



# Does the Stark Law Apply?

## A Quick Checklist for Research Site and Investigator Contracts

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# Stark Law Prohibits...

1. A Physician
2. From Making a Referral
3. Of a Medicare or Medicaid Patient
4. To an Entity that Furnishes "Designated Health Services"
5. If the Physician has a Financial Relationship with the Entity
6. Unless an Exception Applies



## Question 1

- Are you dealing with Medicare or Medicaid covered services?
  - If no, Stark does not apply
  - If yes, proceed to the next question



## Question 2

- Are you an entity that furnishes one of the “designated health services” covered by Stark?
  - If no, Stark does not apply
  - If yes, proceed to the next question



# Designated Health Services

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services
- Radiation therapy services and supplies



## Designated Health Services (con't)

- Durable medical equipment and supplies
- 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



## An "Entity" Furnishes DHS if...

- ...it is the person or entity to which Medicare makes payment.
- As a result, pharmaceutical or medical device manufacturers generally are not covered by the Stark law.
- But if you do bill and receive payment for DHS, proceed to next question.



## Question 3

- Will the arrangement create a “financial relationship” with a physician, meaning an ownership interest or, more likely, direct or indirect compensation to the physician?
  - If no, Stark does not apply
  - If yes, proceed to next question





## Question 4

- Does an exception apply?
  - If no, Stark law prohibits referrals
  - If yes, referrals are permitted



# Personal Services Exception

1. Written agreement
2. Term of at least 1 year
3. Compensation set in advance, consistent with fair market value and not determined based on volume or value of referrals or any other business generated between the parties
4. Commercially reasonable and legitimate transaction



# Fair Market Value Exception

1. Written agreement
2. That specifies timeframe, which can be for any time period (but compensation cannot change in < 1 year)
3. Compensation set in advance, consistent with fair market value and not determined based on value or value of referrals or any other business generated by the referring physician
4. Commercially reasonable and legitimate transaction
5. Does not violate anti-kickback statute



# Other Exceptions

- Publicly-Traded Entities
- Rural Providers
- Hospital Ownership
- Bona Fide Employment Relationships
- Physician Incentive Plans
- Risk-Sharing Arrangements