New Stark Rules Effective October, 2008: Are You In Compliance?

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“Stand In The Shoes” Rulemaking

- Stark II, Phase III
  - Final Rule (September 5, 2007)
  - Temporary Delay (November 15, 2007)
  - CMS Frequently Asked Questions (January 31, 2008)

- “Stark III”
  - 2008 PFS Proposed Rule (July 12, 2007)
  - CMS Change Request (August 15, 2008)
  - 2009 IPPS Final Rule (August 19, 2008)

- Relevant Effective Dates
  - December 4, 2007
  - October 1, 2008
Before “Stand In The Shoes”: An Indirect Compensation Arrangement World

- Definition of “indirect compensation arrangement” has been and remains narrow:
  - Aggregate compensation received must vary with or reflect volume or value of referrals (or other business) that physician makes to (or generates for) the DHS entity
  - If DHS entity does not know whether such compensation varies with referral volume (or business generated), there is no ICA unless the entity recklessly disregards such knowledge or remains deliberately ignorant
  - Catch: fair market value

- CMS acknowledged this “loophole” in Stark II, Phase III
- CMS also said “[a]ny 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).
Before “Stand In The Shoes”: Example of Arrangement Failing to Effectuate an Indirect Compensation Arrangement

HOSPITAL

GROUP PRACTICE

MD 1

MD 1

MD 2

MD 3

Salaried, employed physicians

EKG READ CONTRACT ($10 per read)
“Stand In The Shoes” - History

- **Stark II, 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

- **Stark II, 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

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

- **“Stark III”: Extension of concept retracted**
  - Only physicians with ownership interests in their physicians organizations now “stand in the shoes” of such physician organizations
Stark II, Phase III “Stand In The Shoes”: Application

- Relevant timeframe: December 4, 2007 through September 30, 2008
- 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.”
Stark II, Phase III “Stand In The Shoes”: Application Resulting in the Need for a Direct Compensation Arrangement Exception

HOSPITAL

EKG READ CONTRACT
($10 per read)

GROUP PRACTICE

MD 1

MD 1

MD 2

MD 3

Salaried, employed physicians
Stark II, Phase III “Stand In The Shoes” – Application Resulting in the Need for the Indirect Compensation Arrangement Exception

HOSPITAL

OWNERSHIP

MANAGEMENT COMPANY

EKG READ CONTRACT
(compensation varies on basis of referral volume)

MD 1

GROUP PRACTICE

MD 1

MD 2

MD 3

Salaried, employed physicians
Stark II, Phase III “Stand In The Shoes” – Application Resulting in an Arrangement that Remains Outside the Scope of Stark Law

HOSPITAL

MANAGEMENT COMPANY

OWNERSHIP

MD 1

GROUP PRACTICE

Fixed, $900,000
24/7/365 Coverage Contract (FMV!)

Salaried, employed physicians

MD 1

MD 2

MD 3
Stark II, Phase III “Stand In The Shoes”: The Impact

- Many arrangements previously determined to be outside the scope of the Stark regulations came within the scope of the Stark regulations
- Many arrangements previously excepted by the exception for indirect compensation arrangements were required to 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
“Stand In The Shoes”: Definitional Issues

- “Physician Organization” means:
  - A physician
  - Solely-owned professional corporation
  - Group practice meeting requirements of 42 CFR §411.352
  - A “physician practice”

- Stark II Phase III did not define “Physician Practice”
  - Sep. 5 Final rule:
    - 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)” (emphasis added).
  - 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 continues to be “medical practice”
Grandfathering and Implementation Timeframes

- Certain arrangements were grandfathered, i.e., those that:
  - Were entered into on or before September 4, 2007; and
  - Satisfied the exception for indirect compensation arrangements as of September 5, 2007

- If grandfathered, SITS does not apply until the expiration of the arrangement’s “current” term (i.e., current as of September 5, 2007)

- Nov. 15, 2007 Final Rule: SITS delayed until Dec. 4, 2008 when:
  - The DHS entity is an AMC as defined in 42 CFR 411.355(e)(2), and the physician organization is a FPP; or
  - 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
“Stark III” “Stand In The Shoes”: Application

- A referring physician “stands in the shoes” of his or her physician organization only if he or she maintains an ownership interest in that physician organization
  - Ownership interests that are “titular” in nature do not cause shoe-standing
  - “Non-owning” (and titular owning) physicians are “permitted” to stand in the shoes of their physician organizations

- Relevant timeframe: On and after October 1, 2008

- More grandfathering: if SITS effectuates an ICA, but the arrangement complies with a DCA exception, the arrangement need not be restructured to meet the ICA exception until the expiration of its original or current renewal term (i.e., “current” as of Aug. 19, 2008)
  - Intent: protect parties who restructured their arrangements to comply with Stark II, Phase III “Stand In The Shoes”
“Stark III” “Stand In The Shoes”: Application Resulting in the Need for a Direct Compensation Arrangement Exception

HOSPITAL

GROUP PRACTICE

EKG READ CONTRACT
($10 per read)

MD 1

MD 2

MD 3

Salaried, employed physicians
“Stark III” “Stand In The Shoes” – Application Resulting in the Need for the Indirect Compensation Arrangement Exception

HOSPITAL

OWNERSHIP

MANAGEMENT COMPANY

EKG READ CONTRACT (compensation varies on basis of referral volume)

GROUP PRACTICE

MD 1

MD 1

MD 2

MD 3

Salaried, employed physicians
“Stark III” “Stand In The Shoes” – Application Resulting in an Arrangement that Remains Outside the Scope of Stark Law

HOSPITAL

OWNERSHIP

MANAGEMENT COMPANY

543x243 PRACTICE

24/7/365 Coverage Contract (FMV!)

Fixed, $900,000

GROUP PRACTICE

Salaried, employed physicians

MD 1

MD 2

MD 3

MANAGEMENT COMPANY

MD 1

MANAGEMENT COMPANY

MD 1
“Stark III” “Stand In The Shoes”: Effects

- Any direct arrangement between a DHS entity and a physician organization owned by 1 or more physicians will still need to be restructured to meet an exception for direct compensation arrangements… but failure to do so very likely taints far fewer referrals and claims.

- “Stand In The Shoes” is now irrelevant for arrangements with physician organizations that are not owned by any physician (AMCs, FPPs).

- What about arrangements effective at any point from December 4, 2007 through September 30, 2008?

- CMS has both acknowledged and preserved the ICA loophole.
“Stand In The Shoes”: Timeframes

Up to and thru 12/3/07:

Nobody
Stands In
Anybody’s
Shoes

12/4/07 thru 9/30/08:

All physicians stand in the shoes of their physician organizations

On and after 10/1/08:

Only certain physicians (those holding an ownership interest in their physician organizations) stand in the shoes of such physician organizations
“Stand In The Shoes”: Questions / Observations

- Physicians as “party” to the contract – contractual liability? CMS: No comment
- Must physicians become signatories in order to satisfy certain exceptions? CMS: No
- If a DHS entity – physician organization agreement is terminated within one year: can the DHS entity and the referring physician enter into a new (or substantially similar) agreement?
  - What if a physician leaves his or her physician organization?
- Cross-referencing / master lists?
- Non-monetary compensation?
Burden of Proof (Effective October 1, 2008)

- Changes to §411.353(c)(2)
- Burden is on provider to demonstrate compliance, i.e., that claims were *not* made pursuant to improper referrals
- Only applies to administrative appeals of claims denials under 42 C.F.R. Part 405, Subpart I (eye)
  - CMS: Specifically stated that this does not apply to FCA cases
- Practical effect: documentation of satisfying an exception (or not satisfying definition of ICA) even more necessary
- But when does CMS ever deny claims on the basis of a Stark Law violation?...
CMS Change Request 6131 (Effective January 5, 2009)

- CMS created Claim Adjustment Reason Code No. 213
- Contractors instructed to use CARC No. 213 when denying claims based on non-compliance with the Stark Law
- But how could / would a contractor determine that a Part A provider has violated the Stark Law?...

- In a one-time effort, CMS will query 500 Medicare-participating hospitals regarding the nature of their financial relationships with referring physicians
- Responses will be due within 60 days (extensions for good cause only)
- Government will not be estopped from further investigation / sanctions
- If CMS does not “find” any violations, that should not be interpreted as an affirmative statement that the hospital’s financial relationships with referring physicians are compliant
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