Stark & Clinical Research:
5 Compliance Scenarios & 5 Practical Safeguards

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Structure

- Hour 1: Why is this important? Stark risks in research

- Hour 2: Practical ways to tackle Stark risks in research through contracts

- Hour 3: Walk through 5 compliance scenarios
  (hand-out at seminar for workshop portion)
Overview

- What is the Stark Law?
- What types of Stark “financial relationships” could exist between a physician and other parties in the research enterprise?
- Case studies on complying with Stark during research

Disclaimer!

**WARNING:**
The Stark Law may be hazardous to your:
- heart rate
- sleep patterns
- sanity
- pocketbook
Further disclaimer!

- This lecture is not designed to teach you everything about the Stark Law (that is a three day course that is much more boring than this session)

Why the concern?

- The Stark Law is a sleeping giant in clinical research because:
  - The Stark Law is counter-intuitive to normal business practices
  - It is a strict liability law that does not require intent to break the law
  - “Ignorance is no excuse” – actors do not need to know of or about the law to have liability
  - Government mostly relies on whistleblower suits to learn about non-compliance
What’s happening?

- Audits
- Investigations
- Whistleblowers
- Industry expectations
- Heightened stakeholder scrutiny
- Confronting historical decentralization
- Both academic and community settings are at risk

Stark Law issues and “parties”

- U.S. physician self-referral law (Stark):
  - Prohibits referrals of “designated health services” to a provider with which the physician (or an immediate family member) has a “financial relationship”
  - Prohibits the provider who has received the referral from billing Medicare for the item or service
  - Allows “exceptions” if financial relationship can be structured into one of the “exceptions”
  - “Designated health services” includes hospital inpatient and outpatient services
  - “Financial relationship” is broadly defined to include ownership interests and compensation arrangements
Technical citations

- **Stark Law:**
  - Statute: 42 USC 1395nn
  - Regulations: 42 CFR §411.350, et seq

- **Enforcement:**
  - Centers for Medicare & Medicaid Services
  - HHS-Office of Inspector General
  - Department of Justice

**Stark Law**
42 USC 1395nn

- Civil law
- Its own penalties and connected to False Claims Act
- Prohibits certain referrals
- Prohibits billing Medicare for items and services that are the result of certain services
- Strict liability law – Stark relationship must fit into one of 38 exceptions
- Some compliance corrective actions allowed but must be set out in regulation
- Non-compliance period is "disallowance period”
  - No billing Medicare or patient during disallowance period
Important Terms

- Arrangement
- Designated health services (DHS)
- Financial relationship
  - Ownership or investment interest
  - Compensation arrangement
- Immediate family member
- Fair market value

Stark Basics

42 USC 1395nn(a)

- [Unless an arrangement meets an exception], if a physician (or an immediate family member of such physician) has a financial relationship with an entity..., then:
  - (A) the physician may not make a referral to the entity for the furnishing of DHS [reimbursed by Medicare]
  - (B) the entity may not present or cause to be presented a claim [to Medicare or bill the Medicare beneficiary or any related payor]
A physician has a financial relationship with another provider to which the physician refers Medicare services.

Note: “Financial relationship” is very broad and includes:
- when the physician is providing services to Party 2
- when Party 2 is providing services to the physician

What types of Stark “financial relationships” could exist between a physician and other parties in the research enterprise?
Physician/Hospital Research Relationships

- Is there a financial relationship between the hospital and the physician during a research study?
  - Depends on how the contract is structured
  - Depends on if the hospital is performing services for the physician
  - Depends on whether the physician takes money for hospital services

- If there is a Stark “financial relationship” between the physician and the hospital, then the financial relationship must be structured under a Stark exception

Physician/Hospital Research Relationships

- Relevant Stark exceptions for research:
  - Personal services arrangements 42 CFR 411.357(d)
  - Fair market value 42 CFR 411.357(f)

- All relevant Stark exceptions require a contract between the hospital and the physician

- If there is a Stark relationship, then extra compliance monitoring needed

- Additional Compliance Risk: A hospital must be sure to invoice (and pursue collection) from a physician that owes the hospital money or there is a danger of implicating the Anti-kickback Statute or Civil Monetary Penalties Act
Which exception to use?

- Is the physician providing a service to the hospital?
  - Then use personal service arrangement exception

- Is the hospital providing a service to the physician?
  - Then use fair market value exception

**Personal Services Exception: Hospital-Physician Financial Relationship Must Meet these Criteria (42 CFR 411.357(d))**

1. Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

2. The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

3. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

4. The term of each arrangement is for at least 1 year.

5. The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

6. The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
**Fair Market Value Exception: Hospital-Physician Financial Relationship Must Meet these Criteria (42 CFR 411.357(l))**

1. The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

2. The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

3. The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

4. The arrangement would be commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

5. It does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

6. The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

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**Practical ways to tackle Stark risks in research through contracts**
Analyzing Stark Risks: How do the Parties and the Money in Research Relate?

- **Key:** Does the physician owe the hospital money for services?
- **Options:**
  - Three-party agreements in which the hospital invoices the sponsor directly
  - Hospital agreement with physician-investigator
  - Site agreements directly between the hospital and the sponsor
- **Managing Stark risk in research:** either do not enter into a financial relationship with a physician or fit financial relationship into “personal services exception” or “fair market value exception”

CASE STUDY: Academic Models

- In classic “peer” academic model:
  1. Sponsor enters into CTA with University
  2. Faculty member signs CTA to “acknowledge” investigator’s responsibilities
  3. Money given to University
  4. Investigator orders protocol required services at hospital and physician practice
  5. Hospital and physician practice need to invoice University
CASE STUDY: Community Hospital Model 1

1. Sponsor enters into CTA with Physician/Physician Practice
2. Hospital not a party to CTA
3. Money given to Physician/Investigator
4. Investigator orders protocol-required services at local Hospital
5. Hospital needs to invoice Physician for research services ordered at Hospital

CASE STUDY: Community Hospital Model 2

1. Sponsor enters into CTA with Physician and Hospital
2. Three-party agreement
3. Investigator orders protocol-required services at local Hospital
4. Hospital invoices Sponsor for research services ordered at Hospital per CTA
Complying with Stark during research

- Compliance tips to manage Stark during clinical research:
  1. Written contracts with physician-investigators
  2. Invoicing process for research services
  3. Establishing consistent fair market value research charges

Infrastructure to manage Stark risk during research

- Financial relationships analysis process
- Contracts management
- Compliance reviews and audits
Stark infrastructure 1: financial relationships analysis process

- Different configuration of parties based on local circumstances and research relationship
- Figure out how CTAs in provider’s community are currently structured
- To figure out who should be the parties:
  - Follow the money!
  - Follow the liability!

Stark infrastructure 2: contracts management

- Does the organization have a contracts management system?
- Does the organization have a contracts review policy?
- Incorporate clinical trial agreements or agreements with physicians into contracts management process
Stark infrastructure 3: compliance reviews and audits

- Regularly select sample of clinical trial agreements:
  1. Have all parties signed a contract?
  2. Is clinical trial agreement being included in any contract management databases?
  3. Are clinical trial agreements included in any contract management monitoring process that already exists?
  4. Are invoices being sent to the sponsor or physician?
  5. Is the sponsor or physician paying for services invoiced?

Compliance Tip 1: identify financial relationships with physicians

- If organization has a Stark analysis process, incorporate research into the process

- If organization does not have a Stark analysis process, consider establishing one (cross-reference to the previously mentioned boring three day course)

- Systematically analyze physician financial relationships and establish contracting process
Compliance Tip 2: written contracts with physician-investigators

- Obtain written contracts with the physician-investigator
- Identify clearly the services that will be charged to the physician
- Consider 1: a master agreement for all research studies
- Consider 2: contracting with sponsor to avoid “financial relationship” with physician

Compliance Tip 3: invoicing process for research services

- Establish an invoicing process to physician
- Monitor accounts receivable
Compliance Tip 4: establishing consistent fair market value research charges

- What will the organization charge the physician?
- Do not go above charges and do not go below Medicare rates
- Pick a research rate a stick to it

Compliance Tip 5: standardized contracts as ideal, but prepare for reality

- Standardized contracts with sponsors or physicians is the ideal
- Attempt to enter into master agreements
- However, have Plan B in place when needing to deal with sponsor’s contract:
  - Have policies on standard issues
  - Insist on clarity in the financial terms
Questions?