

Hidden Treasure or Hidden Kickback? If It Looks too Good to Be True, It Might Be an Anti-Kickback/Stark Violation

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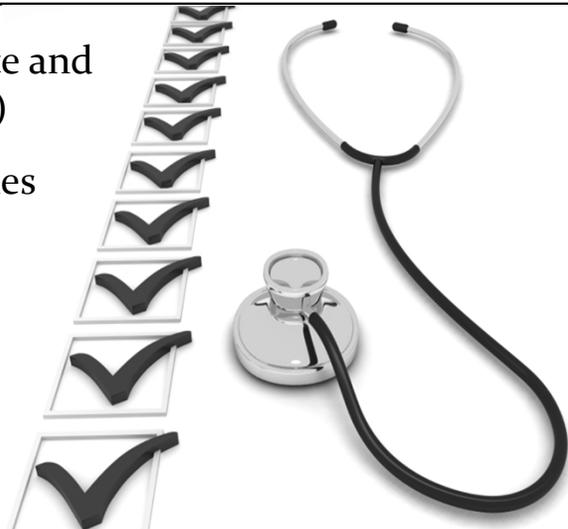
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Agenda

- Overview of anti-kickback statute and physician self-referral law (Stark)
- Common AKS and Stark law issues
- What to do when a problem is identified
- Fraud and abuse waivers
- New developments



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Anti-kickback Statute Overview



Prohibits providing or receiving anything of value to induce or reward referrals of Federal health care program business

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Statutory Elements 42 U.S.C. 1320a-7b(b)

Anti-kickback Statute prohibits:

- Knowingly and willfully
- Directly or indirectly offering, paying, soliciting, or receiving
- Remuneration
- In order to induce or reward the referral or purchase of (or arranging for the purchase of) items or services for which payment may be made by a Federal healthcare program

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Purpose of the Anti-kickback Statute

Prevent improper referrals to avoid:



- Overutilization
- Increased costs
- Corruption of medical decision-making
- Patient steering
- Unfair competition

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Exceptions and Safe Harbors

- Statutory exceptions (Congress) / regulatory safe harbors (OIG)
- Transactions satisfying *all* elements of a safe harbor are protected. Transactions *not* satisfying all elements are not *per se* illegal, but are subject to a facts-and-circumstances analysis

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OIG Guidance

- Advisory Opinions
- Fraud Alerts, Special Advisory Bulletins, Compliance Program Guidance

<https://www.oig.hhs.gov/compliance/index.asp>

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Overview of the Stark Law: General Prohibition

(1) Prohibits a physician from referring a Medicare patient to an entity for any designated health services if the physician (or an immediate family member of the physician) has a financial relationship with the entity, unless an exception applies.

(2) Prohibits the entity receiving the referral from billing Medicare (or any one else) for the designated health services.

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Overview of the Stark Law: Designated Health Services

1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Radiology services, including MRI, CT and ultrasound
5. Radiation therapy services and supplies
6. Durable medical equipment and supplies
7. Parenteral and enteral nutrients, equipment and supplies
8. Home health services
9. Outpatient prescription drugs
10. Inpatient and outpatient hospital services.

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Overview of the Stark Law: Sanctions and Penalties

- Denial of payment for Designated Health Services referred in violation of the Stark Law
- Refund of amounts collected for Designated Health Services rendered pursuant to prohibited referrals
- Monetary penalties of up to \$15,000 per service and assessment of up to twice the amount claimed
- Exclusion from the Medicare and Medicaid programs
- Mandatory Repayment and Disclosure of Known Overpayments Within 60 Days

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Overview of Stark Law: Exceptions

- (1) Categorical or service exceptions (e.g., HMO, ASC, in-office ancillary services)
- (2) Ownership Exceptions (e.g., large companies, rural providers, hospitals)
- (3) Compensation Exceptions
 - (a) indirect
 - (b) direct (e.g., lease, personal services, employment)
 - (c) generally require signed, written agreements

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AKS v. Stark

Anti-kickback Statute 42 USC 1320a-7b(b)	Physician Self-referral Law (Stark) 42 USC 1395nn
Referrals from everyone	Referrals from a physician
Any items or services	Designated health services
Intent required (knowing and willful)	No intent standard for overpayment (strict liability) Intent required for civil monetary penalties for <i>knowing</i> violations
Criminal and civil penalties	Not criminal
Voluntary safe harbors (if not in safe harbor, may still be legal)	Mandatory exceptions (if not excepted, illegal)
OIG advisory opinion process http://www.oig.hhs.gov/compliance/advisory-opinions/index.asp	CMS advisory opinion process https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html

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Case Examples – Hospitals

- Health Quest Systems - July 2018 - \$14.7M
- William Beaumont Hospital - Aug 2018 - \$84.5M
- Kalispell Regional Healthcare System - Sept 2018 - \$24M
- (formerly) Health Management Associates - Sept 2018 - \$260M
- Avanti Hospitals, LLC - January 2019 - \$8.1M

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Case Examples – Drug Companies

Relationships with Patient Assistance Programs

- United Therapeutics - Dec 2017 - \$210M
 - First CIA with specific provisions overseeing relationships with PAPs
- Pfizer - March 2018 - \$23.85M
- Actelion Pharmaceuticals - Dec 2018 - \$360M

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Case Examples – EHR Companies

- eClinicalWorks - May 2017 - \$155M
 - First CIA with specific provisions overseeing software quality
- Greenway Health - Feb 2019 - \$57.25M

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Case Example - Individual Owner

- Ros Lazo, owner of T.L.C. Health Services of Miami (Feb 2019)
 - 87 months in prison; \$8.6M in restitution
 - Kickbacks for referrals of home health services; unlicensed therapy services
- Bipartisan Budget Act of 2018
 - AKS criminal penalties increased:
 - Max prison time from five years to ten years
 - Max fine from \$25,000 fine to \$100,000

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Speaker Fees

- Are services reasonable, necessary and appropriate?
- Fair Market Value v. Commercially Reasonable
- What do these terms mean?

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Lease Arrangements

- Offices and/or equipment
- Calculating fair market rent (beware of variable rent, e.g., “per click” or percentage of revenue!)
- Commercial reasonableness
- Market comparables
- Apples to apples (net v. gross, class A, B, etc.)?
- Subleases?

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Business Deals



- Swapping
- Joint ventures
- Subcontracts
- Joint Marketing

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Freebies

- Routine waivers of copayments
- Gifts to beneficiaries
- Free items and services between referral sources

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Marketing

- Compensation Arrangements
 - Personal services and management safe harbor
 - Employee safe harbor
- Identity of sales agent and relationship with audience
- Nature of the promotional activity
- Item or service being marketed
- Composition of target audience

Advisory Opinions 12-02; 11-17; 99-8, and 98-01



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Physician-Owned Labs

- Stark Law complexity
 - Meeting “Group Practice” Definition
 - Satisfying “In-Office Ancillary Services” Exemption
- Beware of “EKRA” (Eliminating Kickbacks in Recovery Act)

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Eliminating Kickbacks in Recovery Act (“EKRA”)

- EKRA is an “All Payor” anti-kickback law that applies to:
 - Clinical treatment facilities (for drug/alcohol rehabilitation)
 - Recovery homes (for drug/alcohol rehabilitation)
 - Laboratories (all)
- Includes remuneration to induce referrals and “in exchange for an individual using the services of ...”
- Exemptions are different from traditional anti-kickback
- Beware of remuneration to patients who will receive laboratory services!!
- Beware of commission-based marketing

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Identifying AKS/Stark Issues

- Importance of an effective compliance program
 - Training
 - Risk assessments
 - Audits
 - Disclosure programs
 - Arrangements tracking systems



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Problem identified – now what?

- Best practices for addressing Stark violations:
 - SRDP for self-disclosure
 - Alternatives (OIG, AUSA, MAC)
- What to Expect?
 - Confess your sins!
 - Timing issues
 - Range of settlements
 - Negotiations?

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OIG Self-Disclosure



- Cooperative Process
- Likely a smaller settlement amount
- Usually no integrity obligations

<https://www.oig.hhs.gov/compliance/self-disclosure-info/index.asp>

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Fraud and Abuse Waivers

- Innovation Center Models: Section 1115A(d)(1) of the Social Security Act
- Medicare Shared Savings Program: Section 1899(f) of the Social Security Act
- “As necessary” standard

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>

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What is a Fraud and Abuse Waiver?

- Makes certain laws inapplicable; affirmative defense
 - AKS, Stark, Beneficiary Inducement CMP
- Responsive to what the model is trying to test
- Arrangements must satisfy specific conditions
- Not a get out of jail free card

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Different Types of Waivers

- ACOs
- Bundled Payments
- Beneficiary Inducements
- Some waivers are broad and some are narrow
 - Designed to allow the model to be tested as intended by the Innovation Center
 - Designed to allow the program to be tested as intended by the Shared Savings Program

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ACO Waivers

- Broadest waivers
- Pre-Participation and Participation Waivers
- Governing Body
- “Reasonably related” to the purposes of the model or program

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Bundled Payment Waivers

- Protect particular streams of remuneration; typically payment distributions
- Rely on defined terms in participation agreement
- Remuneration paid pursuant to the model should not be tied to business generated outside of the model
- No governing body

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Beneficiary Inducement Waivers

- Preventive care items or services or advance one or more clinical goals
- Item or service is not tied to the receipt of items or services reimbursable by Federal health care programs outside of the model
- Who can furnish the item or service

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New Developments

- Regulatory Sprint
- Proposed rule 84 Fed. Reg. 2340 (Feb. 6, 2019)
 - Discount safe harbor amendment
 - New safe harbors protecting:
 - Point-of-sale price reductions on prescription drugs
 - Certain PBM service fees

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Conclusion

Questions

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