

Morgan Lewis

***FAST BREAK:***  
**STARK LESSONS PART II:**  
**HOSPITAL-PHYSICIAN**  
**ARRANGEMENTS**

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# Agenda

- What is the Stark Law and what kind of hospital arrangements does it apply to?
- What kind of hospital-arrangements are not subject to the Stark Law?
- Discussion of Arrangements – Is it permitted?
- What does enforcement of Stark Law violations look like for hospitals?

# **WHAT IS THE STARK LAW AND WHAT KIND OF HOSPITAL ARRANGEMENTS DOES IT APPLY TO?**

# Stark Law Prohibition

- Physician may not refer Medicare / Medicaid patients to a DHS entity if the physician or immediate family member of the physician has a financial relationship with the entity
- DHS entity cannot bill for the services
- Unless the financial relationship qualifies for an exception
- Strict liability statute; intent is irrelevant
- Proscriptive statute – if the statute applies, referrals are prohibited unless an exception applies

# Penalties for Violation

- Civil sanctions
  - Denial of payment
  - Refunds of amounts collected
  - Up to \$23,863 for each bill/claim submitted
  - \$100,000 for each arrangement or “scheme”
  - Program exclusion
- Bootstrap FCA liability
  - 3x amount claimed

# Elements of a Stark Law Violation

- Is there financial relationship between physician (or family member) and entity furnishing DHS?
- Will physician refer Medicare/Medicaid patients to entity for DHS?
- Is an exception applicable?

# Financial Relationship

- Very broadly defined to include
  - Ownership or investment interest
  - Compensation arrangements
  - Direct and indirect financial relationship

# Designated Health Services

Clinical laboratory services	Radiology services
Physical and occupational therapy services	Durable medical equipment
Radiation therapy services	Outpatient prescription drugs
Parenteral and enteral nutrients, equipment, and supplies	Home health services
Prosthetics, orthotics, and prosthetic devices and supplies	Inpatient / outpatient hospital services



# Applicable Exceptions

- Bona fide employment relationships
- Personal service arrangements
- Rental of office space
- Payments by a physician
- Remuneration unrelated to DHS
- Nonmonetary compensation / medical staff incidental benefits

**WHAT KIND OF HOSPITAL  
ARRANGEMENTS ARE NOT  
SUBJECT TO THE STARK  
LAW?**

# Exceptions to the Definition of Remuneration

The definition of remuneration does not include a payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if –

- i. No contract between the plan and physician;
- ii. Benefit owed to a patient/beneficiary; and
- iii. The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

# Exceptions to the Definition of Referral

The definition of referral does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if –

- i. The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated);
- ii. The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist; and
- iii. Can be in any form, including, but not limited to, written, oral, or electronic.

# Other Arrangements Outside of the Stark Law

- Ambulatory Surgical Centers Joint Ventures
- Lithotripsy Arrangements
- Split Billing Arrangements: CMS policy on split bill arrangements—no remuneration is transferred between the hospital and the physician if the hospital bills the technical component for services it provides and the physician separately bills for his professional fees

# **DISCUSSION OF ARRANGEMENTS**

# Arrangement #1

Surgeon's mother owns a business that sells trinkets. Hospital purchases trinkets from mother to sell in hospital gift shop. There is no written agreement between the hospital and the mother. Is this permitted?

## Arrangement #2

Group of diagnostic radiology physicians enter into a contract with the hospital for the provision of services. The compensation exceeds fair market value. Is it permitted?

But, what if one of the diagnostic radiologists is married to an orthopedic surgeon employed by the hospital?



# Arrangement #3

Hospital wants to engage a cardiology group to co-manage an outpatient cardiac cath lab. Is it permitted?

But, what if the group wants to provide general administrative services, in addition to medical direction?

But, what if the group also wants to provide clinical personnel?

## Arrangement #4

Hospital prepared an announcement with respect a new bariatric surgery program. A local newspaper picked up the announcement and publicized it. The announcement included information about the new bariatric surgery program, as well as information relating to the physician involved in the program, including the physician's name and phone number.

Does this implicate the Stark Law?

# RECENT ENFORCEMENT

# Recent Enforcement

## Beaumont Health (August 2018)

Hospital system paid \$84.5 million to settle allegations that it provided kickbacks to physicians in exchange for patient referrals. The settlement resolved allegations relating to the hospital system providing physicians with excessive pay and low-cost or free office space.

# Recent Enforcement

## **UPMC Hamot (March 2018)**

UPMC Hamot (a hospital now affiliated with the University of Pittsburgh Medical Center) and Medisor agreed to pay nearly \$21 million to resolve claims that Hamot improperly utilized medical director agreements, priced above fair market value, to secure patient referrals.

# QUESTIONS



# Thanks!



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Donna advises healthcare providers on issues concerning US federal laws governing the relationships between physicians and other healthcare providers, and the entities to which they refer patients. Donna has practiced healthcare law exclusively for nearly 35 years and is intimately familiar with the potential issues healthcare providers may encounter, as well as the solutions available to them. Donna also advises on structuring joint ventures and contractual relationships in compliance with laws governing referral relationships, including the federal and state Anti-Kickback Statute and Stark Law, and assists in investigations when problems arise.

# Thanks!



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Banee focuses her practice on healthcare law, including transactional, regulatory, and compliance matters. She represents hospitals, health systems, academic medical centers, large physician groups, and private equity clients in mergers, acquisitions, joint ventures, and other collaborative and alignment strategies. Additionally, Banee frequently advises clients with respect to fraud and abuse laws, including the Stark Law and state and federal anti-kickback laws, billing compliance, as well as state and federal privacy laws. Before completing law school, Banee worked as pharmacy technician.



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Please join us for next month's webinar:

*"Fast Break: Congressional Mid-Term Elections"*

Featuring Susan Feigin Harris, Tim Lynch, Kathleen Rubinstein, and David Mendelsohn

➤ Tuesday, November 27, 3:00 PM (EST)