

# Is it Time to Unwind?

## *Stark and Other Regulatory Changes*

**FULBRIGHT**  
*& Jaworski L.L.P.*  
Attorneys at Law

## Arrangements

- ❖ Percentage and “Per Click” Arrangements.
- ❖ “Under Arrangements” Transactions.
- ❖ The “Stand in the Shoes” Rules.
- ❖ Purchased Diagnostic Test Rule, including Shared Services Arrangements.

## Other Issues

- ❖ Financial Arrangement Disclosure Rules
- ❖ Shared Savings and Incentive Payments
- ❖ New Designated Health Services

## Where Is This Coming From?

- ❖ Stark Phase III Final Rule published in September, 2007.
- ❖ 2009 Final Inpatient Prospective Payment System Regulations published in August, 2008.
- ❖ 2009 Proposed Medicare Physician Fee Schedule published in July, 2008.
- ❖ 2009 Final Medicare Physician Fee Schedule published November 19, 2008.

## Percentage Based Compensation

- ❖ Effective date 10/1/2009
- ❖ Only prohibited with respect to rental of office space or equipment
  - Formula cannot be a percentage of revenue, earnings, billings, collections, or otherwise attributable to the services performed or business generated in the space or through the use of the equipment
- ❖ Modifies equipment and space rentals, fair market value compensation, and indirect compensation exceptions

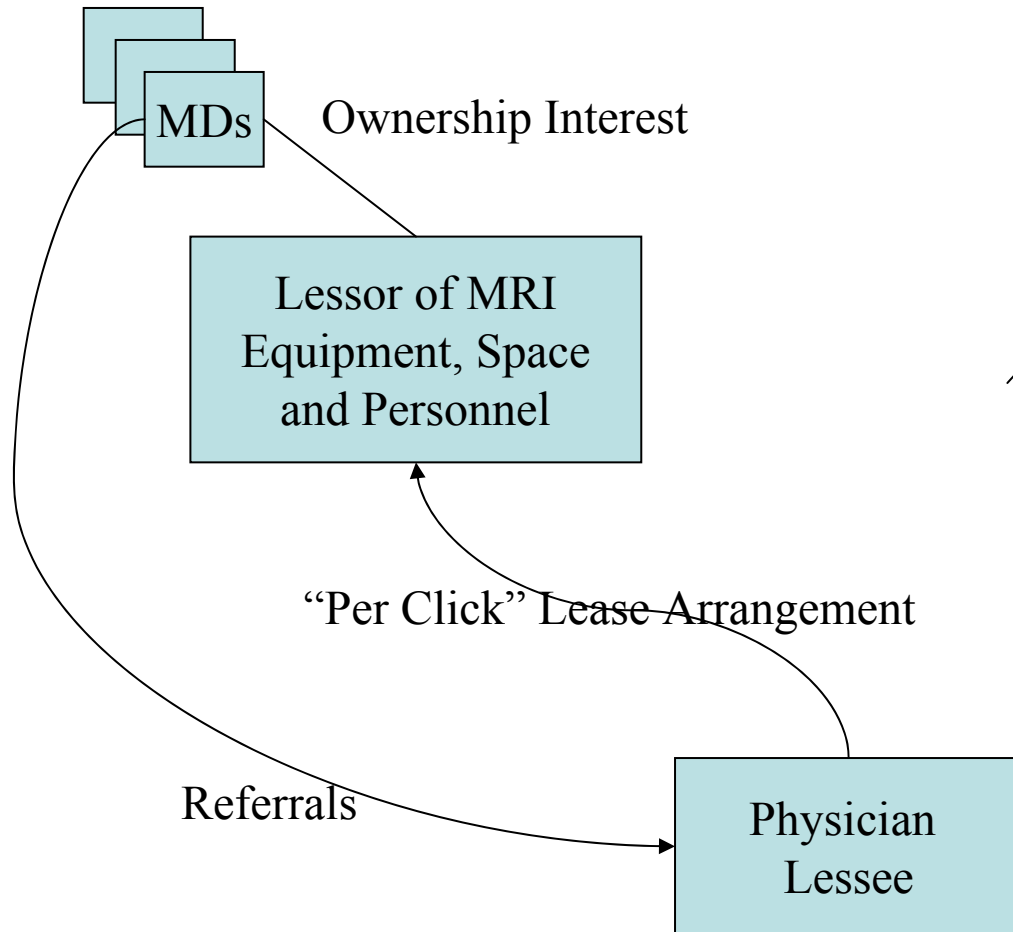
## Percentage Based Compensation (*cont'd*)

- ❖ Stark Phase III says percentage based formula is ok under the “set in advance” rule, 411.354(d)(1)
- ❖ Stark Phase III says percentage based formula is not deemed to comply with the ubiquitous requirement that arrangements “not take into account or otherwise reflect the volume and value of referrals or other business generated” 411.354(d)(2),(3)
- ❖ When does a percentage based formula NOT take into account the v/v of referrals or other business generated?

## Per Click Compensation

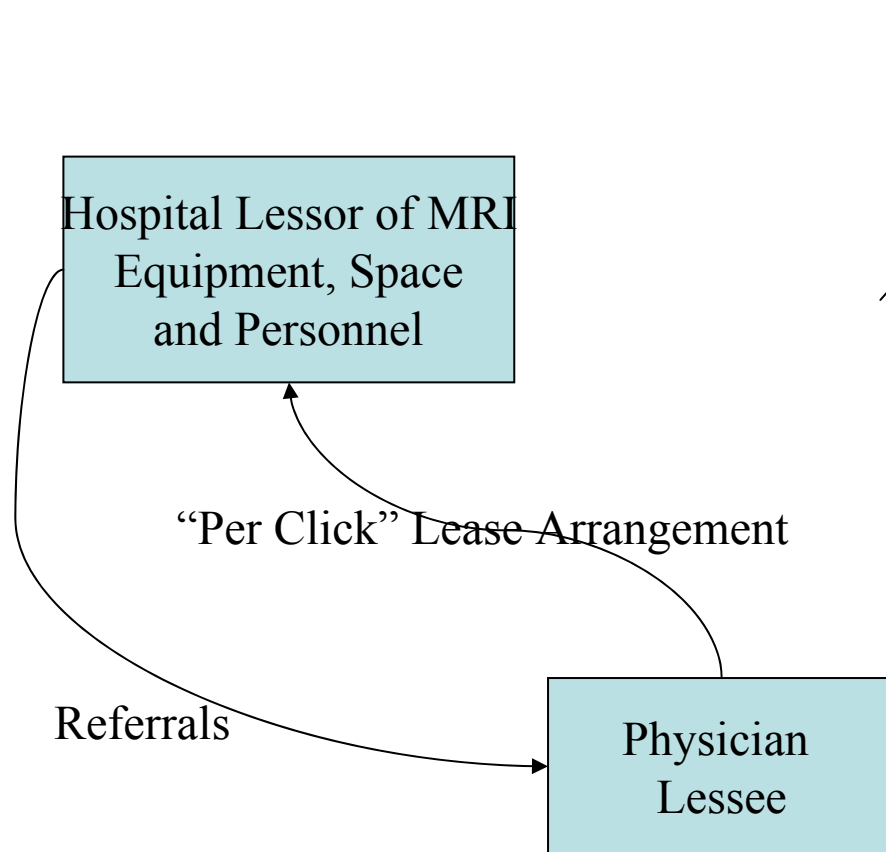
- ❖ Effective date 10/1/2009
- ❖ Only applies to equipment and space leases
  - But whether under equipment and space lease, fair market value compensation, or indirect compensation exceptions
  - Applies if DHS entity or physician is lessor
- ❖ Rental charges may not be determined on per unit of service to the extent such charges reflect services provided to patients referred by the lessor to the lessee
  - (see correction notice, 73 FR 57541 (10/3/2008))
- ❖ What about a fixed annual contract for 1,000 clicks where lessee pays regardless of use

# “Per Click” Arrangement Example 1



- Per Click arrangement is not acceptable for equipment and space lease.
- Referrals by the physician owners of the Lessor to the Physician Lessee for MRI services will result in higher rental payments for the Lessor
- Same for percentage arrangements.

## “Per Click” Arrangement Example 2

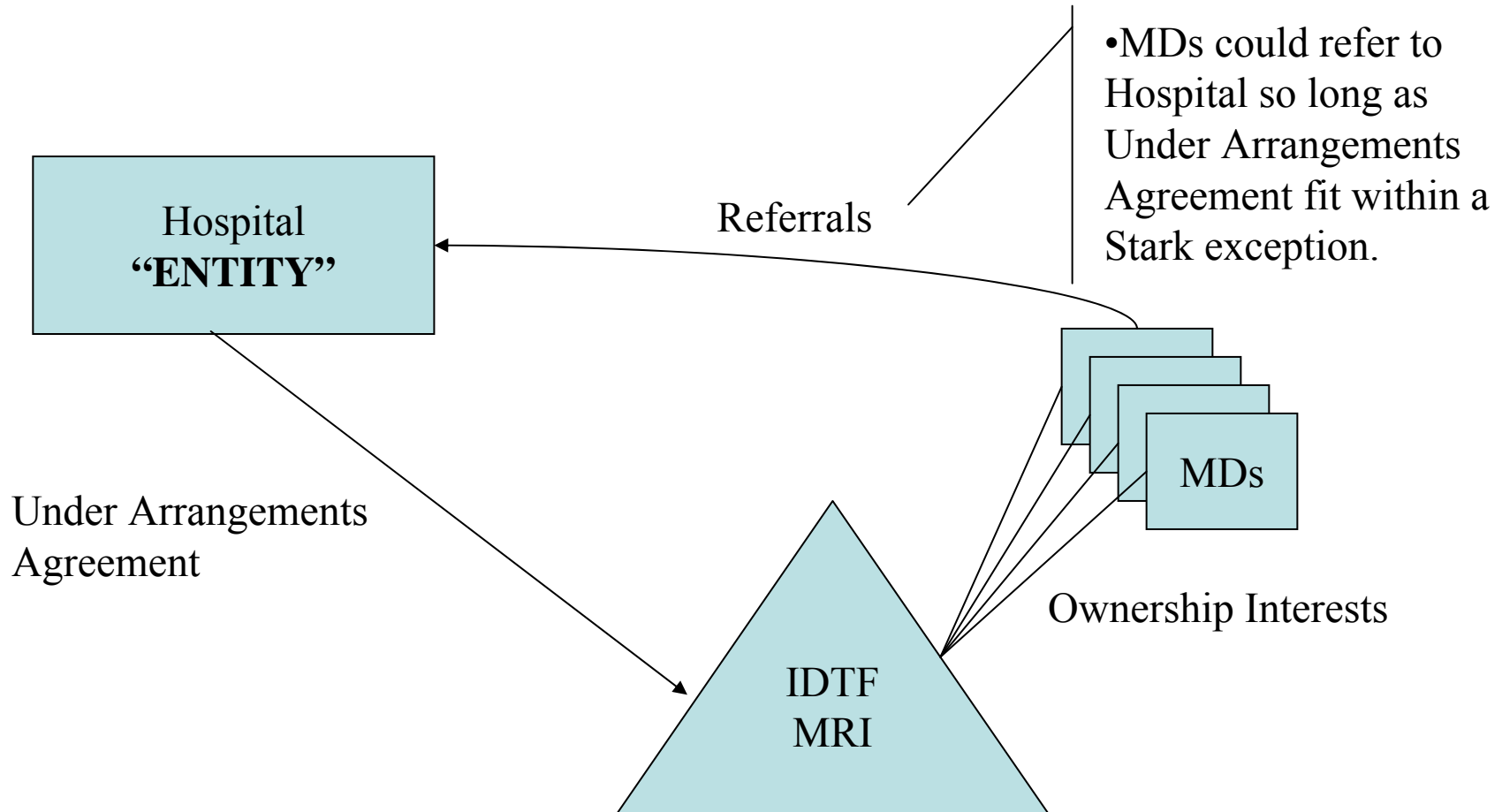


- Per Click arrangement is not acceptable for equipment and space lease.
- Per Click arrangement may be acceptable for personnel.
- Referrals by the Hospital Lessor to the Physician Lessee for MRI services will result in higher rental payments for the Hospital Lessor
- Same for percentage arrangements.

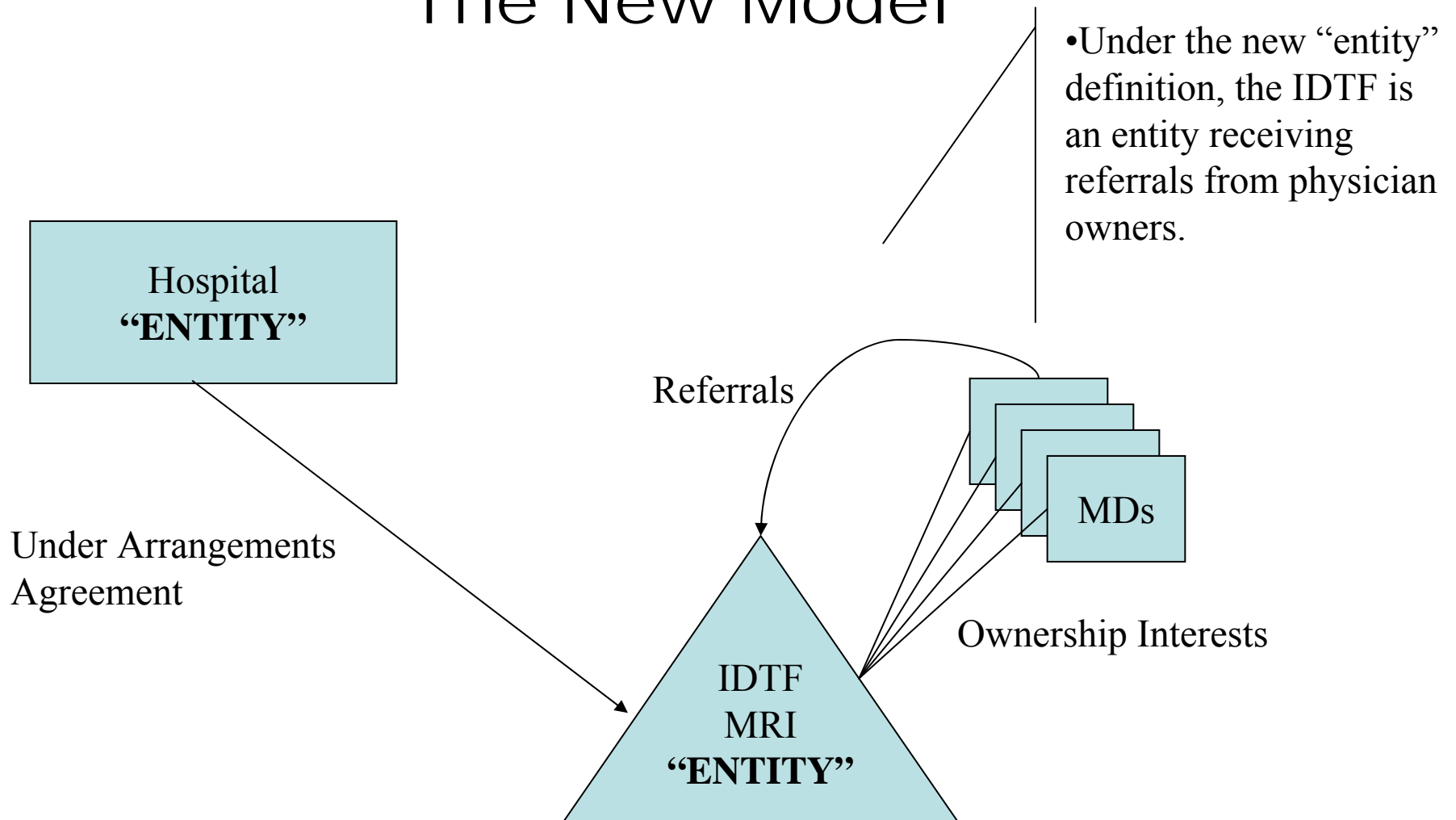
## “Under Arrangements” Transactions

- ❖ Medicare allows certain providers to furnish services “under arrangements,” *e.g.*, the hospital bills for services that are essentially furnished by another contracted entity under the hospital’s oversight.
- ❖ Under previous Stark regulations, physicians were allowed to invest in entities which provided services “under arrangements” to hospitals because the physicians did not have an ownership interest in the hospital.
- ❖ Effective October 1, 2009, an “entity” subject to Stark prohibitions includes the person or organization that has: (1) billed for the DHS or (2) performed the DHS.
- ❖ Does not impact under arrangements entities that qualify as rural providers.

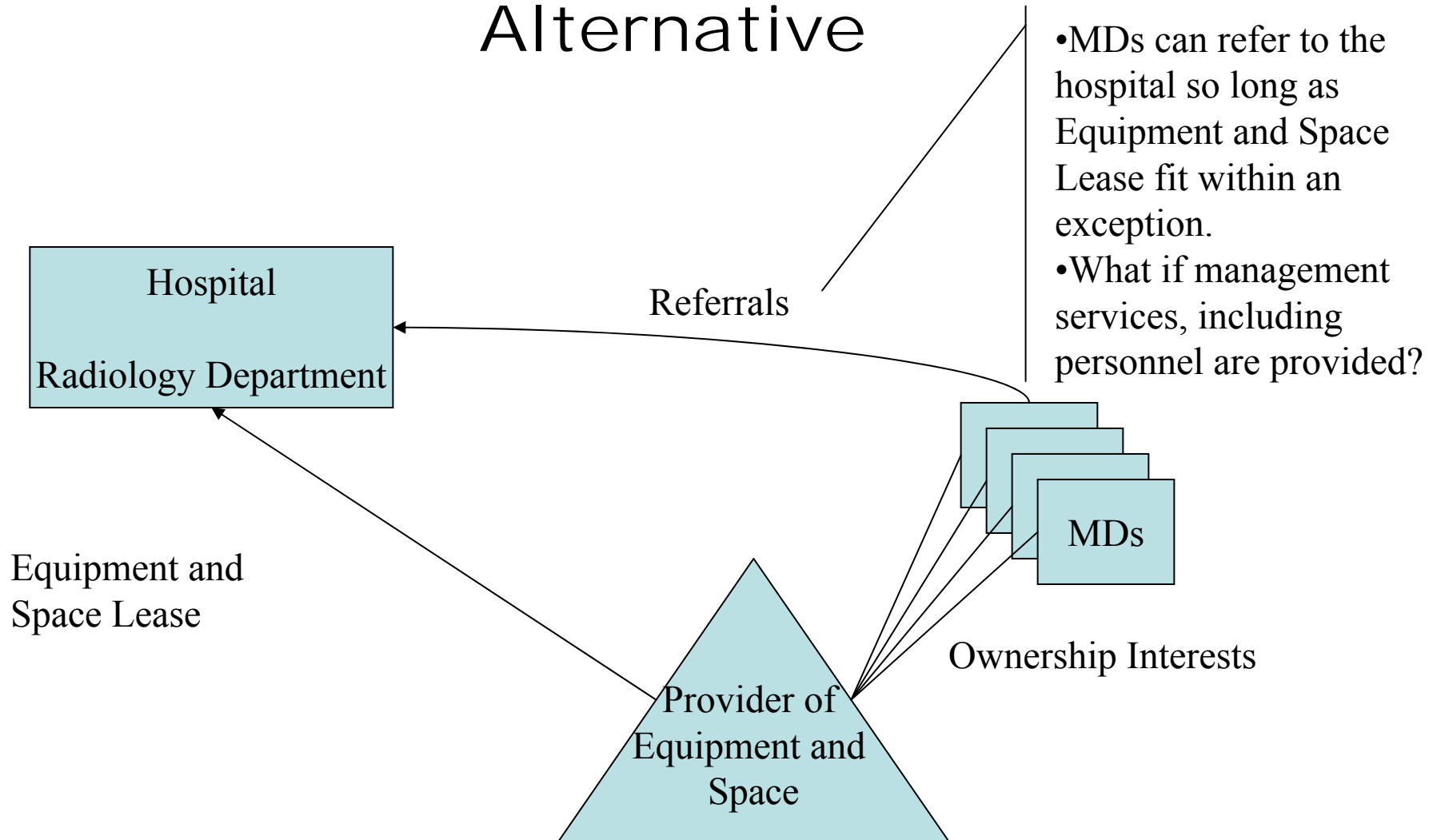
# “Under Arrangements”: The Old Model



# “Under Arrangements”: The New Model



# "Under Arrangements": Alternative



*Colorado Heart Institute, LLC et al v. Leavitt,*  
1:2008cv01626 (D.C. Cir. Sept. 25, 2008)

- ❖ In response to new definition of “entity,” a group of cardiologists and vascular surgeons in Colorado filed a class action lawsuit in the U.S. District Court for the District of Columbia.
- ❖ They claim that, by expanding the definition of “*entity furnishing DHS services*,” the cath labs in which they perform services (and have an ownership interest in) are now considered an “*entity*” under the Stark Law will, thereby prohibiting them from making referrals to the cath labs in which they have an ownership interest.
- ❖ CHI alleges that by characterizing under arrangements as involving a Stark Law ownership interest in addition to a Stark compensation interest, CMS has exceeded its authority and impermissibly “voided” the statutory Stark Law, which allows the operation of similar under arrangement joint ventures if they meet a compensation exception. *See*, 42 U.S.C. § 1395nn.
- ❖ While CMS has expressed concern over such under arrangements leading to overutilization of services, CHI argues that physician-owned cath labs are capable of performing services more efficiently than the hospitals themselves, thereby providing significant savings to the Medicare program.

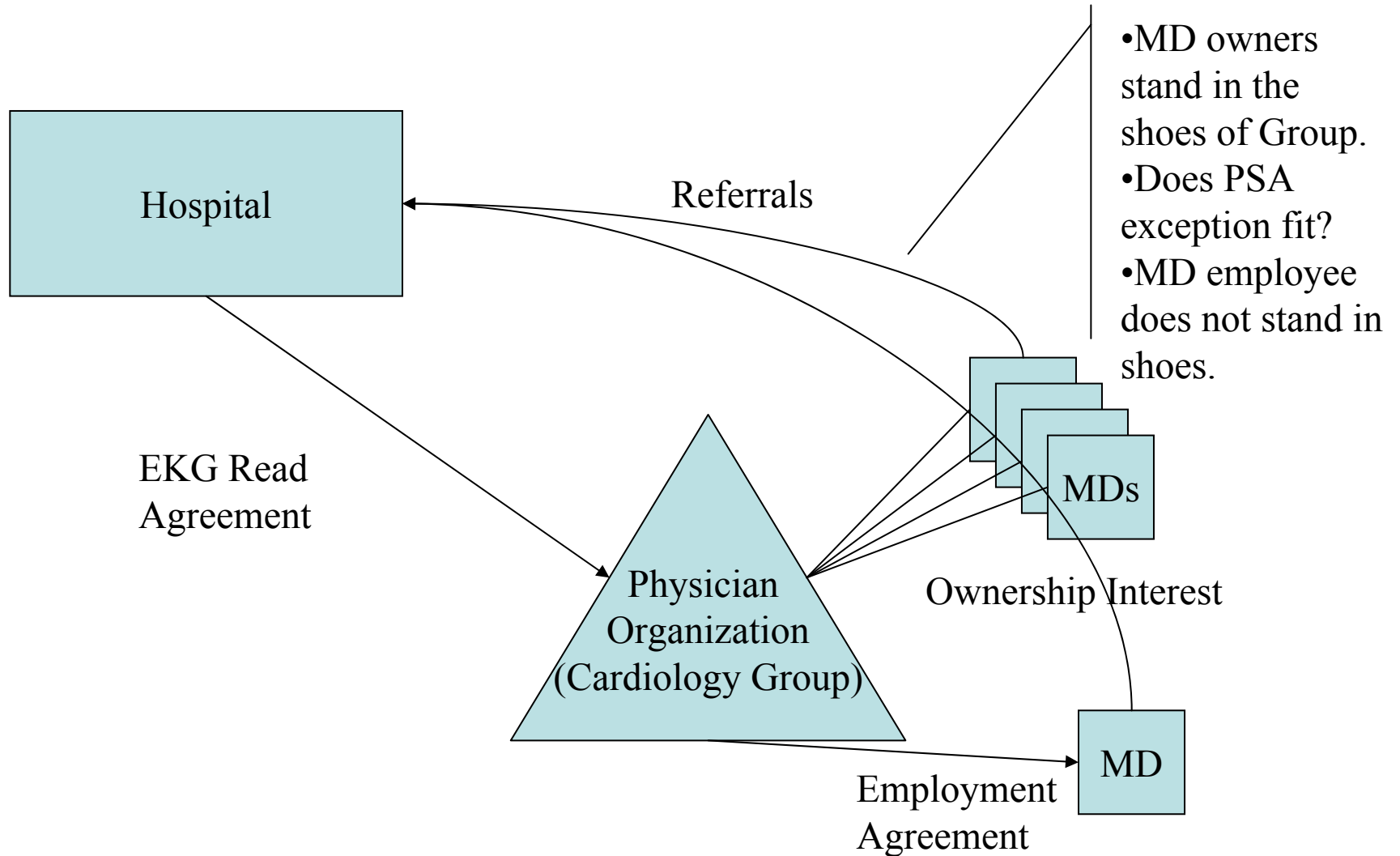
## “Stand in the Shoes”

- ❖ Addressed first in the Stark Phase III final rule published in September, 2007.
  - Under this provision, referring physicians were considered to stand in the shoes of their physician organizations.
  - The referring physician was treated as having the same compensation arrangements with the entity billing or performing the DHS as did his or her physician organization
- ❖ Arrangements that were previously compliant under the indirect compensation arrangement exception must now fit within one of the Stark exceptions for direct compensation arrangements.

## “Stand in the Shoes” (*cont’d*)

- ❖ Under the new provisions set forth in the 2009 IPPS final rule, only physicians who have an ownership or investment interest in a physician organization are deemed to stand in the shoes of that physician organization.
  - Does not apply to physicians who solely have compensation arrangements with the physician organization.
- ❖ Exception for “Titular Owners” who do not receive any financial benefits of ownership or investment

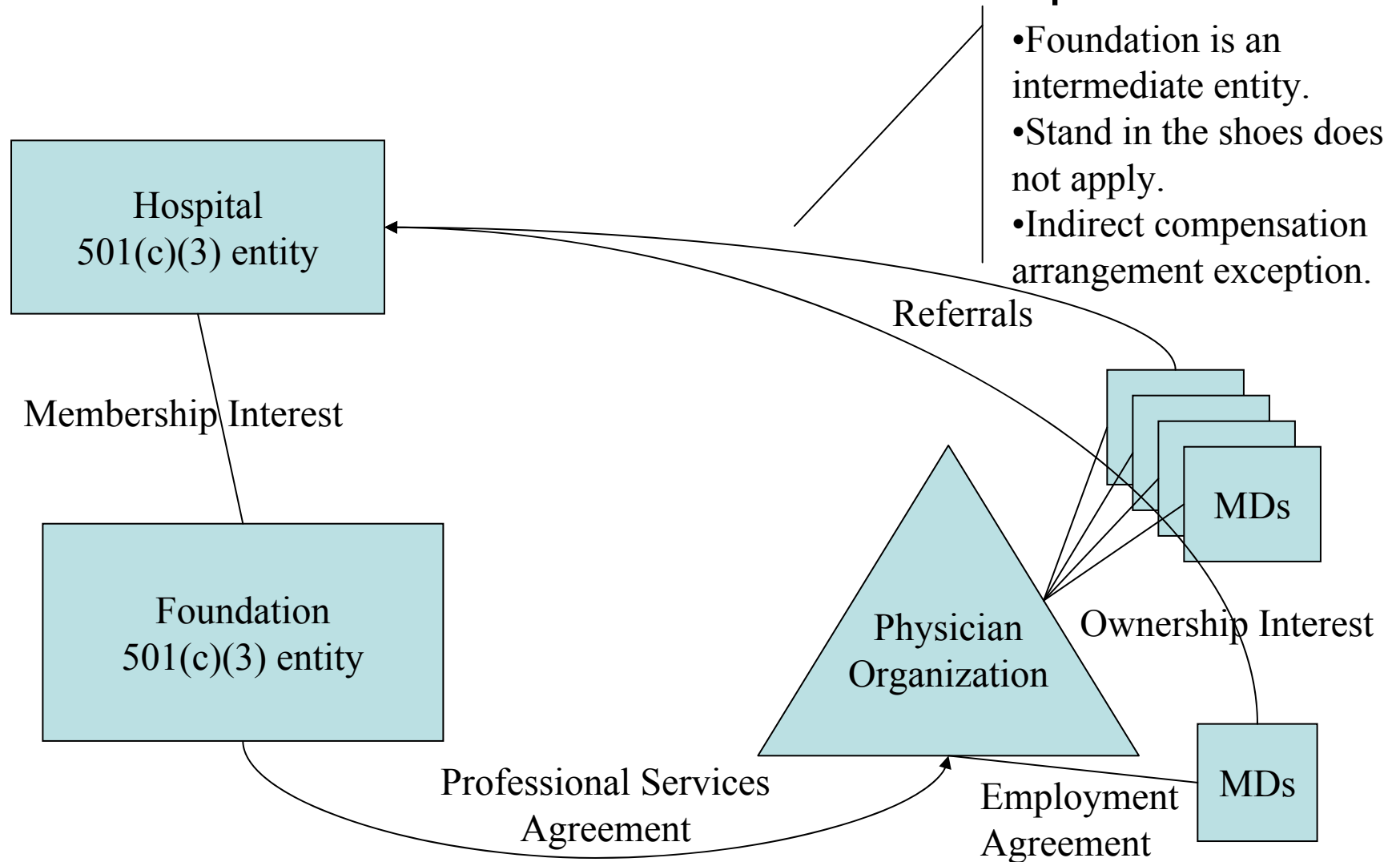
# “Stand in the Shoes” Example



## “Stand in the Shoes” (*cont’d*)

- ❖ CMS did not finalize its DHS entity stand in the shoes analog
  - So, if a DHS entity runs through sub or foundation, stand in the shoes does not apply.
- ❖ CMS warns that interposing entities in a chain of financial relationships between a DHS entity and a referring physician may violate the physician self-referral law, constitute a circumvention scheme, or violate the anti-kickback statute. 73 FR 48699
- ❖ But see Stark III preamble, 72 FR 51063

# “Stand in the Shoes” Example



## Purchased Diagnostic Test Rule

- ❖ In 2008, Medicare Physician Fee Schedule, CMS expanded the Purchased Diagnostic Test Rule (“PDT”) or the “Anti-Mark-Up Prohibition” in two significant ways:
  - CMS expanded PDT Rule to apply to both the technical component of a diagnostic test and the professional component of a diagnostic test.
  - CMS expanded the PDT Rule to cover both (a) the technical component or professional component of a diagnostic test that is purchased by the billing physician or medical group from an outside supplier and (b) the technical component or professional component of a diagnostic test that is performed by the billing physician or medical group at a location other than the office where the billing physician or medical group regularly furnishes the full range of patient care services.

## Purchased Diagnostic Test Rule (*cont'd*)

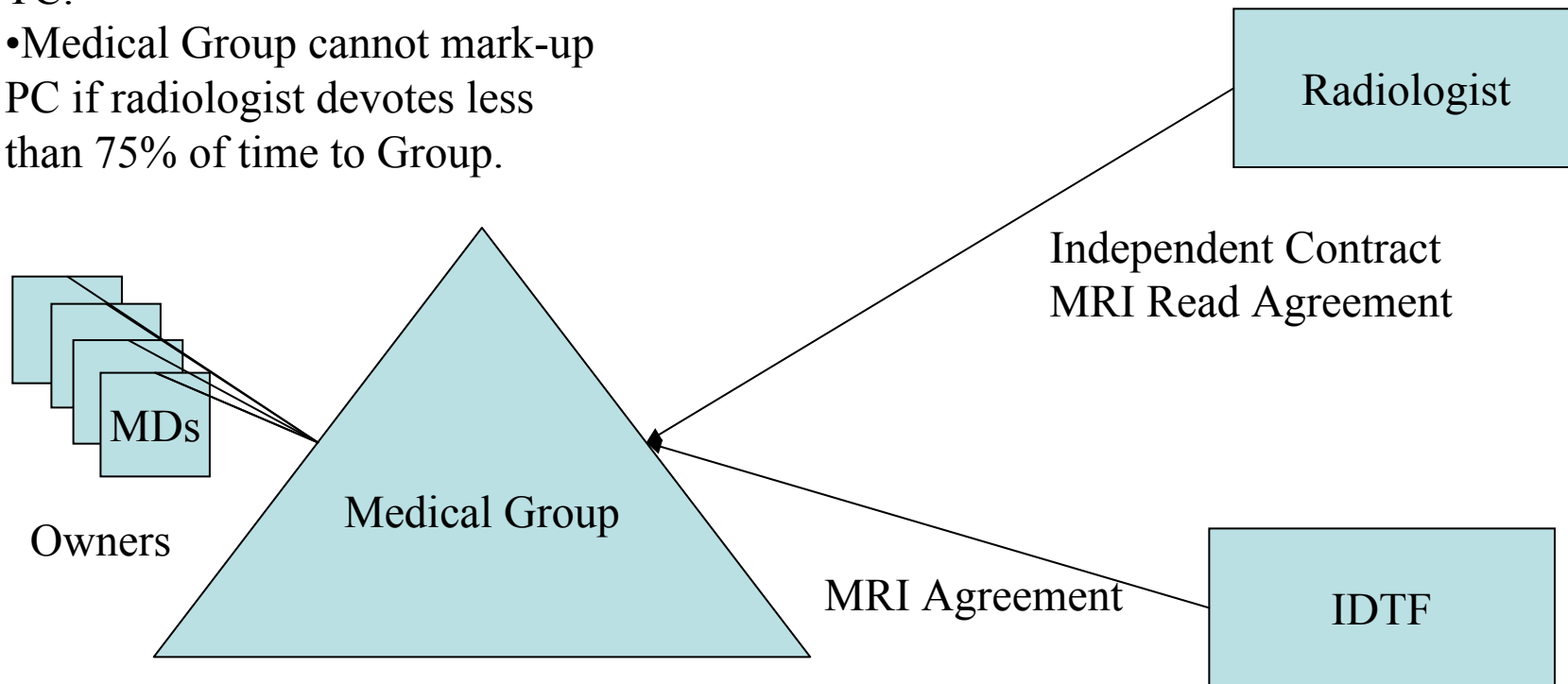
- ❖ CMS intend that the changes to the PDT go into effect on January 1, 2008.
- ❖ Due to concerns expressed by the health care industry, CMS announced that it would postpone the implementation date to January 1, 2009.
- ❖ On November 19<sup>th</sup>, 2008, CMS issued the final 2009 Medicare Physician Fee Schedule regulations and amended the anti-mark-up provisions in a way that should preserve shared service arrangements.

## Purchased Diagnostic Test Rule (*cont'd*)

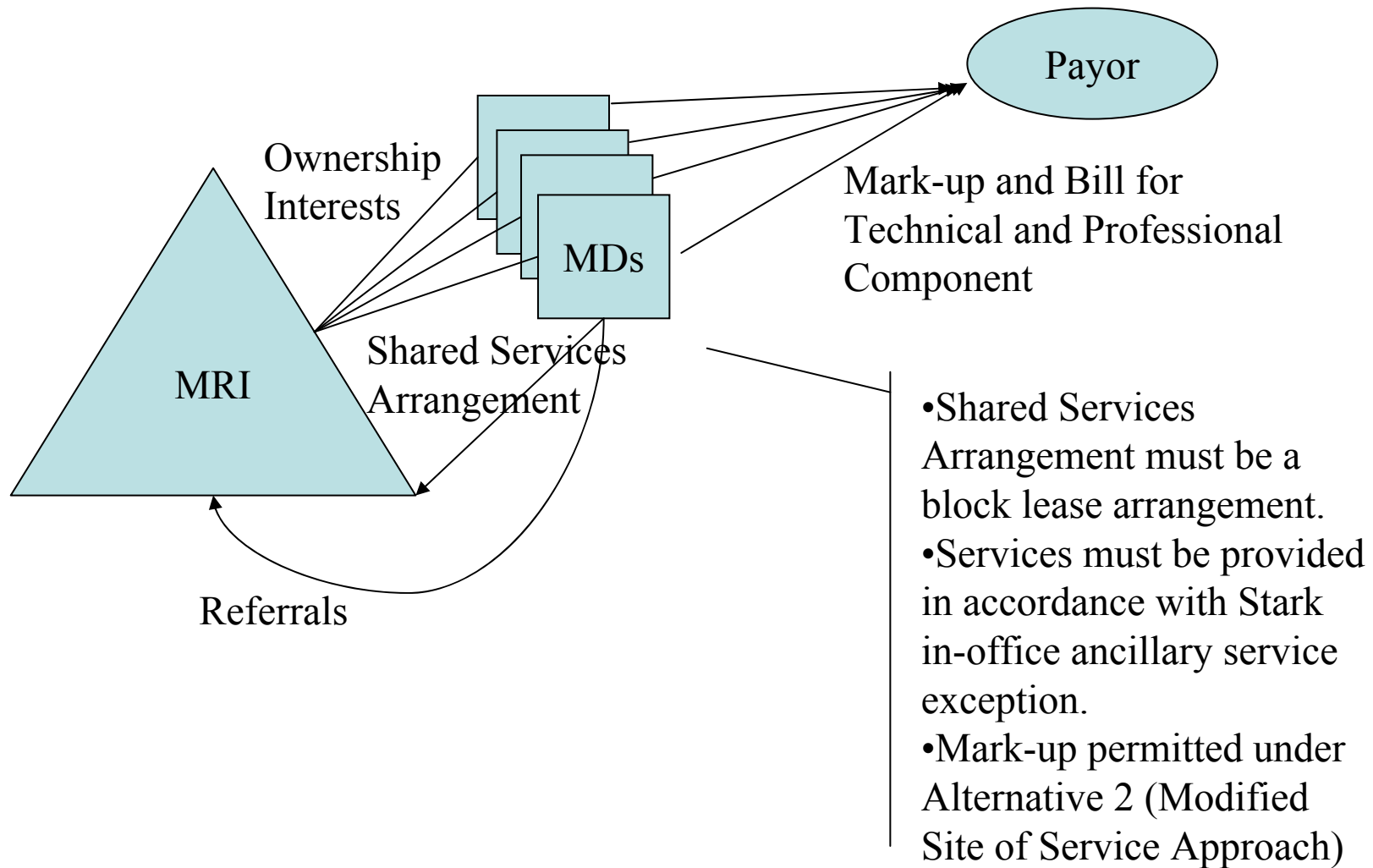
- ❖ In the final rule, CMS uses a combination of alternative approaches:
  - **Alternative 1:** If physician supervising technical component (TC) or professional component (PC) performs substantially all (at least 75%) of his or her professional services for the billing physician or supplier, the anti-markup rule would not apply.
  - **Alternative 2** (if Alternative 1 does not work): Modified site of service approach—TCs supervised and conducted in same office as billing physician, and PCs performed in same office as billing physician will not be subject to PDT.
  - The office of the billing physician is the same building where the ordering physician performs substantially the full range of patient care services that the ordering physician generally provides. For the TC, the physician supervising must be an owner, employee, or independent contractor, and the physician supervising the PC must be an employee or independent contractor.

# Purchased Diagnostic Test Rule Example

- MRI provided by IDTF in remote location.
- Medical Group cannot mark-up TC.
- Medical Group cannot mark-up PC if radiologist devotes less than 75% of time to Group.



# Shared Services Example



## Exception for Incentive Payment and Shared Savings Plans

- ❖ In 2009 Physician Fee Schedule proposed rule, CMS proposed a single exception for incentive payment (quality improvement) and shared savings (cost savings or gainsharing)
- ❖ Exception was relatively narrow, in many ways tracking requirements contained in favorable advisory opinions issued by OIG
- ❖ Any exception must meet requirement of Section 1877(b)(4) of the Act that it not pose a risk of program or patient abuse

## Exception for Incentive Payment and Shared Savings Plans (*cont'd*)

- ❖ CMS received comments from those generally in favor of an exception, which said that proposed exception was too narrow to be of real use
  - Concerned that independent medical review requirements too expensive.
  - Objected to proposal to limit quality measures for which physicians could receive incentive payments to those listed in CMS's Specification Manual for National Hospital Quality Measures. For example, NQF measures are predominantly process measures with few outcomes, efficiency or structural measures to choose from, and cover only limited clinical areas.
  - Objected to the proposal that payments must be distributed on a per capita basis to participating physicians-- problematic if some physicians within the pool of participating physicians contribute substantially to achievement of the performance measures and others contribute only marginally or not at all.
  - Suggested splitting the one proposed exception into separate exceptions, i.e., one for incentive payment programs, and one for shared savings programs

## Exception for Incentive Payment and Shared Savings Plans (*cont'd*)

- ❖ Commenters opposed to any exception (device manufacturers) claimed that any exception for shared savings would not satisfy standard of no program or patient abuse
  - Claimed CMP statute would be violated.
  - Claimed that any payment that violates CMP statute poses a risk of program or patient abuse.
  - Objected that patient notification provisions were not sufficient.
  - Objected that proposed rule was too vague to be finalized.

## Exception for Incentive Payment and Shared Savings Plans (*cont'd*)

- ❖ NO exception finalized in 2009 Physician Fee Schedule final rule
- ❖ Instead, comment period reopened for 90 days
- ❖ CMS gives lengthy and specific laundry list of issues for which it wants comments
- ❖ Rebukes naysayers, reaffirms this is a priority and says it can issue an exception
- ❖ Reminds parties that existing exceptions (e.g., employment, personal service arrangement and FMV) may be used, depending on circumstances
  - Identified services? Fair market value?

## Speech-Language Pathology

- ❖ Section 143 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Stark statute to specify that "outpatient speech-language pathology services" are DHS, effective July 1, 2009.
- ❖ CMS has made changes to the Stark regulations to reflect this change. These provisions will be effective July 1, 2009.
- ❖ CMS also made some modifications to the list of CPT/HCPCS codes that CMS maintains to specify the scope of certain DHS categories.

## Financial Arrangement Disclosure Rules

- ❖ Under the IPPS Rule, CMS finalized a proposed financial disclosure requirement under which CMS would require 500 acute care and specialty hospitals to complete a one time Disclosure of Financial Relationships Report (DFRR).
- ❖ Hospitals that receive the DFRR will have to provide CMS with detailed information about their ownership, investment, and compensation arrangements with physicians (The DFRR is now projected to take 100 hours to complete rather than the originally projected 31 hours).

# Disclosure of Physician Ownership in Hospitals

- ❖ The FY 2009 IPPS Final Rule finalizes several proposals regarding the Medicare provider agreement regulations with which all Medicare providers must comply. These finalized rules, effective October 1, 2008, provide:
  - Physician-owned hospitals must furnish written notice to patients at the beginning of their hospital stay or outpatient visit that physicians (or immediate family members of physicians) hold ownership or investment interests in the hospital, unless such an owner does not refer patients to the hospital and the hospital maintains a written attestation of such representation in its file.
  - A physician-owned hospital must furnish its patients with the list of owners and investors who are physicians (or immediate family members of physicians) at the time the list is requested by, or on behalf of, the patient.
  - Physician-owned hospitals must require medical staff members, as a condition of continued membership or admitting privileges, to disclose in writing to patients at the time of any referral to the hospital that they (or an immediate family member) hold an ownership or investment interest in the hospital.
  
- ❖ CMS may terminate a provider agreement if a physician-owned hospital fails to comply with these provisions.

# Is it Time to Unwind?

*Kenneth J. Yood, Esq.*  
**Fulbright & Jaworski, LLP**  
**555 South Flower Street, Suite 4100**  
**Los Angeles, California 90071**  
**(213) 892-9353**  
**[kyood@fulbright.com](mailto:kyood@fulbright.com)**

**FULBRIGHT**  
*& Jaworski L.L.P.*  
Attorneys at Law