Stark Law Primer (Part 2): The Physician Perspective

State Bar of Michigan

Health Care Law Section

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The Stark Law: General Overview

- Stark's Basic Prohibition
  - A physician may not **refer**:
    - Medicare patients
    - For **designated health services (DHS)**
    - To an **entity** with which the physician (or immediate family member) has
    - A **financial relationship** unless an exception applies

The Stark Law: General Overview

- **Sanctions and Penalties**
  - Denial of payment/refund of amounts collected
  - CMPs of up to $15,000 for each service a person "knows or should know" violated Stark
  - CMPs of up to $100,000 per circumvention scheme
  - Exclusion from Medicare/Medicaid
  - Qui Tam

The Stark Law: General Overview

- **Key Definitions**
  - **Referral**
    - Does not include personally performed services (e.g., E/M)
    - Does include "incident to" services (e.g, physical therapy)
    - In Phase III, CMS rejected a commenter's request to expand the consultation referral exception to anesthesiologists

The Stark Law: General Overview

- **Entity**
  - Receives payment for DHS (e.g., group practice, hospital)
  - Future rulemaking proposes to revise definition of entity to include the person/entity that provides DHS or causes a claim to be submitted (e.g., an MRI venture providing services to a hospital "under arrangements")

The Stark Law: General Overview

- **Financial Relationship**
  - Direct and indirect ownership and compensation relationships (e.g, medical director agreements, ownership in a group practice)
- **Designated Health Services (DHS)**
  - Stark includes 11 categories of services:
    - Physical and occupational therapy
    - Radiology- MRI/ CT /ultrasound, other diagnostic tests
    - DME
    - Clinical lab

General Application in the Physician Practice Setting

- **Does Stark apply?**
  - Is there a referral of DHS?
    - Orders and Referrals within the group practice or sole practitioner setting are referrals
    - Personally performed services not referrals
    - Evaluation and management services not DHS
    - Physical therapy services are DHS
    - MRI/CT/ultrasound services are DHS
    - Inpatient/outpatient hospital services are DHS
    - "Incident to" services are referrals
    - The entire global service (TC and PC) is DHS

General Application in the Physician Practice Setting

- Common Examples of Stark's application in the physician practice setting:
  – Physicians who provide PT/diagnostic testing in their offices
  – Physicians with a financial relationship with a hospital or other DHS provider (DME) (e.g, medical director /lease agreements)

The Group Practice Definition

- Group Practices who provide PT/diagnostic testing in the office
  - Group practice definition
    - Groups must meet definition to utilize in-office ancillary and physician services exceptions
    - Definition- not an exception
  - Elements of the group practice definition:
    - Single legal entity (at least 2 members)- members = employees or owners
    - Each member provides substantially the full range of their patient care services

The Group Practice Definition

- Group Practice Definition Cont'd:
  - **Substantially all** (at least 75%) of the **members** (no independent contractors) services are furnished and billed through the group
  - Expenses and revenues distributed by predetermined methods
  - Unified business

The Group Practice Definition

- Group Practice Definition Cont'd:
- Members not compensated based on vol/value of referrals except:
  - Share of overall profits (can be entire group or subgroup of at least 5)
    - Phase III- CMS now states that overall profit shares cannot relate directly to "incident to" services
    - Indirectly for other DHS
  - Productivity bonus based on personally performed services
    - Stark III- CMS clarifies that productivity bonuses can be based directly on "incident to" services, even if those services are otherwise DHS referrals (PT). Productivity bonus cannot be directly related to other DHS referrals, such as diagnostic tests.

In-Office Ancillary Services Exception

- Group Practice Definition Cont'd:
  - Members conduct 75% of all patient encounters
- <u>In-Office Ancillary Services Exception</u>
  - Applies to compensation and ownership
  - Designed to protect the in-office provision of certain DHS
  - Not applicable to most DME
  - 3 requirements (supervision/location/billing)

In-Office Ancillary Services Exception

- **Supervision**
  - Furnished by referring physician, group physician, or person supervised by them
- **Location**
  - Centralized building
    - Requires exclusive use/group practices only
    - Effective January 1, 2008- New Anti-Markup Rule essentially eliminates centralized building option for pathology services
  - Same building (3 Alternative tests)
    - Office open 35 hrs/wk/ group regularly practices at location 30hrs/wk

In-Office Ancillary Services Exception

- Same building (cont'd)
  - Office open 8hrs/wk and referring doc regularly practices at location 6hrs/wk
  - Office open 8 hrs/wk and group regularly practice at location for 6 hrs/wk if:
    - Referring MD present and orders DHS during visit or
    - Group MD present while DHS furnished
- **Billing**
  - Billed by physician, group practice, or wholly owned entity

In-Office Ancillary Shared Services Arrangements

- In-office Ancillary Sharing Arrangements
  - Physicians sharing a facility in the same building
  - Each physician/group must independently meet IOAS exception
  - Phase III commentary:
    - CMS states physicians sharing a DHS facility must control the facility and staffing at the time the DHS is furnished to the patient
    - CMS states as a practical matter this necessitates a block lease for the space and equipment used to provide the DHS
    - CMS notes per-use/per-click arrangements unlikely to satisfy the supervision requirements of IOAS

In-Office Ancillary Services Exception

- IOAS Exception Cont'd
  - In the 2008 MPFS CMS announced it will publish a separate rulemaking addressing potential future changes to the IOAS exception
    - Whether certain services should qualify for the exception?
    - Whether the location requirements should be tightened?
    - Whether non-specialists should use the exception?

Physician Services Exception

- Physician Services Exception
  - Applies to compensation and ownership
  - Enables group practices to make referrals of physician services that are DHS (e.g, professional component of radiology tests or pathology tests)
  - Performed or supervised by either a member of the group practice or by a *physician in the group practice* (independent contractor)
    - *physician in the group practice*- only considered in the group when he/she is performing in the group practice's facilities

Physician Services Exception

- Physician Services Exception (Cont'd)
- **What does this mean?**

Example: Orthopedic group bills globally for diagnostic tests. Group has an independent contract with a radiology group in which the radiologist reads off-site.

Problem: Group cannot bill for the professional component of the test unless the independent contractor radiologist reads physically on-site at the group's facilities.

Other Stark Phase III Updates

- "Stand in the shoes"
  - Phase III provides that group practices that have a financial relationship with a hospital will need to structure the financial relationship with the hospital to meet a direct exception (e.g., personal service/lease arrangement) not the indirect exception.
- "Direct relationships"
  - For groups that provide DHS, phase III requires that an independent contractor physician have a direct contractual arrangement with the group (e.g, no staffing company).

Stark Hypothetical

- 3 physicians (Drs. A, B, and C) are considering breaking away from their current group and forming a new group in which they will provide MRI and physical therapy services to their patients. All 3 physicians will be owners in the group and will practice full time through the group. The group is also considering hiring a part-time independent contractor physician (Dr. D). Dr. D will practice 50% through the new group and 50% through another practice.
  - Can the new group meet the group practice definition?
    - Do they meet the 75% test?
  - Can the new group hire Dr. D and comply with the definition?
    - Direct contract issues
  - Can the MRI and PT services be provided under the IOAS exception?

Stark Hypothetical

- Dr. A informs Drs. B and C that he has the ability to generate a larger portion of revenues because of the high volume of MRI tests that he orders. In light of this information, Dr. A wants a larger percentage of the group's profits.
  - Will the group be able to distribute profits as requested by Dr. A?
  - What if it were PT instead of MRI?
    - "Incident to" services
  - What about E & M services?
    - Non-DHS and personally performed

Anti-Markup Provisions

- Anti-Markup of Diagnostic Tests
  - Under current Medicare regulations, there is a prohibition on the markup of the technical component (TC) of certain diagnostic tests performed by outside suppliers and billed to Medicare by a different individual or entity
  - In the 2008 MPFS, CMS finalized an expanded anti-markup rule; the final rule imposing an anti-markup provision on the TC and PC of diagnostic tests ordered by a billing physician or other supplier (or related party) if: (1) the TC or PC is outright purchased or (2) if the TC or PC is performed at a site other than "the office of the billing physician or other supplier".

Anti-Markup Provisions-Location Requirement

- Anti-Markup of Diagnostic Tests
  - CMS has created a new location requirement without regard to the Stark law “same building” or “centralized building” location requirements.
    - Under the final anti-markup provisions, the “office of the billing physician or other supplier” is defined as space where the physician or other supplier regularly furnishes patient care. If the physician or other supplier is a “physician organization” as newly defined under the Stark regulations, the anti-markup rule defines “office of the billing physician or other supplier” as the space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.

Anti-Markup Provisions-Net Charge

- Anti-Markup and Diagnostic Tests
  - Arrangements that fall within the ambit of the newly expanded anti-markup rule will be subject to harsh payment limitations.
  - Payment to the billing entity will be limited to the lowest of: (1) the performing physician's or other supplier's net charge to the billing entity; (2) the billing entity's actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing physician or supplier billed directly

Anti-Markup Provisions-Net Charge

- Anti-Markup and Diagnostic Tests
  - Net charge amount must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.
  - Two potential interpretations

Anti-Markup Provisions- Examples

- Anti-Markup Examples
  - A physician in a group practice orders an x-ray and the part-time employed technician performs the x-ray in the group's office. A physician who is an independent contractor with the group practice performs the PC of the test in the group's office and reassigns his right to payment to the group. The anti-markup rule does not apply to the group's billing of the TC or the PC of the x-ray testing services. If, however, the independent contractor physician performs the PC of the test off-site, the anti-markup rule would apply to the group's billing of the PC of the test because the service was not performed in the office of the group.

Anti-Markup Provisions-Examples

- Anti-Markup Examples
  - A physician orders a diagnostic test from an IDTF. The IDTF bills globally for the test (TC and PC). The anti-markup rule does not apply because the IDTF did not order the test, rather it was ordered by an outside physician.

Anti-Markup Provisions-Delayed Rule

- Anti-Markup Delayed Applicability
  - Subsequent to the publication of the 2008 MPFS, CMS received informal comments from stakeholders claiming that the rule was unclear with respect to certain types of arrangements.
  - On December 28, 2007 CMS displayed a final rule delaying the applicability of the newly expanded anti-markup provisions until January 1, 2009, except with respect to the technical component of a purchased diagnostic test and with respect to certain anatomic pathology diagnostic testing services.
    - Anatomical pathology services furnished in space that: (1) is utilized by a physician group practice as a "centralized building" (as defined by Stark) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a "same building" (as defined by Stark) are subject to the expanded anti-markup rule effective January 1, 2008.

IDTF Sharing Restrictions

- Other relevant updates:
  - 2008 MPFS IDTF Standards
    - Effective 1/2009, fixed IDTFs (that are located somewhere other than in a hospital) will be precluded from entering into an arrangement with a physician or physician's practice for the (1) subleasing of the IDTFs office space and/or imaging equipment (2) subleasing space for the practice to establish a medical office location or (3) offering block-time arrangements to such physicians for the leasing of office space and equipment.

Questions?

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