▶ Certifying or re-certifying the need for any DHS
- ▶ DHS ordered by a consulting physician is a referral by the physician who ordered the consult



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Stark Definitions

“Designated Health Services”



1. Clinical Laboratory Services
2. Physical Therapy, Occupational Therapy and Speech-Language Pathology Services
3. Radiology and Certain Other Imaging Services
4. Radiation Therapy Services & Supplies
5. Durable Medical Equipment and Supplies
6. Parenteral and Enteral Nutrients, Equipment and Supplies
7. Prosthetics, Orthotics and Prosthetic Devices and Supplies
8. Home Health Services
9. Outpatient Prescription Drugs
10. Inpatient and Outpatient Hospital Services



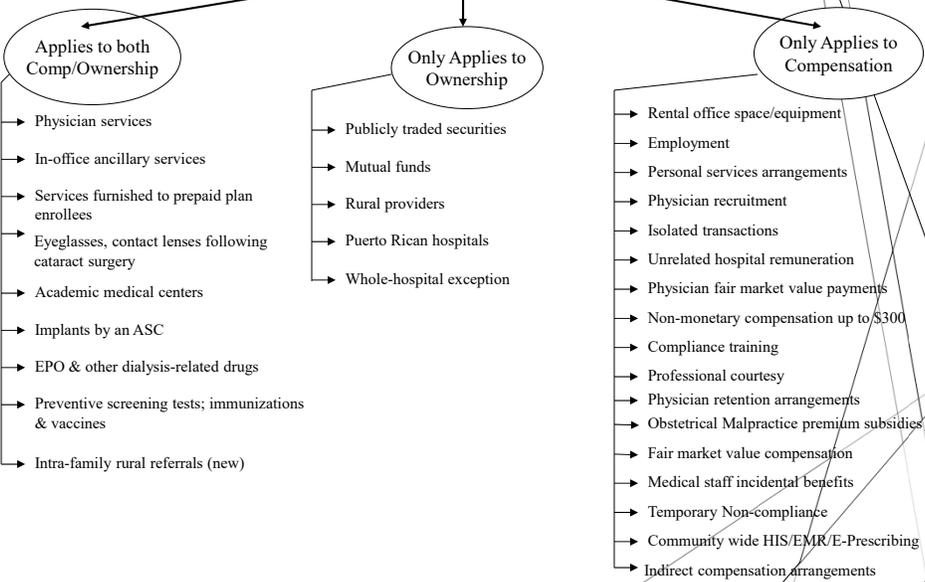
X-Ray



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Key Stark Exceptions



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