

THE NEW STARK REGULATIONS: CONTENT AND CMS COMMENTARY

**STATE BAR OF MICHIGAN
HEALTH CARE LAW SECTION**

OCTOBER 14, 2008

Today's Panel:

Moderator:

Jennifer Benedict, Honigman, Miller, Schwartz and Cohn, LLP

Speakers:

Arthur F. deVaux, Hall Render Killian Heath & Lyman

Thomas J. McGraw, Dykema Gossett, PLLC

Lisa M. Ohrin, Deputy Director, Division of Technical Payment Policy, CMS

Donald H. Romano, Director, Division of Technical Payment Policy, CMS

Where Can I Find the New Regulations?

- ❑ 73 Fed. Reg. 48434 (August 19, 2008)
 - CMS Commentary begins on p 48688
 - New regulations are found on pp 48751-48754

Topics Covered:

- Stand in the Shoes
- Amendment of Compensation Terms
- Services Provided "Under Arrangements"
- Unit of Service ("Per Click") Payments
- Percentage-Based Compensation Formulas
- Disclosure of Financial Relationship Reports

Topics Not Covered:

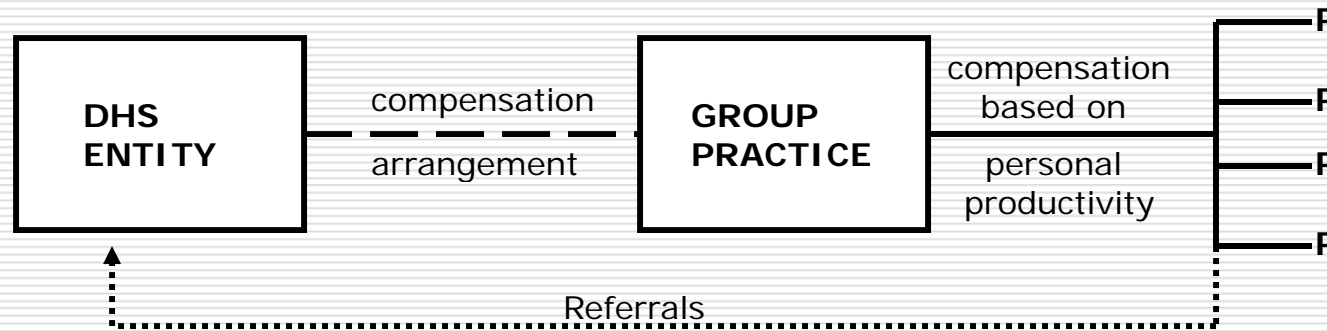
- Period of Disallowance For Non-Compliant Arrangements (411.353(c)(1))
- Accommodations for Temporary Noncompliance with Signature Requirements (411.353(g))
- Alternative Exception for OB Insurance Subsidies (411.357(r))
- Investment Interests in Retirement Plans (411.354(b)(3)(i))
- Burden of Proof (411.353(c)(2))

Format:

- Explanation of New Rule
- Comments from CMS
- Q & A Session

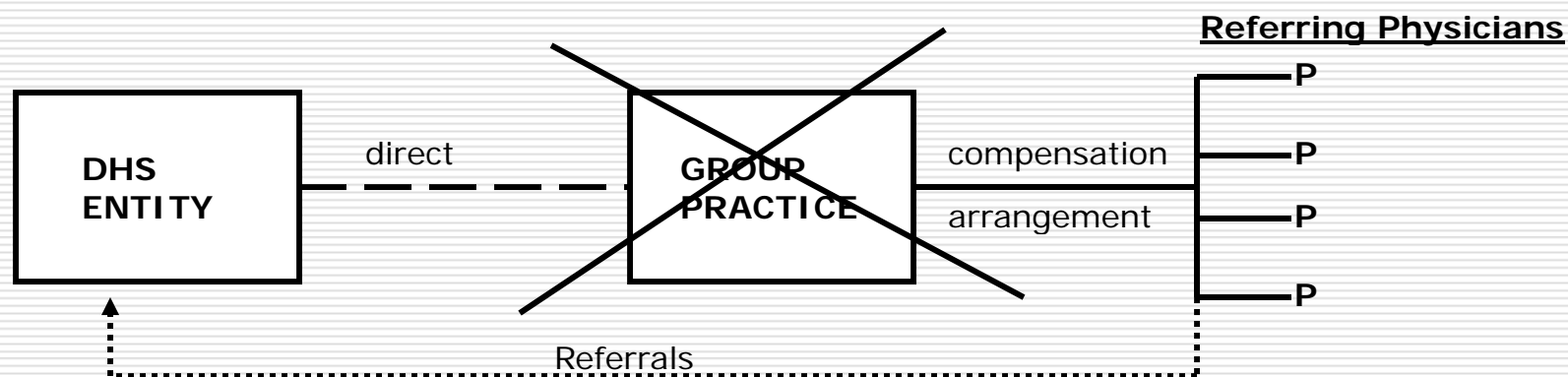
Physician Stand in the Shoes (SITS) -- Background

- ❑ The "Unintended Loophole:" (72 Fed. Reg. 51012, 51026 (September 5, 2007))
Referring Physicians



- ❑ In order to have an indirect compensation arrangement, the referring physician must receive compensation that varies with, or takes into account, the volume or value of referrals or other business generated by referring physician for the DHS entity. (411.354(c)(2)(ii)).
- ❑ Some parties took the position that the arrangement depicted above was *not* subject to the Stark law because compensation paid by the group practice to the referring physicians is based on personal productivity, not referrals to the DHS entity. (72 Fed. Reg. 51012, 51027-28 (September 5, 2007)).

Physician Stand in the Shoes (SITS) -- Background



- ❑ **Phase III rule:** Referring physician is deemed to stand in the shoes of his or her physician organization (e.g., physician practice, group practice).
- ❑ As a result, Phase III rule disregards the intervening physician organization and treats the arrangement depicted above as a direct compensation arrangement, between the DHS entity and each referring physician, that must satisfy the more stringent requirements of a direct compensation exception (e.g., 1-year term, compensation set in advance, fmV compensation for services provided).
- ❑ **Problem:** "mission support" payments made to physician organizations by academic medical centers and integrated 501(c)(3) systems cannot satisfy the requirements of a direct compensation exception. (72 Fed. Reg. 64161 (November 15, 2007))

Physician Stand in the Shoes (SITS) – New Rule (411.354(c))

- ❑ **Mandatory SITS Rule**: A physician who has an *ownership or investment interest* in a physician organization will be deemed to stand in the shoes of his or her physician organization.
 - Exception: A physician whose ownership or investment interest is *titular* (e.g., no right to distributions) is not required to stand in the shoes of his or her physician organization.
 - Example: owner of a captive PC.
- ❑ **Permissive SITS Rule**: A non-owner (employee or independent contractor) or titular owner is permitted (but not required) to stand in the shoes of his or her physician organization.

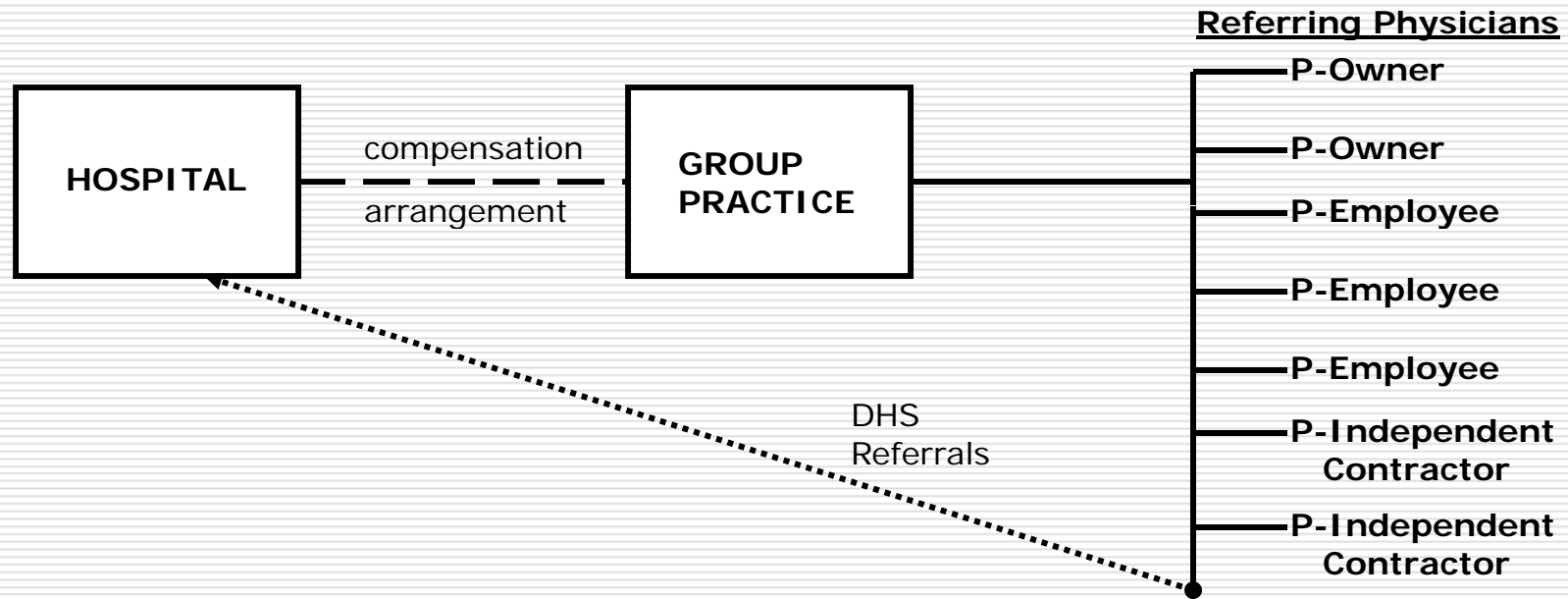
Physician Stand in the Shoes (SITS) – New Rule (411.354(c))

- ❑ SITS provisions do not apply to an arrangement that satisfies the requirements of the exception in 411.355(e) for academic medical centers.
- ❑ New rule does not require restructuring of agreements structured to comply with the Phase III SITS rules.
- ❑ **Effective Date:** New rule is effective October 1, 2008.

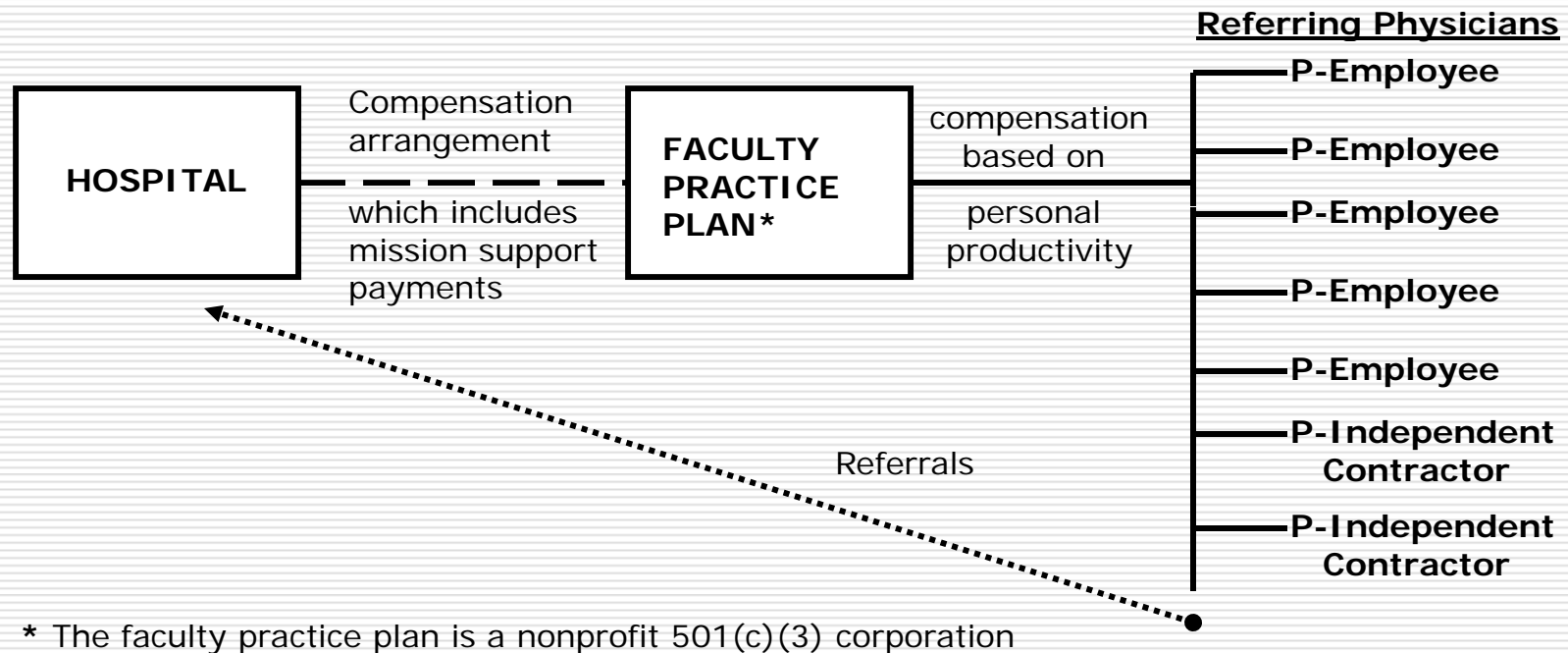
Entity Stand in the Shoes (SITS)

- ❑ **Proposed rule**: A DHS entity would stand in the shoes of an organization in which it holds a 100% ownership interest.
- ❑ Proposed rule not finalized. (73 Fed. Reg. 48434, 48699-48700 (August 19, 2008))
 - eliminates the need for conventions governing the application of the physician SITS rules and entity SITS rules when both rules could apply to the same chain of financial relationships.
- ❑ **CMS warning**: Interposing shell entities between the DHS entity and referring physicians to evade the Stark regulations may violate the Stark law, constitute a circumvention scheme or violate the antikickback statute. (73 Fed. Reg. 48434, 48699 (August 19, 2008))

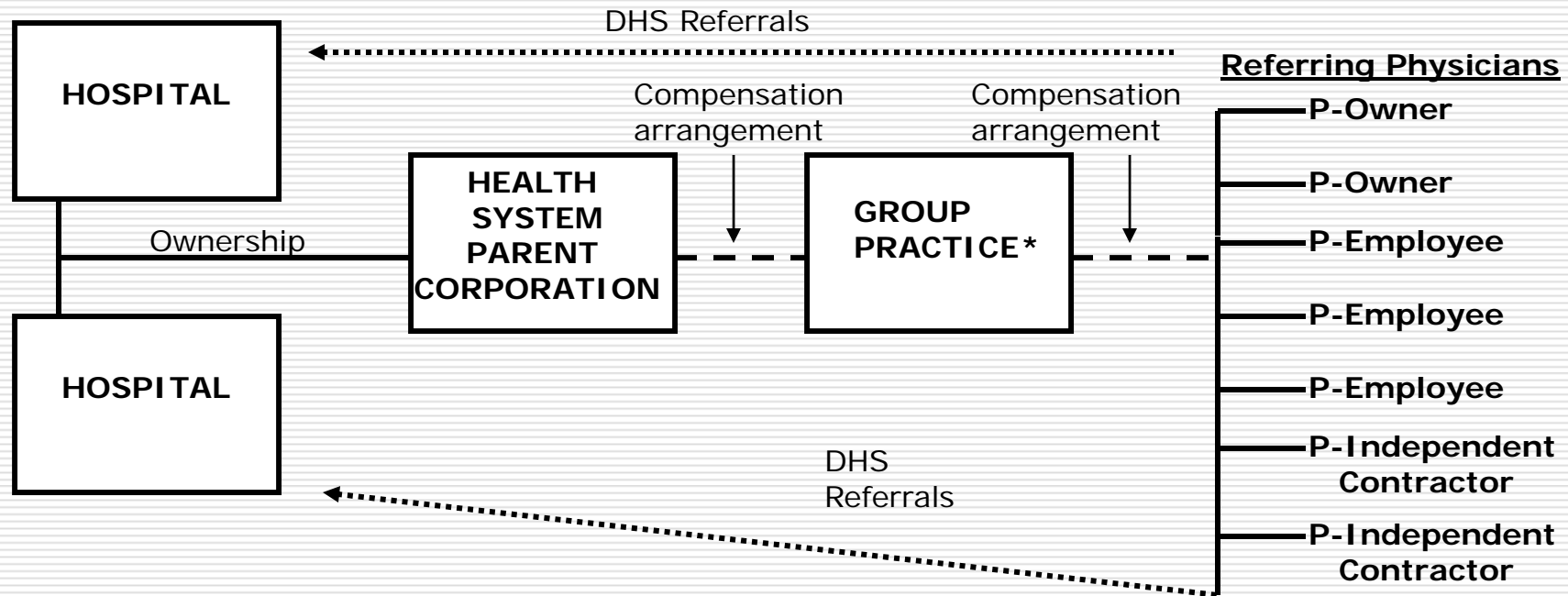
Physician Stand in the Shoes (SITS) – Example #1



Physician Stand in the Shoes (SITS) – Example #2



Physician Stand in the Shoes (SITS) – Example #3



* The group practice is a for-profit entity

Amendment of Compensation Terms

- ❑ **Issue**: May rental charges or compensation terms be changed during the term of an agreement?
 - ❑ **Phase III rule (9-7-07)**:
 - May not change at any time during term.
 - Parties wishing to change must terminate the agreement and enter into a new agreement.
 - Cannot enter into new agreement until after the first year of the original agreement.
 - New agreement must be for a term of at least 1 year and comply with the other requirements of the relevant exception.
- (72 Fed. Reg. 51012, 51044 (September 5, 2007))

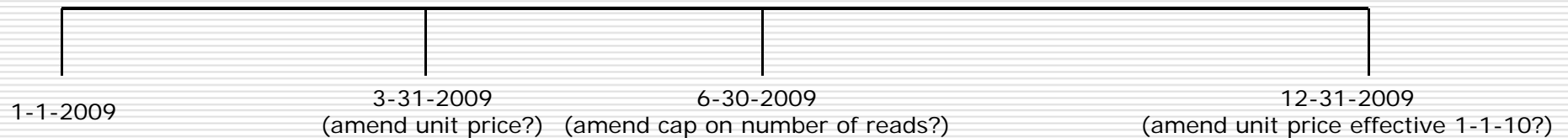
Amendment of Compensation Terms

□ **New Interpretation:**

- Amendment of rental charges or compensation terms (or formulas) is permitted provided that:
 - (i) all of the requirements of the applicable exception are satisfied.
 - (ii) the amended rental charge or other compensation (or formula) is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be verified objectively.
 - (iii) formula does not take into account the volume or value of referrals or other business generated by the referring physician.
 - (iv) the amended rental charge or compensation must remain in place for at least 1 year from the date of the amendment (73 Fed. Register 48434, 48697 (August 19, 2008)).
 - New interpretation applies to all of the compensation exceptions that include a 1-year term requirement (rental of office space, rental of equipment, personal service arrangements).
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Amendment of Compensation Terms -- Example

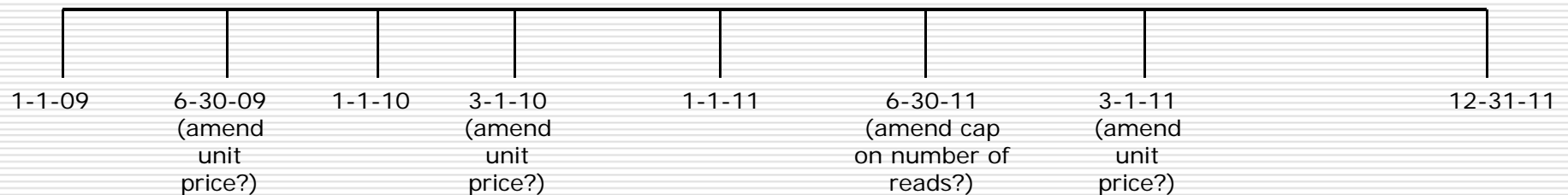
- ❑ Physician provides personal services (reading EKG's at FMV unit price) for hospital; contract cap on number of reads per year.
- ❑ Contract signed 1-1-09 for 1-year term.
- ❑ Agreement renews automatically.



- May parties amend the per read unit price on March 31, 2009 based on new FMV valuation?
- May parties amend to increase cap on maximum number of reads to be performed in 2009? How many times may they amend?
- May the parties amend the unit price beginning in 2010 based on new FMV valuation?

Amendment of Compensation Terms -- Example

- ❑ Same Facts Except that Contract Has 3-Year Term.



- May parties amend the per read unit price on June 30, 2009 based on new FMV valuation?
- May parties amend the per read unit price on March 3, 2010 based on new FMV valuation?
- Between January 1, 2009 and December 31, 2011, may the parties increase the maximum cap on reads? If so, how often may the parties make such an amendment?
- May the agreement have a price escalation formula? How often can the per unit fee escalate?

"Under Arrangements" -- Background

❑ Authority

- Hospitals allowed to bill Medicare for services furnished "under arrangements" (42 USC §1395x(w)).

❑ Requirements (partial list):

- Not intended for hospital merely to serve as billing mechanism for the service provider.
- Hospital must exercise professional responsibility over the arranged-for-service.
- The same quality controls are applied to under arrangements services as are applied to services furnished by salaried employees.
- Hospital must ensure that the medical necessity of the services is reviewed on a sample basis.

(Medicare General Information, Eligibility and Entitlement Manual (CMS Pub. 100-01), Chapt5, §10.3.)

“Under Arrangements” – Final Rule: Definition of “Entity” (411.351)

□ Current Rule:

- An entity is considered to be furnishing DHS if it is the entity to which CMS makes payment for the DHS.

□ New Rule:

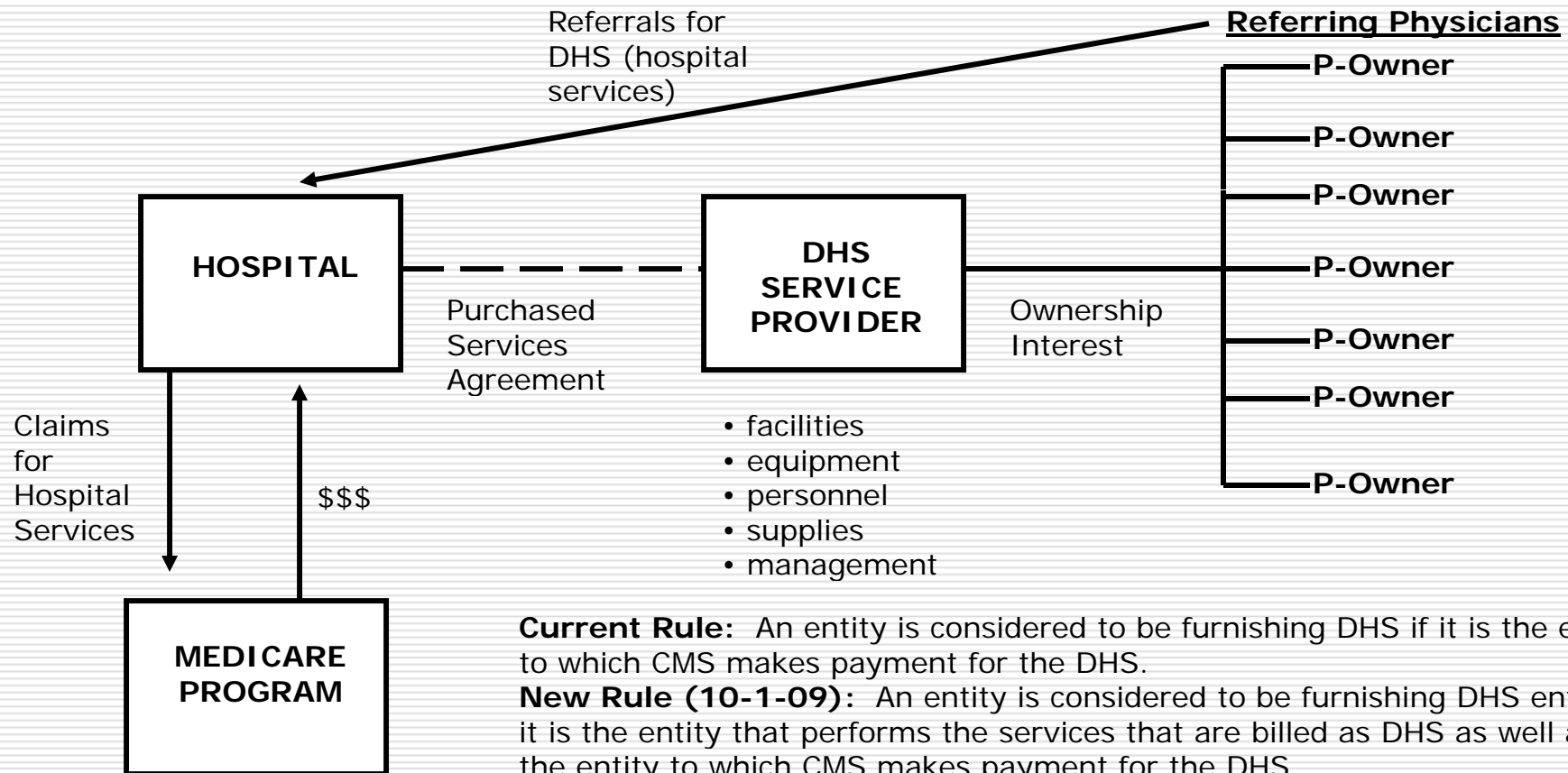
- An entity is considered to be furnishing DHS entity if it is the entity that performs the services that are billed as DHS as well as the entity to which CMS makes payment for the DHS.

- Effective Date: October 1, 2009.

□ Issue:

- When is an entity “performing” the services that are billed as DHS?

UNDER ARRANGEMENTS -- EXAMPLE



Under Arrangements -- Litigation

- *Colorado Heart Institute v. Levitt*, No.: 1:08-cv-0126-RMC (D.D.C).
 - 9-25-08 – Three Colorado-based physician-owned companies, that furnish cardiac catheterization services under arrangements to local hospitals, file suit in federal court.
 - Seek to invalidate the “under arrangements” portion of the new regulations on the ground that it is based on an impermissible interpretation of the Stark law and that CMS exceeded its authority in promulgating the new regulation.

Prohibition on Per Click Lease Arrangements

- ❑ CMS identified per-click leases as at risk for over-utilization
- ❑ CMS expressed concerned that hospitals were "forced" to enter into such agreements for fear of losing physician-lessor referrals
- ❑ CMS raised concerns with commercial reasonableness of per click leases for high volume services

Per Click Lease Arrangements

- ❑ Prohibits per unit of service rental charges when payment reflects services provided to patients referred between the parties
- ❑ Affected Stark Exceptions
 - Rental of Office Space
 - Rental of Equipment
 - FMV
 - Indirect Compensation

Per Click Lease Arrangements

- Effective October 1, 2009
- "On Demand" Lease will be deemed to be per click arrangements

Per Click Questions

- Does the language "referred between the parties" prohibit a per click lease between a DHS entity-lessor and a physician-lessee? What if the DHS entity is a hospital? What if the hospital has employed primary care physicians?
- Will a weekly lease of a four hour block of time be an "on-demand" lease?
 - What if the weekly block is cancellable upon 24 hours notice
 - What if the weekly block is subject to schedule changes on 24 hours notice

Per Click Questions

- Will an agreement to obtain services from a physician or physician group that are provided by the physician in his/her office utilizing space and equipment fall under the definition of a "per click" lease arrangement?
- If the "under arrangements" service is provided by a hospital owned by physicians under the whole hospital exception, would that service fall under the definition of a "per click" lease compensation?

Prohibition on Percentage-Based Lease Arrangements

- ❑ CMS limited the restriction on percentage based compensation formulae to "percentage of revenue raised, earned, billed collected or otherwise attributable to the services performed or business generated"
- ❑ The current rules do not prohibit percentage based compensation for personal services, management or billing services (the last two arrangements are under on-going evaluation)
- ❑ Effective October 1, 2009

Percentage-Based Lease Arrangements

- Affected Stark Exceptions
 - Rental of Office Space
 - Rental of Equipment
 - FMV
 - Indirect Compensation
- Does not prohibit a lessor from charging pro rata share of expenses (i.e., common area charges)

Percentage Formulae Questions

- Can parties allocate the total rental expenses between themselves based upon each party's respective revenues?

Disclosure of Financial Relationships Report

- Current proposal -- send the DFRR to 500 hospitals
 - Identify non-compliant arrangements
 - Allow CMS to refine reporting requirements and other Stark provisions
 - CMS indicated that it may decide to decrease (but not increase) the number of hospitals to which the DFRR will be sent
- Hospitals will have 60 days to respond
- Failure to disclose information in a timely manner could result in a \$10,000 per day CMP
 - CMS will strive to avoid CMP

DFFR

- ❑ Estimated time to complete DFRR was increased dramatically as was the anticipated cost
- ❑ CMS is not, at this time, adopting a regular reporting or disclosure process (current DFRR will be a one-time collection effort)

DFRR – Practical Considerations

- Does the Hospital have a process for tracking all arrangements with physicians?