

Session P5: Kickback and Stark Developments

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Panel

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Federal Anti-Kickback Statute (AKS) 42 USC § 1320a-7b(b)(1) and (2)

- Makes it a crime to **knowingly and willfully [offer or pay] or [solicit or receive] any remuneration** to induce a person --
 - (A) to refer an individual to a person for the furnishing of any item or service covered under a Federal health care program; or
 - (B) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a Federal health care program.

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Remuneration Defined Broadly

- **“Any remuneration”** includes --
 - any kickback, bribe, or rebate
 - directly or indirectly
 - overtly or covertly
 - in cash or in kind
 - ownership interest or compensation interest

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Examples of Illegal Remuneration

- 40% of the Medicare payment for cardiac monitoring paid to referring physician (*Greber*)
- \$1,000 per month from hospital to physician for unspecified marketing duties (*Jain*)
- alcoholic beverages received by nursing home administrator from drug supplier (*Perlstein*)
- free clerical entry and billings services (*Medtronic*)

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Covered Under a Federal Health Care Program

- Federal AKS does not apply to private payors, although some state statutes do cover all payors
- Distinguish federal payment methodologies:
 - Traditional fee-for-service (Medicare Parts A and B): each referral generates another federal payment
 - Managed care (Medicare Part D): deprivation of medically necessary services

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Civil False Claims Based on AKS Violations

- PPACA clarified law so claims resulting from AKS violations are false claims under FCA
- Compliance with AKS is *per se* material
- Continued payment of claims does not necessarily undermine a materiality finding

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Key AKS Statutory Exceptions and Regulatory Safe Harbors

- Employment exception
 - No FMV requirement
- Discounts
 - Statutory exception requires disclosure of price reduction (seller has no control)
 - Regulatory safe harbor prohibits bundling, discrimination against Medicare and waivers of co-pays or deductibles

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Federal Physician Self-Referral (Stark) 42 USC § 1395nn

- If a **physician** (or an immediate family member of such physician) has a **financial relationship with an entity**, then—
 - (A) **the physician may not make a referral to the entity** for the furnishing of **designated health services covered under a Federal health program**, and
 - (B) **the entity may not present a claim** or bill to any individual, third party payor, or other entity for **designated health services** furnished pursuant to a prohibited referral.
- Intent to induce referrals is irrelevant

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Financial Relationship With an Entity

- Ownership or investment interest in the entity, including:
 - equity
 - debt
 - indirect ownership through controlling entities
- Compensation arrangement involving any remuneration between a physician (or an immediate family member of such physician) and the entity

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Designated Health Services (DHS)

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- **Inpatient and outpatient hospital services**
- Outpatient speech-language pathology services

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Civil False Claims Based on Stark Violations

- Government may recover single damages based on equitable claims premised on Stark violations under mistake of fact and unjust enrichment
- No private right of action for Stark violations
- Whistleblowers can bring FCA actions based on Stark violations because compliance with Stark is material to payment decisions

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Key Stark Statutory and Regulatory Exceptions

- Employment exception
 - Consistent with FMV
 - Cannot take into account volume or value of referrals
 - Commercially reasonable in the absence of referrals
- In-Office Ancillary Services (IOAS)
 - Allows sharing of DHS with physician group practice

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Enforcement Trends and Other Recent Developments in Kickback and Stark Law: Charitable Contributions

- a. Lundbeck - \$52.6 million settlement – June 6, 2018
- b. Pfizer - \$23.85 million settlement – May 25, 2018
- c. Jazz Pharmaceuticals – \$57 million settlement – May 8, 2018
- d. United Therapeutics - \$210 million settlement – Dec. 20, 2017
- e. Medco Health Solutions – Defense MSJ upheld on appeal – Jan. 19, 2018

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HMA \$260 Million Settlement

- Emergency department patient admissions without regard to whether the admissions were medically necessary
- Inpatient admissions instead of less costly outpatient or observation setting
- Physician inducements including free office space, staff and equipment, as well as direct payments up to \$40,000 per month
- Excessive physician compensation in return for two businesses owned by the physician group and for services allegedly performed by the group

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Beaumont Hospital \$84.5 Million Settlement

- Physician compensation in excess of FMV
 - Cardiologists making \$750,000+ in 2009
- Free or below FMV office space and employees

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HDL Bankruptcy and Related Litigation

- a. HDL Kickback Settlement – \$485 Million (Apr. 9, 2015)
- b. HDL Bankruptcy (filed June 9, 2015)
- c. HDL Bankruptcy Trustee Sues Doctors and Non-Profits to Recover Kickbacks (June 12, 2017)

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(Stark) Self-Referral Disclosure Protocol (SRDP)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-1106

CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL: CHECKLIST

Checklist of required items for a complete submission:

- SRDP Disclosure Form
- Physician Information Form(s) (one for each physician included in the disclosure who made referrals in violation of section 1877 of the Act)
- Financial Analysis Worksheet, submitted in Microsoft Excel-compatible format
- Certification

The disclosing party may also submit an optional cover letter. All the items listed above (and the optional cover letter, if included) must be submitted electronically to 1877SRDP@cms.hhs.gov. In addition, a hard copy of the certification **only** must be mailed to Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21244-1850.

Obligation to update: Disclosing parties are reminded of the obligation to update the disclosure if the disclosing party files for bankruptcy, undergoes a change of ownership, or changes its designated representative. The update must be submitted electronically to 1877SRDP@cms.hhs.gov within 30 days of the change. Include the word "UPDATE" in the subject line of the e-mail.

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf> (last viewed Oct. 5, 2018)

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Stark Law Self-Disclosure Protocol

- Used for “Stark only” self-disclosure
- Tolls the 60-day repayment obligation, but doesn’t require or permit payment with the self-disclosure!
- Requires detailed submission, including:
 - facts and circumstances of violation
 - legal analysis of why it doesn’t comply
 - calculations of financial damage
 - New: Formula for calculating pervasiveness of non-compliance
- New: Requires certification of non-compliance
- What types of compromise might be available?

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Tips on SRDP

- What is the settlement timeline?
- What is the settlement process?
 - Offer amount
 - Negotiable?
 - Timing?
 - Financial Distress?

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Alternatives to Stark SRDP

- Report and Repay (in full) to Medicare Administrative Contractor (MAC)
- Use OIG Self-Disclosure (if colorable AKS violation)
- AUSA/DOJ (for FCA liability)

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Practical Tips for Navigating Kickback and Stark Law Compliance

1. Physician Compensation and Practice Acquisitions
 - a. Use kickback employment exception if possible
 - b. Relative Value Unit (RVU) based compensation models:
 - Limit to work RVUs (wRVUs) – exclude practice expense and malpractice components
 - wRVU rate should not increase with productivity – may exceed FMV
 - wRVUs should be limited to the physician's personally performed services
 - c. Physician group practices - Follow all 8 requirements for Stark-compliant physician group practices
 - d. Get valuations to support FMV for medical directorships and call coverage

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Practical Tips for Navigating Kickback and Stark Law Compliance

2. Distinguishing Between FMV and Commercial Reasonableness (CR)

- a. FMV - The value in arm's length transactions, consistent with the **general market value**
- b. General Market Value -
 - Bona fide bargaining between well-informed buyers and sellers
 - Not in a position to general business for the other party
 - Not determined in a manner that takes into account the volume or value of anticipated or actual referrals
- c. CR – Arrangement would make commercial sense if entered into by a reasonable entity of similar scope and size and a reasonable physician of similar scope and specialty, **even if there were not potential DHS referrals.**
- d. Practice loss theory – FMV and CR?

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Practical Tips for Navigating Kickback and Stark Law Compliance

3. Considerations for Compliance Officers

- a. What new risk areas may impact your organization given recent case law and regulatory developments in kickback and Stark?
- b. Would any new kickback or Stark developments warrant an internal investigation in your organization?
- c. How would the organization calculate the amount of any overpayments received in non-compliant kickback or Stark arrangements?

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Practical Tips for Navigating Kickback and Stark Law Compliance

3. Considerations for Compliance Officers
 - d. Should the compliance officer recommend new policies or modifications to existing policies for kickback and Stark compliance?

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Questions???

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Thank you!