Stark Law Questions for the Stark Law Professionals

- To Ask Stark Law Questions, either
  1. Go to a microphone
     - or -
  2. Send question through Conference App., Session #701. There may be a limitation of characters.

Robert A. Wade, Esq.
Partner
Barnes & Thornburg LLP
700 1st Source Bank Center
100 North Michigan
South Bend, Indiana 46601
Telephone: 574.237.1107
Email: bob.wade@btlaw.com

Lester J. Perling, Esq.
Partner
NELSON MULLINS BROAD AND CASSEL
100 S.E. 3rd Avenue, Ste. 2700
Fort Lauderdale, FL 33394
Telephone: 954.745.5261
Email: lester.perling@nelsonmullins.com

Charles Oppenheim, Esq.
Partner
Hooper, Lundy & Bookman, PC
1875 Century Park East, Ste. 1600
Los Angeles, CA 90067
Telephone: 310.551.8110
Email: copenhheim@health-law.com
Polling Question

• What is the degree of experience that the audience has with respect to the Stark Law?
  a) I have heard of the Stark Law;
  b) I have worked with the Stark Law to some extent;
  c) I have worked with the Stark Law considerably; or
  d) I am an expert regarding the Stark Law.

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.

Potential False Claims Act liability of treble damages and up to $11,500 per claim submitted.
Examples
Simple Example

Dr. X Practice  Referral  Lab Owned by Dr. X

How Stark II has been applied:

Dr. X Practice  Medical Directorship Payments
Medical Suite Rent Payments
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;
  - 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)

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 …”
What Is a Financial Relationship?

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.
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