

**Session P5:  
Kickback and Stark Developments**

HCCA Healthcare Enforcement Compliance Conference  
Nov. 4, 2018, 10:45 am to 12:15 p.m.  
Washington, DC

---

---

---

---

---

---

---

**Panel**

Marlan B. Wilbanks  
Senior Partner, Wilbanks & Gouinlock, LLP  
Atlanta, GA  
mbw@wilbanksgouinlock.com

Charles B. Oppenheim  
Partner, Hooper Lundy Bookman, PC  
Los Angeles, CA  
coppenheim@HEALTH-LAW.COM

Scott C. Withrow  
Partner, Withrow, McQuade & Olsen, LLP  
Atlanta, GA  
swithrow@wmolaw.com

2

---

---

---

---

---

---

---

**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.

3

---

---

---

---

---

---

---

## 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

4

---

---

---

---

---

---

---

---

## 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*)

5

---

---

---

---

---

---

---

---

## 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

6

---

---

---

---

---

---

---

---

### 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

7

---

---

---

---

---

---

---

### 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

8

---

---

---

---

---

---

---

### 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

9

---

---

---

---

---

---

---

## 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

10

---

---

---

---

---

---

---

---

## 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

11

---

---

---

---

---

---

---

---

## 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

12

---

---

---

---

---

---

---

---

**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

13

---

---

---

---

---

---

---

---

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

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

14

---

---

---

---

---

---

---

---

**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

15

---

---

---

---

---

---

---

---

## 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

16

---

---

---

---

---

---

---

---

## 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)

17

---

---

---

---

---

---

---

---

## (Stark) Self-Referral Disclosure Protocol (SRDP)

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

Form Approved  
OMB No. 0938-1186

**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](mailto: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](mailto: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/FraudandAbuse/PhysicianSelfReferral/Download/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf> (last viewed Oct. 5, 2018)

18

---

---

---

---

---

---

---

---

### **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?

19

---

---

---

---

---

---

---

---

### **Tips on SRDP**

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

20

---

---

---

---

---

---

---

---

### **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)

21

---

---

---

---

---

---

---

---

## 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

22

---

---

---

---

---

---

---

---

## 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?

23

---

---

---

---

---

---

---

---

## 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?

24

---

---

---

---

---

---

---

---

**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?

25

---

---

---

---

---

---

---

---

Questions???

26

---

---

---

---

---

---

---

---

Thank you!

27

---

---

---

---

---

---

---

---