



# Stark Law Challenges to Exclusive Physician Contracts: Making Sense of a Changing Legal Landscape

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## Today's Presenters



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## Agenda

- Background *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.* (3rd Cir.; January 21, 2009)
- Legal Framework – Understanding Stark
- Interpreting the Third Circuit Decision
- What Should Providers be Doing?



## Background

- *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*
  - January 21, 2009 decision from 3<sup>rd</sup> Circuit Court of Appeals (Del, PA and NJ)
  - *Qui Tam* case; Government declined to intervene
  - D.Ct. granted hospital's motion to dismiss.
  - 3<sup>rd</sup> Cir. reversed and remanded for further proceedings



## Background (cont'd)

- Blue Mountain Anesthesia Associates/Carlisle Hospital.
- 1992 exclusive contract for “anesthesia and pain management”
- 1998 opening of provider-based pain management clinic – no contract amendment
- No money appears to have changed hands



## Background (cont'd)

- Court dealt with 2 questions:
  - Does exclusive service agreement with anesthesia group trigger Stark and Anti-Kickback Statute?
  - If so, are exceptions met?
  
- 3rd Circuit held that Stark was *triggered* and *no exception met*



## Fundamentals of the Relevant Stark Law Issues

- History of Stark
  - Stark I - January 1, 1992
  
  - Stark II - January 1, 1995
    - Phase I - January 4, 2002
    - Phase II - July 26, 2004
    - Phase III - December 4, 2007



## Fundamentals of the Relevant Stark Law Issues (cont'd)

### ■ Overview

- Physician Self-Referral Prohibition, commonly referred to as the “Stark Law”
- Part of Social Security Act (42 USC § 1395nn)
- Prohibits physicians from ordering designated health services (DHS) for Medicare patients from entities with which a physician (or an immediate family member of the physician) has a financial relationship
- “Physician” includes M.D., D.O., D.D.S., D.P.M., chiropractor
- Prohibits entities receiving a prohibited referral from billing Medicare for those services



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- Penalties for violations include:
  - Denial of payments for prohibited referrals and required refunds of amounts collected in violation of statute
  - Civil monetary penalties up to \$15,000 for each improper claim
  - Civil monetary penalties up to \$100,000 for each circumvention scheme
  - Exclusion from Medicare/Medicaid participation
- Intent is irrelevant
- Covers only relationships with physician
- Exceptions are required (if you have a financial relationship with a physician referring “DHS”)



## Fundamentals of the Relevant Stark Law Issues (cont'd)

### ■ Basic Concept:

- Create bright lines to prevent physician conflict of interest
- Civil statute that applies **regardless of intent** – if there is a financial relationship that does not meet an exception, then referrals are prohibited
- A **financial relationship** means (i) an ownership or investment interest, or (ii) a “compensation arrangement” between the referring physician and the provider
  - A compensation arrangement means any arrangement involving any remuneration, direct or indirect, between the referring physician and the provider. “Remuneration” means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind
  - An ownership or investment interest includes any kind of equity or debt arrangement



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- A “**Referral**” is defined more broadly than merely recommending a provider of designated Health Services to a patient; instead, it is defined as “the request by a physician for the item or service” or the “establishment of a plan of care by a physician which includes the provision of the designated health service”
- Designated health services:
  - Clinical laboratory services
  - Physical therapy services
  - Occupational therapy services
  - Radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services (also nuclear medicine)
  - 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



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- **General exceptions from the scope of the Stark Law:**
  - Physician services
  - In-office ancillary services
  - Pre-paid plans
  
- **Exceptions relating only to ownership or investment interests:**
  - Publicly traded companies
  - Mutual funds
  - Whole hospital
  - Rural provider



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- **Exceptions relating only to compensation arrangements:**
  - Rental of office space/equipment
  - Employment
  - Personal services
  - Physician recruitment
  - Isolated transactions
  - Remuneration from a hospital unrelated to DHS
  - Fair market payments by a physician
  - Charitable donation by a physician
  - Non-monetary compensation up to \$300
  - Fair market value compensation
  - Medical staff incidental benefits
  - Risk sharing arrangements
  - Indirect compensation arrangement
  - Referral services
  - Obstetrical malpractice
  - Professional courtesy
  - Physician recruitment
  - Community-wide health information systems
  - Electronic prescribing
  - Electronic health records



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- **Common Compensation Arrangement Exceptions (42 C.F.R. § 411.357):**
  - Rentals Agreements (Office Space or Equipment), and
  - Personal Services Arrangements
    - Written agreement, term of at least one year, signed by the parties
    - Space/Equipment leased or services contracted for do not exceed what is reasonable and necessary for legitimate business purposes
    - Rent or Compensation must:
      - be “commercially reasonable”
      - be “set in advance”
      - not vary with the value or volume of referrals, or other business generated between the parties



## Fundamentals of the Relevant Stark Law Issues (cont'd)

- **Basic Stark Analysis:**
  - Is there a physician or immediate family member involved?
  - Is there a direct or indirect financial relationship?
  - Is there a referral for a designated health service?
  - Is there a statutory/regulatory exception?



## Understanding What the Court is Saying?

### ■ Analytical Issues

- Group's provision of anesthesiology and pain management need to be analyzed separately



## Understanding What the Court is Saying? (cont'd)

### ■ Exclusive Anesthesiology Arrangement

- Court implies that granting group an exclusive is remuneration that should be factor into the economic arrangement
- Court cites OIG Supplemental Compliance Guidance for Hospitals regarding HBP contracts
- Appears to misunderstand the Guidance, since OIG says that charging HBPs for the right to an exclusive (e.g., forcing them to overpay for services like transcription) would be a reverse kickback



## Understanding What the Court is Saying? (cont'd)

### ■ Exclusive Anesthesiology Arrangement (cont.)

- If the right to use hospital space, equipment and personnel is remuneration, does that mean hospitals should charge surgeons for the “privilege” of working in their ORs?
- Clearly absurd, but court’s reasoning threatens to go down this path
- Court seems to lack understanding of how hospitals typically operate



## Understanding What the Court is Saying? (cont'd)

### ■ Pain Management

- Court rejects argument that Medicare facility fee is already reimbursing hospital for space, equipment and personnel
- But isn’t this true?
- Different analysis may arise with commercial payors paying a global fee



## What Should Providers do (Both in the 3<sup>rd</sup> Cir and Outside)?

- **What should hospitals be doing in response to decision? Particularly hospitals in the 3<sup>rd</sup> Cir. (NJ, MD and PA?)**
  - Ignore it? It's the only published case law
  - Getting appraisals for each HBP arrangement?
  - Internal evaluation on benefits each party receives and that it is equivalent?
  - If so, how should the appraiser be advised with regard to applying the court's holdings?
  
- **Are provider-based clinics particularly at risk?**
  - Be careful if a space within provider-based clinic is used as a physician office and not licensed and owned as part of hospital



## What Should Providers do (Both in the 3<sup>rd</sup> Cir and Outside)? (cont'd)

- Case stresses the critical importance of maintaining current written agreements for all physician relationships
  - If the parties weren't operating under a previous, expired agreement, this case may never have come to life



# Questions and Answers



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