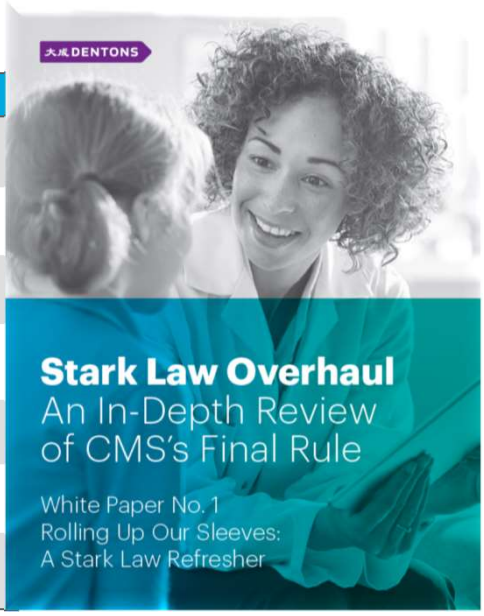
Stark Law Overhaul Series

Date	Topic
March 18	**Rolling Up Our Sleeves: A Stark Law Refresher (and Clearing the Brush)**
April 1	Separating the Wheat From the Chaff: Providing Greater Flexibility for Technical and Low-Dollar Violations
April 15	Key Standards (Part I): Distinguishing and Defining the 'Volume or Value' Requirement
April 29	Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Requirements
May 13	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	What's Past is Prologue: Technology Subsidies Part Deux
June 10	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide



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Webinar 1

Rolling Up Our Sleeves:
A Stark Law Refresher (and Clearing the Brush)

Agenda

Stark Law Refresher…

- Policy Objectives
- Timeline
- Basic Prohibitions
- Step One - Financial Relationship
- Step Two - Referral
- Step Three - Exceptions
- Sanctions

…Clearing the Brush

- Physician
- Remuneration
- Ownership Interests - Titular
- Ownership Interests - ESOPs
- Designated Health Services

Policy Objectives

Overutilization

Physicians with a financial stake in determining whether and where to refer patients for medical care may order items and services that, absent a profit motive, they would not otherwise have ordered.

1

Patient Steering

Patient choice can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers, just because the physicians are sharing profits with, or receiving remuneration from, those providers.

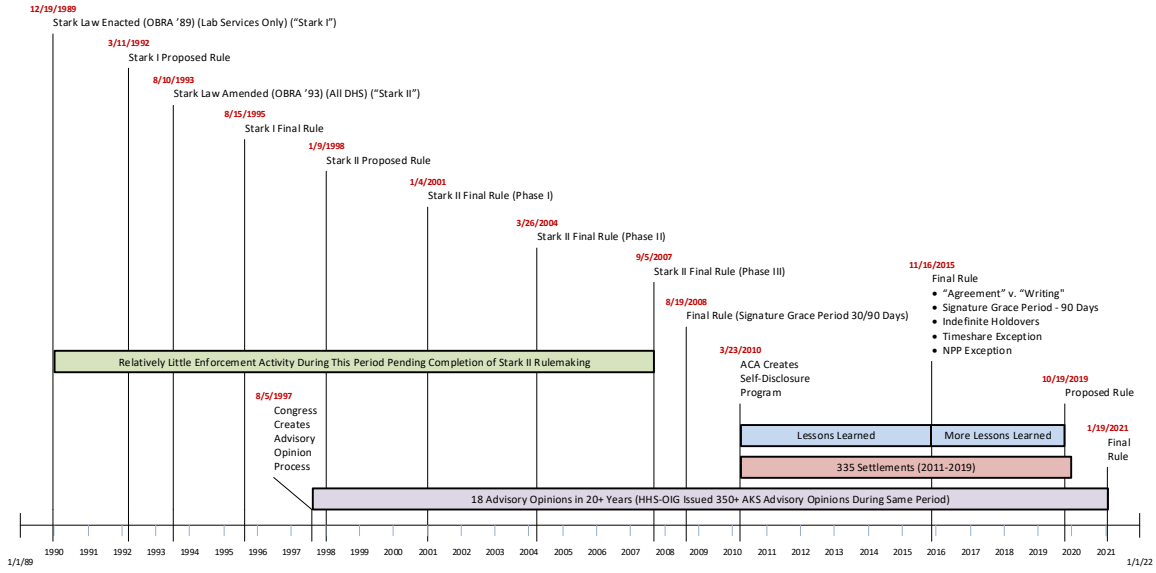
2

Unfair Competition

Where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price.

3

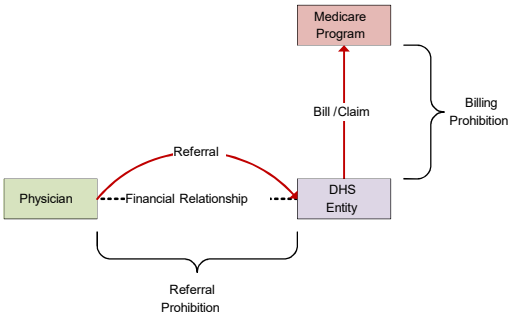
Timeline



Stark Law Refresher

Basic Prohibitions

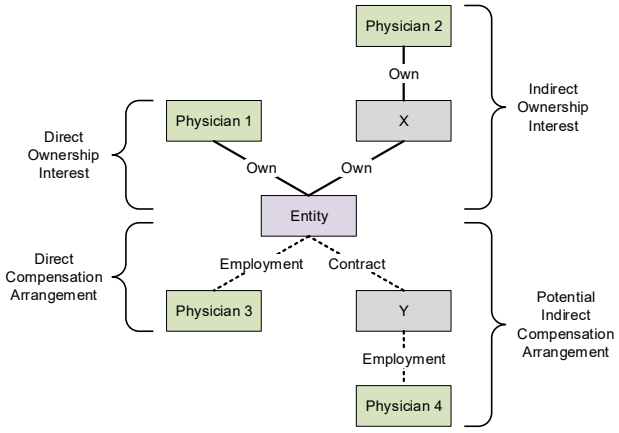
- Referral Prohibition
  - In absence of applicable ***exception***, a ***physician*** who has a ***financial relationship*** with an ***entity***—personally or through an ***immediate family member*** (IFM)—may not make a ***referral*** to that entity for the ***furnishing*** of ***designated health services*** (DHS) for which payment may be made by Medicare.
- Billing Prohibition
  - In absence of applicable exception, a provider may not bill for improperly referred DHS. Specifically, an entity that furnishes DHS pursuant to a prohibited referral may not ***present*** or ***cause to be presented*** a claim or bill for such services to the Medicare program or to any other individual or entity, including secondary insurers and the patient.

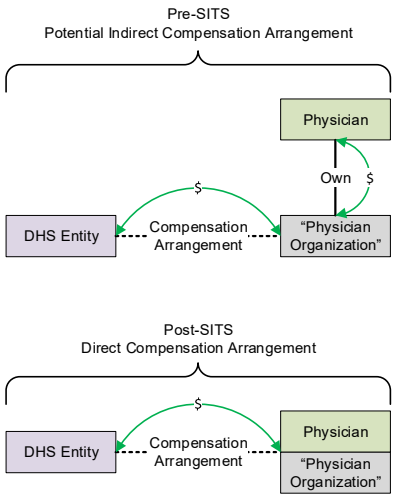


Step 1 - Financial Relationship

- Do we have a ***physician*** or ***IFM*** who has a ***financial relationship*** with an ***entity***?
- "Physician"
  - A doctor of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, optometry, or a chiropractor.
- "Immediate Family Member"
  - A husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in- law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.
- "Entity"
  - Any "corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association," or any "other person, sole proprietorship, public or private agency or trust," and a "physician's sole practice or a practice of multiple physicians."

Step 1 - Financial Relationship





Step 2 - Referral

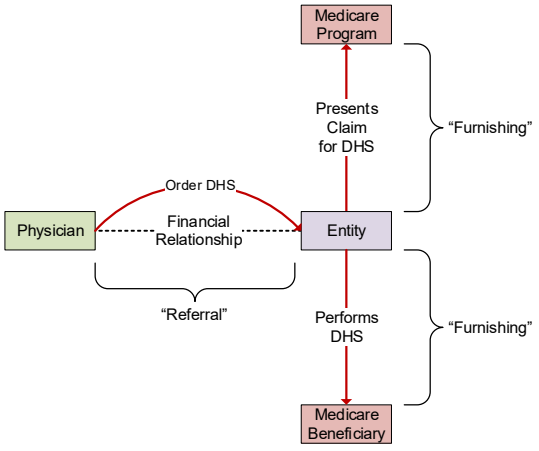
- If a physician/IFM and an entity have a financial relationship, then—in the absence of an applicable exception—the physician may not make a ***referral*** to the entity for the ***furnishing*** of ***designated health services*** covered by Medicare.
- First four categories are CPT code driven.

"Designated Health Services"

1. Clinical laboratory services.
2. Physical therapy, occupational therapy, and outpatient speech-language pathology services.
3. Radiology and certain other imaging services.
4. Radiation therapy services and supplies.
5. Durable medical equipment and supplies.
6. Parenteral and enteral nutrients, equipment, and supplies.
7. Prosthetics, orthotics, and prosthetic devices and supplies.
8. Home health services.
9. Outpatient prescription drugs.
10. Inpatient and outpatient hospital services.

Step 2 - Referral

- **"Referral"**
  - Either (i) requesting, ordering, or certifying the need for DHS, or (ii) establishing a plan of care that includes the provision of DHS.
  - A number of exceptions (e.g., personally performed services).
- **"Furnishing"**
  - Generally speaking, an entity is deemed to be "furnishing" DHS if the entity either (i) "perform[s]" the services or (ii) "present[s] a claim to Medicare" for the services.
  - Almost (but not) always the same legal entity is doing both.

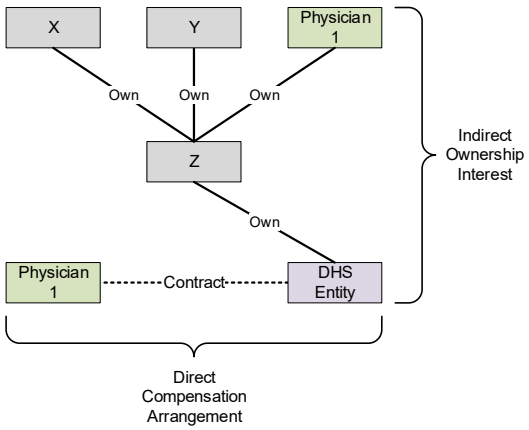


Step 3 - Exceptions

- If:
  - a physician and entity have a financial relationship (Step 1), and
  - the physician makes a referral to the entity for the furnishing of DHS (Step 2),
- Then:
  - the referral will violate the Stark Law's referral prohibition, and any claim seeking reimbursement for the DHS will violate the Stark Law's billing prohibition, unless an ***exception*** applies (Step 3).
- Two categories of exceptions:
  - Exceptions that apply to certain types of ***services***.
  - Exceptions that apply to certain types of ***financial relationships***.

Step 3 - Exceptions

- **Service Exceptions (9)**
  - Broadest, most sweeping protection.
  - Type and number of referring physician's financial relationships with DHS entity is irrelevant.
  - Example
    - Prepaid Plans Exception - 42 C.F.R. § 411.355(c).
- **Financial Relationship Exceptions (31)**
  - Only protect particular financial relationships.
  - Examples
    - Employment Exception - 42 C.F.R. § 411.357(c).
    - Whole Hospital Exception - 42 C.F.R. § 411.356(c).



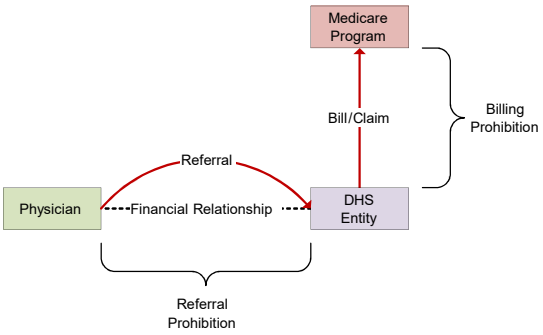
Sanctions & Collateral Consequences

- Stark Law
  - Claim Denial. A claim for Medicare payment for DHS performed pursuant to a prohibited referral must be denied.
  - Refund. An entity that collects payment for DHS performed pursuant to a prohibited referral must refund all collected amounts on a timely basis.
  - CMP/Assessment/Exclusion. A person "who presents or causes to be presented a bill or claim" for improperly referred DHS and "knows or should know" that the claim is for improperly referred DHS is subject to (i) a civil monetary penalty of up to $25,820 per service; (ii) an assessment (in lieu of damages) of up to three times the amount claimed; and (iii) exclusion from participation in any federal healthcare program.
  - Circumvention. A physician or entity that knowingly participates in a "scheme" to circumvent the operation of the Stark Law is subject to a CMP of up to $172,137 and may be excluded from participation in federal healthcare programs.
- Overpayment Statute
- False Claims Act (FCA)

Final Rule

Physician

- Proposed Rule
  - Definition of "physician" in Stark Law and Social Security Act (SSA) should be but are not "entirely harmonious."
  - Specifically, SSA provides for certain "limitations" on when individuals are considered to be "physicians."
  - A doctor of optometry, for example, is considered a physician but only for certain purposes and only with respect to the provision of certain items and services.
  - Stark Law does not explicitly adopt these SSA limitations
- Final Rule
  - CMS clarifies that Stark Law prohibitions do not "apply to any doctor during the period he or she is not considered to be a physician" for purposes of the SSA.

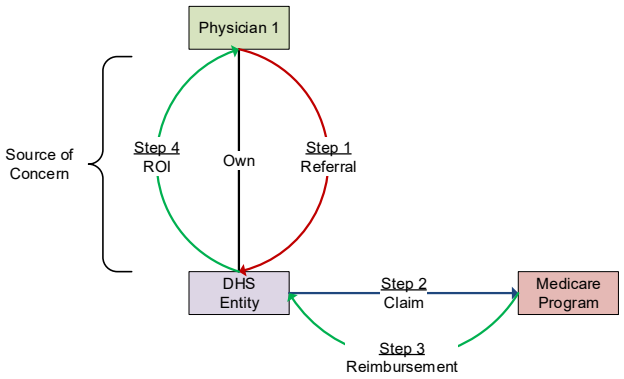


Remuneration

- Another key definition: "financial relationships" include "compensation" arrangements; i.e., any arrangement involving an exchange of "remuneration." "Remuneration" generally includes "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."
- There are exceptions. For example, historical carve-out for "items, devices, or supplies" "used solely" for (i) collecting, transporting, processing, and/or storing specimens, (ii) ordering tests or procedures, or (iii) communicating the results of tests or procedures unless the items/devices/supplies take the form of "surgical items, devices, or supplies."
- Final Rule:
  - Removes caveat: CMS "no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely" for a permitted purpose.
  - Clarifies that even if X can (in theory) be used for something other than a permitted purpose, as long as X is (in fact) "used solely" for a permitted purpose, exception applies.

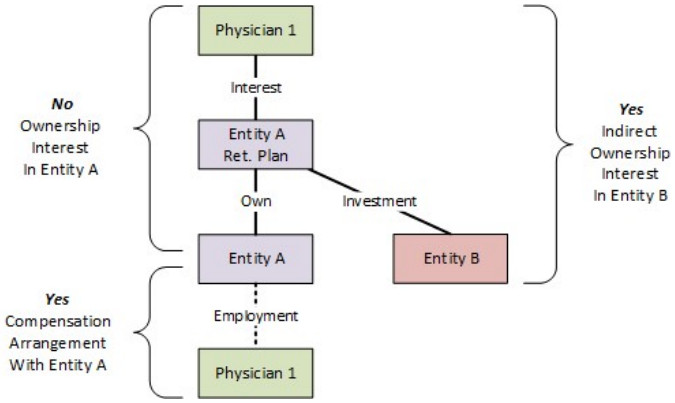
Ownership Interests - Titular Ownership

- 2009: "Titular" owner of physician organization not required to "stand in the shoes" of physician organization.
- 2020: CMS "extend[s] the concept of titular ownership or investment interests to [the] rules governing ownership or investment interests" more generally.
- "Titular" ownership means the physician does not have "the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment."



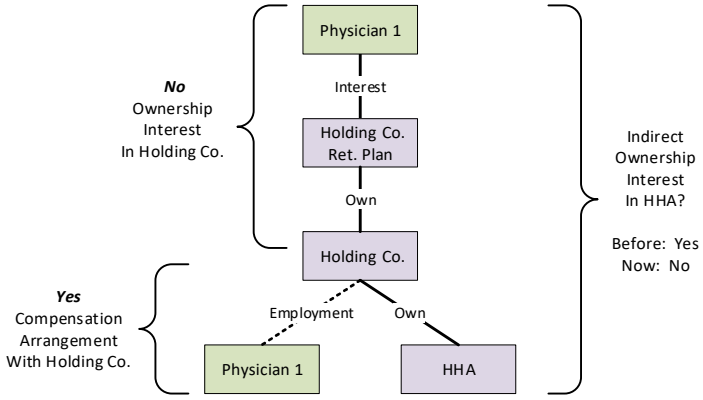
Ownership Interests - Employee Stock Ownership

- Some employers offer retirement plans. These plans, in turn, may have an interest in the employer only or the employer and other entities.
- CMS historically split the baby: the employee's interest in the retirement plan won't make the physician an owner of the employer, but it will make the physician an owner of any other entity in which the plan invests.

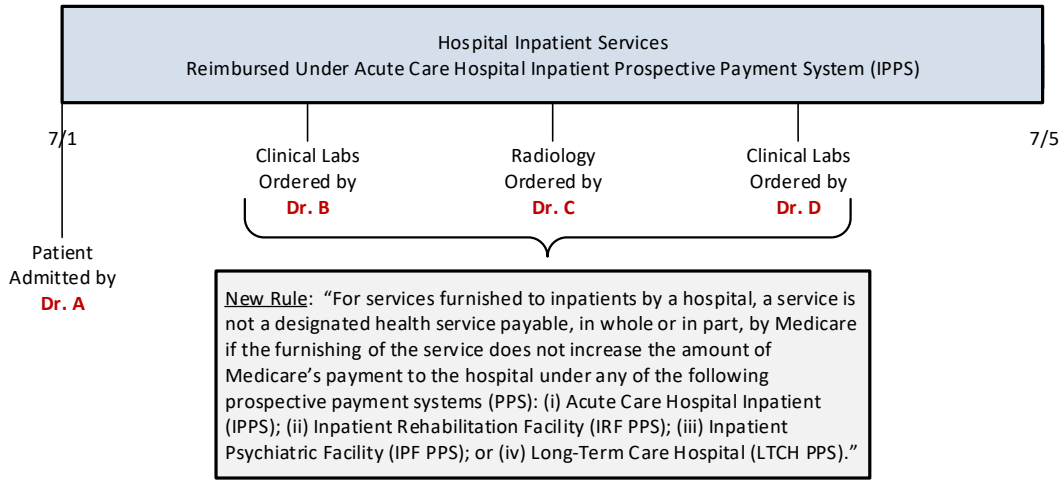


Ownership Interests - Employee Stock Ownership

- This construct doesn't work for some increasingly common IRC and ERISA regulated employee stock ownership plans (ESOPs) that rely on holding companies.
- The new rule creates an exception for these plan structures.



Designated Health Services



Q&A

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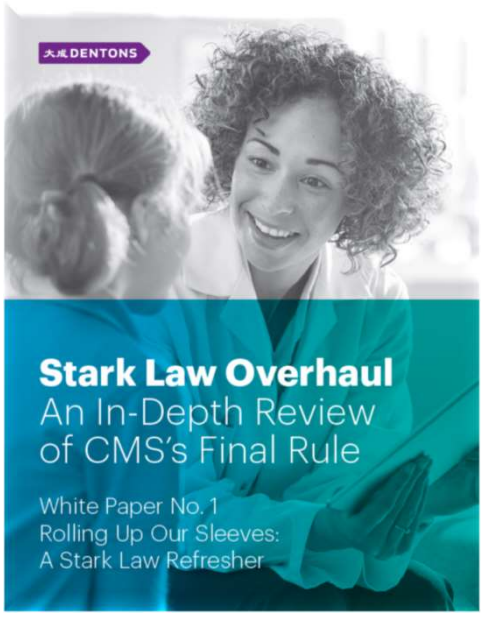

Thank you

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