Learning Objectives

- Recognize when the Stark Act is implicated
- Comply with the components for exceptions for a physician practice

Stark Act § 42 U.S.C. 1395nn

- The Stark II Act prohibits a physician from making a Referral
  - to an Entity
  - for the furnishing of a Designated Health Service
  - for which payment may be made under Medicare
  - if the physician (or an immediate family member)
  - has a Financial Relationship with the entity
Stark II Act

Proof of Intent is Not Required

Penalty

Denial of payment or refund; civil money penalties (up to $100,000) and exclusions from federal and state programs for improper claims or schemes

Examples

Simple Example:

Dr. X Practice

Referral

Lab Owned by Dr. X
Examples
Simple Example:

Dr. X Practice  Referral  Lab Owned by Dr. X

How Stark II has been applied:

Dr. X Practice  Medical Direction
                   Medical Staff
                   Referral
                   Hospital V

In both examples, the referrals violate Stark unless an exception applies

What is a Referral?

A referral includes:

- Request for an item or a service by a physician
- Request by physician for consultation with another physician, and any tests or procedures the other physician orders, performs or supervises
- Request for or of plan of care that includes provision of designated health services

What is a Referral?

- A referral is not a DHS personally performed by a physician
- A referral does not include a request by:
  - Pathologists for clinical diagnostic laboratory tests and pathological examination services
  - Radiologists for diagnostic radiology services
  - Radiation Oncologists for Radiation Therapy
- If the request for such additional services results from a consultation initiated by another physician
Designated Health Services

- **Designated Health Services** include:
  - Clinical laboratory services;
  - Physical therapy and occupational therapy services;
  - Radiology or other diagnostic services (including MRI, CAT scans);
  - Radiation therapy services;
  - Durable medical equipment;
  - Parenteral and enteral nutrients, equipment and supplies;
  - Prosthetics, orthotics and prosthetic devices;
  - Home health services;
  - Outpatient prescription drugs; and
  - Inpatient and outpatient hospital services (encompassing almost every type of medical procedure).

  *Note: Ambulatory Surgery Centers services are not DHS!*

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What is a DHS Entity?

- Entity that bills for DHS service
- Entity that performs DHS service
  - “Perform” is given common meaning

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What Is a Financial Relationship?

A **Financial Relationship** includes:
- Ownership interests
  - Through equity, debt, compensation or other means; and
- Compensation arrangements
  - Includes virtually any form of direct or indirect remuneration (i.e., personal service contracts, medical directorships, lease agreements, consulting arrangements, medical service provider arrangements)
What Is a Financial Relationship?

Remuneration is defined (42 CFR § 411.351) as “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind …”

Benefits:
• Payments for services rendered
• Use of space
• Use of personnel
• CME
• Dinners
• Trinkets
• Parking

Nature of Exceptions

If Financial Relationship exists with an Entity, and patients are being Referred for Designated Health Service, then activity must either comply with an exception or the activity is illegal.