What’s a Doc to Do? Stark Phase III & Anti-Markup Rules:  
The Impact on Physician Relationships and Ventures  

Beyond Anti-Markup: “Stand In The Shoes”  
and Other Practical Implications

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The American Bar Association Health Law Section and the ABA Center for Continuing Legal Education
“Stand In The Shoes” - Background

- **Phase I: Concept borrowed from reassignment provisions**
  - To qualify for “group practice” definition, *locum tenens* physicians “stand in the shoes” of regular physicians
  - For purposes of “substantially all” test of IOAS exception, on-call physicians “stand in the shoes” of group practice members

- **Phase II: Extension of concept suggested, but not adopted**
  - Commenter proposes physicians “stand in the shoes” of their group practices
  - CMS indicates proposal is “inconsistent with exceptions as drafted,” but solicits comments on issue
  - CMS amends definition of “referring physician” to clarify that, for practical purposes, physician *does* “stand in the shoes” of his or her solely-owned professional corporation

- **Phase III: Extension of concept adopted**
  - CMS reveals concern with “unintended loophole” within definition of “indirect compensation arrangement”
  - To close this loophole, physicians now “stand in the shoes” of their “physician organizations”
Stand In The Shoes - Application

- For purposes of determining whether a direct or indirect compensation exists between a physician and an entity to which the physician refers Medicare patients for DHS, the referring physician “stands in the shoes” of his or her physician organization.

- “When a physician stands in the shoes of his or her physician organization, he or she will be deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity.”
“Stand In The Shoes” – Application Resulting in the Need for a Direct Compensation Arrangement Exception

EKG READ CONTRACT ($10 per read)

HOSPITAL

GROUP PRACTICE

Salaried, employed physicians

MD

MD

MD
“Stand In The Shoes” – Application Resulting in the Need for the Indirect Compensation Arrangement Exception

HOSPITAL

OWNERSHIP

MANAGEMENT COMPANY

EKG READ CONTRACT ($10 per read)

GROUP PRACTICE

MD

MD

MD

Salaried, employed physicians
“Stand In The Shoes” – Application Resulting in a Chain of Financial Relationships that Remains Outside the Scope of Stark Regulations

HOSPITAL

MANAGEMENT COMPANY

GROUP PRACTICE

Salaried, employed physicians

Fixed, $900,000 24/7/365 Coverage Contract (FMV!)
Stand In The Shoes – Why It Matters

- Many arrangements previously determined to be outside the scope of the Stark regulations are now within the scope of the Stark regulations
- Many arrangements previously excepted by the exception for indirect compensation arrangements must now meet an exception for direct compensation arrangements
  - “Set in advance” requirements
  - If a lease arrangement, exclusivity provisions apply
  - Term of one year or more; if terminated within first year, prohibition of new agreement applies
  - Cross-referencing requirements apply
  - Solicitations and offerings of charitable donations
Definitional Issues

- “Physician Organization” means:
  - A physician
  - Solely-owned professional corporation
  - Group practice meeting requirements of 42 CFR §411.352
  - A “physician practice”
  - (Per Nov. 15 Final Rule: “another physician who employs the referring physician”)

- Until recently, “Physician Practice” remained undefined
  - Phase III:
    - By inference, not a management company
    - By inference, not a “leasing or other entity”
  - Nov. 15 Final Rule:
    - “that is, a medical practice”
    - By inference, faculty practice plans qualify
    - By inference, physician practice affiliates of integrated §501(c)(3) health care systems qualify
Definitional Issues, cont.

- January 31, 2008 FAQ: “Physician Practice” does not mean:
  - Hospitals
  - Non-hospital Part A providers of services
  - Staffing companies, if they do not directly bill and provide for patient care services but merely facilitate the provision of physicians to hospitals and other providers
  - A single legal entity that operates both 1) a FPP and 2) either a medical school and/or a hospital… unless it qualifies as a “Group Practice” under 42 CFR §411.352
  - A medical school that employs physicians to provide clinical and administrative services… unless it operates a FPP
  - Federally Qualified Health Centers
Definitional Issues, cont.

- January 31, 2008 FAQ: “A ‘physician practice’ is a medical practice comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership).”
  - Level of physician ownership (or lack thereof) is irrelevant to the determination
  - It is also irrelevant whether patient care services are provided by employed or contracted physicians

- Without bright line test, turnkey component of analysis appears to be “medical practice”
Practical Problems

- Physicians as “party” to the contract – contractual liability?
  - Per FAQ: CMS considers physicians to have signed the agreement when the physician organization did

- Counseling physicians: what must / should physicians ask of their “physician organizations”?
  - List of / review all agreements / relationships with DHS entities?
    - Only direct agreements, or indirect relationships as well?
    - Monitor all new agreements? Amendments?
  - Legal assurance re satisfaction of one or more exceptions?
  - Fair market value assurances?
  - Indemnification?
Analytical Problems

- Signatory requirements: must the physician become a signatory in order to satisfy certain exceptions?
- If a hospital-group practice agreement is terminated within one year: can the hospital and the physician enter into a new (or substantially similar) agreement?
- Cross-referencing / master lists
- “Fair market value” as part of Stand In The Shoes
- Provision of non-monetary compensation in excess of $300 to a group practice: how do you calculate it, how can you pay it back?
Grandfathering and Implementation Timeframes

- Certain arrangements were grandfathered, i.e., not subject to Stand In The Shoes on December 4, 2007. Specifically, those that:
  - Were entered into on or before September 4, 2007; and
  - Satisfied the exception for indirect compensation arrangements as of September 5, 2007
  - Jan. 31, 2008 FAQ: grandfathering does not apply to an arrangement that did not meet the definition of an “indirect compensation arrangement,” even if it met the exception for indirect compensation arrangements

- If grandfathered, Stand In The Shoes does not apply until the expiration of the “arrangement’s” current term (i.e., current as of September 5, 2007)
  - But… term of which agreement within the arrangement?

- What about physician organizations such as Group Practices, i.e.:
  - in which 1 or more physicians have an ownership interest, and
  - that employ 1 or more physicians?
Grandfathering and Implementation Timeframes, cont.

- The exception for temporary non-compliance (42 CFR §411.353(f))… a virtual delay for Stand In The Shoes?
  - Note Phase II commentary: non-compliance caused by regulatory changes are “beyond the control” of the DHS entity
  - Would apply to a financial relationship previously excepted by the exception for indirect compensation arrangements, if:
    - The relationship was in place on or before June 7, 2007
    - §411.353(f) had not been used since December 4, 2004 to except a financial relationship with the same referring physician
    - The relationship does not violate the Anti-Kickback Statute, and claims and bills comply with all applicable Federal and State law, rules and regulations
    - The relationship complies with an exception, after the application of the Stand In The Shoes analysis, by March 3, 2008
  - Can this exception apply to financial relationships previously determined to be outside the scope of the Stark Law, i.e., if they “complied with an applicable exception”? 
Grandfathering and Implementation Timeframes, cont.

- Nov. 15, 2007 Final Rule: Stand In The Shoes has been delayed until December 4, 2008 for situations where:
  - The DHS entity is an AMC as defined in 42 CFR 411.355(e)(2), and the physician organization is a FPP;
  - The DHS entity is an affiliate of an integrated §501(c)(3) health care system, and the physician organization is a FPP within that same system

- Rationale: AMC support payments / transfers made to FPPs are not made for specific items or services, but to support the overall mission of the AMC
  - Accordingly, such payments / transfers would be unlikely to satisfy an exception for direct compensation arrangements
Stand In The Shoes – More to Come?

- July 2007 Proposed Medicare Physician Fee Schedule rule: DHS entity would Stand In The Shoes of any entity it owns or controls, if a physician refers patients to the owned or controlled entity for the provision of DHS
  - What is sufficient ownership? 1%? 50%? 51%? 100%
  - What is “control”?

- Purpose: avoid abuse by parties who insert “an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician”

- Achieved? If the owned or controlled entity provides DHS, doesn’t the physician’s arrangement with that entity already have to meet an exception for direct compensation arrangements?
Indirect Compensation Arrangements

- In response to commenter requesting that 90-day “cure period” run from date of discovery of non-compliance, rather than from date of falling out of compliance, CMS: Stark Law “is intended to deter inappropriate financial relationship through a strict liability scheme. A discovery-based rule is contrary to the statutory scheme.”

- Phase III clarification or confusion re “knowledge” element?
  - “Any information in the possession of a hospital may be relevant in assessing whether the hospital knew or had reason to know of an indirect financial relationship involving a referring physician” (emphasis added).
  - However, per §411.354(c)(2)(iii), knowledge pertains to the referring physician’s receipt of aggregate compensation varying with referral volume/value… not to the existence of an indirect financial relationship.

- If the flow of compensation runs from the referring physician to the DHS entity (through an intervening entity), can an indirect compensation arrangement exist?
Percentage-Based Compensation Arrangements

- **Phase II:**
  - Percentage-based compensation arrangements can be “set in advance” if fixed at outset, sufficiently specific, and do not change during course of agreement to reflect referral volumes

- **Phase III:**
  - Confirmation that %-of collections/revenue methodologies *can be* “set in advance”
  - For purposes of exception for ICAs: “actual” collections matter for determining whether compensation “received” is FMV

- **July MPFS proposal:**
  - %-based arrangements 1) can only be used for paying for personally performed physician services and 2) must be based on the revenues directly resulting from the physician services
  - Impact on gainsharing arrangements?
Effectuating Changes to Arrangements

- Compensation rates / methodologies within leases and personal service arrangements cannot be changed at any time without violating “set in advance” requirements
  - Amendments with new rates / methodologies are insufficient… unless they operate to terminate the old agreement and replace it with a new one, e.g., as amended
  - Keep in mind the 1-year rule

- Furthermore, changes to “material” terms of arrangements may cause non-compliance with FMV, referral volume standards
  - Changes to scope of services performed
  - Changes to amount of office space leased
  - Changes to type of equipment leased

- Precisely the type of issues that are not implicated by the exception for Indirect Compensation Arrangements
Group Practice Issues

- Clarification: productivity bonuses may *directly* relate to the volume/value of a physician’s referrals for DHS “incident to” the physician’s personally performed services
  - Justification: heightened supervision requirements of “incident to” billing rules (present in office suite and immediately available)
  - Only services under such direct supervision?

- Reversal: profit shares may *not* directly relate to the volume/value of a physician’s referrals for DHS “incident to” the physician’s personally performed services
  - Justification: inconsistent with statutory language, Phase I interpretation
Group Practice Issues, cont.

- Physicians In The Group
  - Must have “strong and meaningful nexus” to group
  - An independent contractor can qualify, so long as:
    - He or she has a direct contract with the group, and
    - Only when he or she performs services in the group’s facilities
  - An employee leased from another entity does not qualify

- In-Office Ancillary Services Exception
  - Will it be narrowed?
  - Certain DHS (in-office path labs, imaging equipment) to be carved out?
Other Issues

- **Phase III:**
  - Holdover PSAs allowed. Retroactively?
  - In re FMV, professional and administrative services should not be paid at the same rate
    - Be wary of use of clinical salary surveys to justify admin rates
  - In re non-monetary compensation:
    - One annual medical staff free-for-all (no door prizes)
    - Inadvertent, excess NMC can be repaid in certain conditions

- **July MPFS proposals:**
  - “Entity” to include those who “cause a claim to be presented”
  - Period of disallowance – forever tainted?
    - Can compliance problems be confined to a finite period of time?
  - Certain per-click leases to be prohibited
  - Potential expansion of exception for OB malpractice subsidies
  - Alternative methods of compliance?