

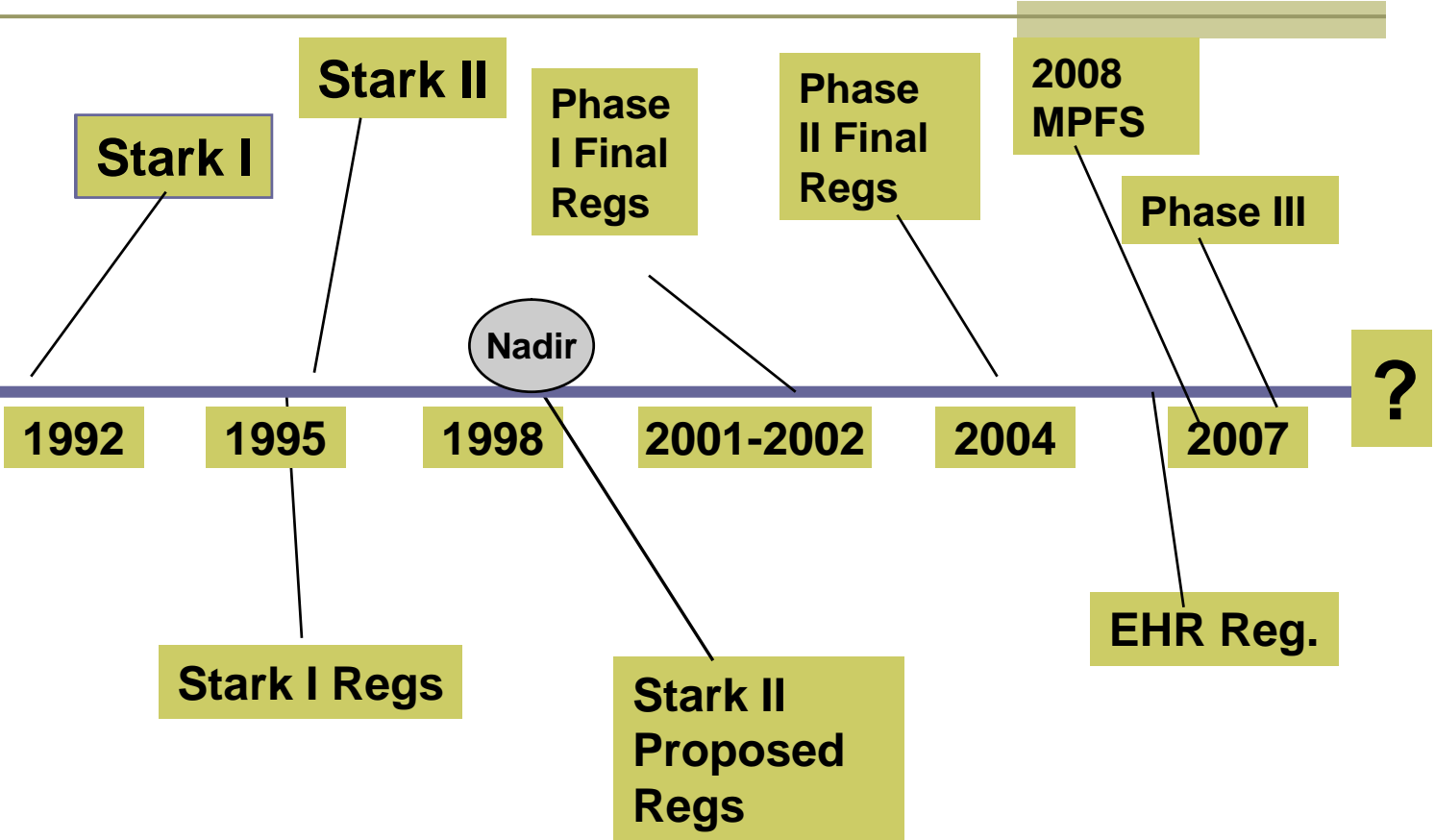
A Conversation About Stark

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Stark Timeline



Stark Law: The Basics

Stark prohibits a physician from referring Medicare patients to an entity for designated health services if the physician (or an immediate family member of the physician) has a financial relationship with the entity, unless an exception applies.

Stark Prohibition/Penalties

- Physicians cannot refer Medicare patients
- Receiving entity cannot bill the program for services provided pursuant to a tainted referral
- Denial of payment, repayment, civil penalties, exclusion
- False Claims Act?

Stark Reality



- **Statute imposes a broad strict liability prohibition.**
- **Compliance is challenging but violations have the potential to be very costly.**
- **“Guidance” from regulators has been slow and inconsistent.**
- **Certifying compliance with the Stark Law can be risky.**

Brief Overview

- **2008 MFPS Proposed Rule**
- **Stark II Phase III Final Rule**
- **Delayed implementation of certain provisions**
- **IPPS Proposed Rule and what's expected next**

2008 Medicare Physician Fee Schedule Proposed Rule

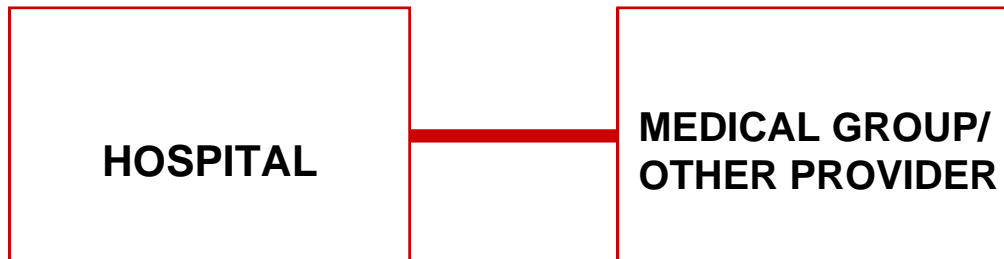
- Summer 2007 CMS used the MPFS Proposed Rule to describe a number of different revisions to the Stark regulations
- Among the most controversial:
 - Revising Definition of Entity (target under arrangements deals)
 - Per click lease arrangements
 - Stand in the shoes applied to Entities
 - Percentage compensation and set in advance

Definition of Entity: Under Arrangements Under Fire

- Proposed Stark change-

“Entity” shall mean:

the person or entity that presents claims to Medicare for DHS (as in the current definition), *and* the person or entity that either *provides* the DHS or “*causes a claim to be presented*” for the DHS



Under Arrangements Under Fire

- **Elimination of under arrangement transactions?**
- **Under what circumstances will an under arrangement service provider be deemed to be “causing a claim to be presented” by the hospital?**
- **How will CMS address services that are not DHS when directly furnished (such as most cardiac catheterization procedures, endoscopy or lithotripsy), but become DHS hospital services when furnished under arrangements?**

Per Click Lease Rates: Misquoted and Misunderstood

- No per-click rent payments to physician lessors when a DHS entity lessee uses the space or equipment to furnish services to patients referred by the physician lessor

- Impact: Significant effect on the equipment/space rental arrangements directly between physicians and DHS entities, BUT

As proposed, the rule would *not* affect most jv leasing companies

Percentage Compensation: Evolving Standards

- **Phase III also raises issues concerning percentage compensation arrangements**
 - **CMS suggests percentage compensation will not be treated like per-unit compensation**
 - **Concerns about FMV and whether percentage compensation is based on volume or value of referrals (back door anti-kickback analysis)**
 - **Proposed rules permit percentage compensation only in connection with revenues derived from services personally performed by the compensated physician**

PHASE III



- Phase III final rule was published Sept. 5th and went into effect Dec. 4, 2007

- Major changes
 - “Stand in Shoes” concept
 - Physician Recruitment

- Issues to Watch
 - Percentage compensation
 - Shared use of leased space/equipment
 - Amendments to agreements
 - Recordkeeping and reporting

Amending Agreements

- Under Phase III, CMS now requires leases for space & equipment to be *terminated* and new agreements must be entered into for any changes in rental rates or other “material” terms
- Similarly, agreements for personal services arrangements must also be *terminated*, rather than amended, for any “material” change in compensation or scope of services

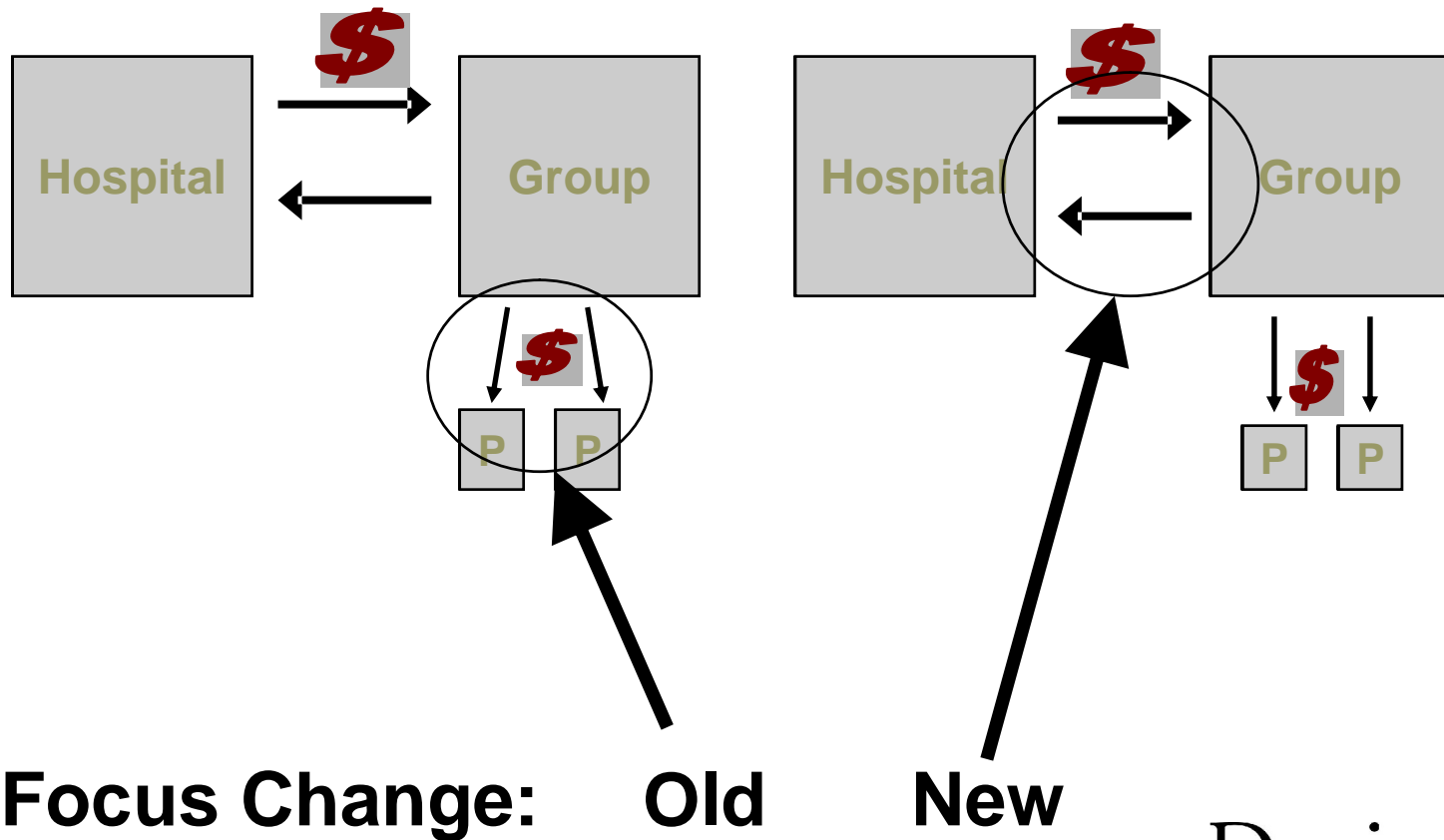
Stand in the Shoes: Why?

- In Phase I of the Stark II regulations, CMS established a broad definition for indirect compensation arrangements
- Anytime there is an intervening entity between the physician and the provider of DHS, the relationship will be indirect (and may not even qualify as a financial relationship under the existing definition)
- CMS is concerned that its indirect compensation arrangements definition has “loopholes” and that the indirect exception is less onerous than most direct exceptions

Stand in the Shoes

- CMS is searching for ways to narrow the indirect analysis
- Under Phase III: a physician is deemed to stand in the shoes of his/her “physician organization” when that organization enters into a financial arrangement with a DHS entity
- Thus, the relationship between the physician organization and the DHS entity must be structured to fit within a direct exception rather than an indirect exception

Stand in the Shoes



Physicians in the Group

- CMS broadly defines the range of physicians deemed to stand in the shoes of a physician organization as any physician who is a member of the organization, employed by it or contracts with it
- Thus, a physician with only passing contact with a group may nonetheless be deemed to stand in the shoes of the group when analyzing any of the group's financial relationships with DHS entities

Stand in Whose Shoes?

- One of the challenges to the “Stand in the Shoes” concept is that a physician stands in the shoes of a “physician organization” he/she is employed by or contracts with
- But what is a “Physician Organization”?
 - Aimed at group practices but . . .
 - Great deal of confusion during Fall of 2007
 - Academic Medical Centers and Integrated Delivery Systems strongly objected

What is a Physician Organization?

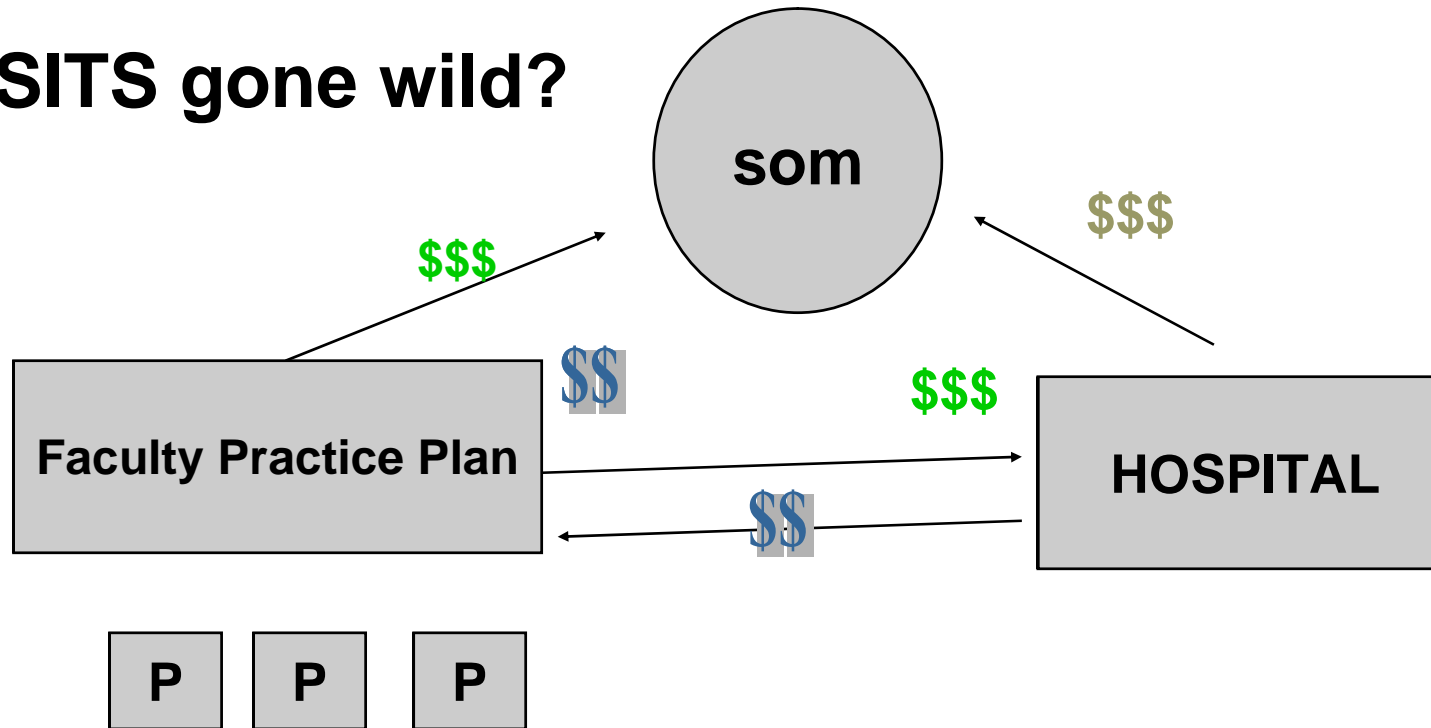
- **CMS gradually provided guidance**
 - **If the primary function of the organization is the delivery of physician services then it is likely a PO**
 - **Not dependent on physician ownership**
 - **But, hospital that employs physicians not PO, nor is a FQHC**

Physician Organization: AMCs

- **Application of Stand in the Shoes in the context of Academic Medical Centers**
- **Most AMCs relied upon indirect compensation exception in addition to the AMC exception to protect transfers between components of the AMC**
- **If physicians stand in the shoes of the Faculty Practice Plan then the transfers to or from the Plan to the Medical Center must all fit within a direct Stark exception**

AMCs

■ SITS gone wild?



Stand in the Shoes: CMS blinks

- After AAMC and others lobbied CMS, the agency delayed the application of Stand in the Shoes to AMCs and tax exempt integrated delivery systems
- One year delay but intention was to craft a permanent solution during that period

Spring 2008: IPPS Proposed Rule

- **CMS proposes that a physician will not Stand in the Shoes of his/her Physician Organization if total compensation from the organization fits within the exception for**
 - **Employment**
 - **Personal Services**
 - **FMV**

IPPS Proposed Rule

- **CMS also proposes not to apply SITS to**
 - **Relationships that meet the AMC exception**
 - **Relationships between Physician Organization and AMC component for purpose of satisfying Graduate Medical Education Rules**

IPPS Proposed Rule

- **Alternative solution: Only physician owners would stand in the shoes of a physician organization**
- **Alternative Solution: New exception for mission support payments**
 - Number of undefined terms, open issues
- **Aside: CMS suggests Indirect Compensation arrangement definition is being construed too narrowly**

“Entity” Stand in the Shoes

- In the 2008 Medicare Physician Fee Schedule Proposed Rule (published in the summer of 2007) CMS proposed to further narrow the indirect analysis by deeming that a DHS entity will stand in the shoes of another DHS entity that it owns or controls
- In the IPPS Proposed Rule (published in April 2008) CMS proposes that a DHS entity will stand in the shoes of an organization in which it has a 100% ownership interest

Entity Stand in the Shoes

- **Entity SITS as proposed**
 - **Includes all wholly owned organizations not just providers of DHS**
 - **Does not include controlled entities or arrangements whereby entity is sole member of another nonprofit**

Entity vs. Physician SITS

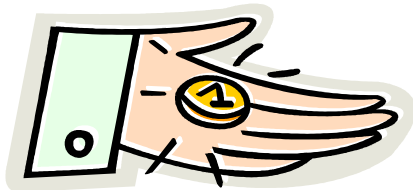
- CMS addresses what one should do when both concepts apply but does not propose regulatory text
- If, after applying Physician SITS, the only relationship between the collapsed physician organization and the DHS entity is an ownership interest then Physician SITS does not apply and entity SITS would apply first
- If more than 2 organization remain after first collapsing the physician organization then one should apply entity SITS
- Are they kidding?

Physician Recruitment

- **Significant changes to Recruitment Exception:**
 - **Who can recruit?**
 - **Geographic area served by hospital?**
 - **Relocation requirement**
 - **Recruitment involving groups**

Who and Where

- Who can recruit expanded to include hospitals, FQHC and rural health clinics
- Geographic area served by hospital – CMS sticks with contiguous zip code test but makes its application more flexible



Relocation Requirement

- **CMS clarifies that relocation is a two-part test:**
 - **Physician must relocate his/her practice from outside hospital's service area into the hospital's service area, and**
 - **Move at least 25 miles or derive 75% of revenues from new patients**

Recruitment Involving Groups

- Practice Restrictions okay?
- Phase II suggested that a host physician group could not impose any restrictions on the ability of the recruit to continue practicing in the community
- Phase III says groups cannot impose requirements that “unreasonably restrict” the recruit’s ability to practice in the community

Recruitment

- **Phase III provides a list of permissible restrictions:**
 - **Restrictions on moonlighting**
 - **Restrictions on solicitation of employees or patients**
 - **Requiring recruit to treat Medicare or indigent patients**
 - **Restricting use of confidential information**
 - **Requiring repayment of losses to group**

Recruitment

- **Phase III clarifies what expenses qualify as recruiting expenses**
- **Host groups of physician with income guaranty still limited to additional incremental cost of new physician, except in limited situations**
- **Must be recruited to join medical staff**
- **If already a medical staff member, a physician is ineligible**

Recordkeeping and Reporting

- Phase III commentary assumes in several places that providers have in place the infrastructure necessary to identify and track their financial relationships with physicians
- The comments suggest a disconnect between CMS' assumptions and reality
- The Disclosure of Financial Relationships Report (DFRR)
 - Withdrawn by CMS in mid April
- New reporting process addressed in IPPS Proposed Rule

Period of Disallowance

- **IPPS Proposed Rule addresses once a violation occurs how long the physician prohibited from referring to the entity and entity prohibited from billing for services referred by physician**
 - **If not related to compensation the date the relationship fits within an exception**
 - **Where noncompliance is due to payment of an insufficient amount date on which the additional compensation is paid**
 - **Where noncompliance due to payment of excess compensation the date on which the compensation is returned**

The Future?

- **Stark will continue to evolve**
- **Indirect Analysis continue to evolve**
- **CMS concerned about under arrangements services agreements, leasing company arrangements and management services**
- **Law of unintended consequences will continue to plague CMS's changes**