

# **NATIONAL HEALTH POLICY** **FORUM**

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**December 14, 2007**

# OVERVIEW

- **Background**
- **Stark in a Nutshell**
- **General Considerations**

# **BACKGROUND**

## **“Referral” Statutes**

- Federal Anti-kickback Statute (42 U.S.C. 1320a-7b(b))**
- Physician Self-Referral Law (“Stark” law) (42 U.S.C. 1395nn)**
- Beneficiary Inducements CMP (42 U.S.C. 1320a-7a(a)(5))**
- State Statutes**

# **BACKGROUND**

## **CORE CONCERNS**

- Overutilization**
- Increased Program Costs**
- Steering/Corruption of Medical Decision-making**
- Unfair Competition**
- Systemic Corruption**

# **OIG REPORT ON GROWTH IN**

## **ADVANCED IMAGING**

**(OEI-01-06-00260)**

- 1995-2005: Fourfold increase in advanced imaging paid under Medicare Physician Fee Schedule (\$1.4M to \$6.2M)
- Increased utilization rates per beneficiary (42/1000 to 163/1000)
- Growth varied among States (24% to over 1,000%)
- 10 frequently billed procedure codes accounted for close to 60% of all advanced imaging services billed under MPFS

# THE “STARK” PROHIBITION

(Section 1877 of the SSA)



If a *physician* (or immediate family member) has a direct or indirect *financial relationship* (ownership or compensation) with an entity that provides *designated health services* (“DHS”), the physician *cannot refer* a Medicare patient to the entity for DHS and the entity *cannot submit a claim* to CMS for such DHS, *unless* the financial relationship fits in an *exception*.

# DESIGNATED HEALTH SERVICES

- ❖ **Clinical laboratory**
- ❖ **Physical therapy**
- ❖ **Occupational therapy**
- ❖ **Radiology services, e.g., MRI, CAT scan, ultrasound, PET**
- ❖ **Radiation therapy services and supplies**
- ❖ **Durable medical equipment and supplies**

# **DESIGNATED HEALTH SERVICES (cont'd.)**

- ❖ **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**

# **FINANCIAL** **RELATIONSHIPS**

- **Ownership**
  - **Direct and Indirect**
  - **Debt or Equity**
- **Compensation**
  - **Direct and Indirect**
  - **Cash or In-kind**

# THREE QUESTIONS

- Is there a *referral* from a *physician* for a *designated health service*? *If yes, then:*
- Does the physician (or an immediate family member) have a *financial relationship* with the entity providing the DHS service? *If yes, then:*
- Does the financial relationship fit in an *exception*?
  - ★ *If no, there's a violation* ★

# **PENALTIES**

- **Automatic overpayment or disallowance**
  - **Strict liability**
  - **DHS entity, not referring physician**

# **PENALTIES CON'T**

- **Civil monetary penalties for knowing violations**
  - **Up to \$15,000/service + 3x claims**
  - **DHS entity and/or physician**
- **False Claims Act liability for knowing violations**
  - **Qui tam exposure**
  - **DHS entity and/or physician**

# **BIG PICTURE**

- **Virtually no physician ownership of DHS**
  - **Exceptions for rural areas, “whole” hospitals, physician practices**
- **Physician compensation must be fair market value, unrelated to volume or value of referrals**
  - **Per-click payments?**
  - **Percentage payments?**

# GUIDANCE

- [www.oig.hhs.gov](http://www.oig.hhs.gov)
- [www.cms.hhs.gov](http://www.cms.hhs.gov)