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
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Dr. X Practice \rightarrow \text{Referral} \rightarrow \text{Lab Owned by Dr. X}

How Stark II has been applied:

Dr. X Practice \rightarrow \text{Medical Directorship Payments} \rightarrow \text{Medical Suite Rent Payments} \rightarrow \text{Referral} \rightarrow \text{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;
  - Parental 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!
What is a DHS Entity?

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

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.