
Take a Second Look at Your Physician Relationships: Tips Based on Experience and Changes in the Law

HCCA Compliance Institute – Dallas, Texas
Session 401- *Monday, April 19, 2010*

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Overview/General Discussion Topics*

- Introductions
- Overview of Stark Law (“Physician Self-Referral Law”) and Federal Anti-Kickback Statute
- Stark “Hot Topics” and Legal/Oversight Trends
- Financial Relationships and Compliance-Interdisciplinary Approach
- Methodologies, Strategies, and Tools for Compliance

** Disclaimer: This presentation is being conducted by an attorney and a consultant. Therefore, the presenters will digress. However, this is a general outline of today’s discussion topics. We will also end on time since we are not billing you.*

The Stark Law

The Stark Law:

- (1) prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a direct or indirect financial relationship (either ownership or compensation), unless an exception applies; AND
- (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or other third-party payer) for those DHS rendered as a result of a prohibited referral.

Federal Anti-Kickback Statute (“AKS”)

“Whoever knowingly and willfully solicits or receives [or offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring [or to induce a referral] . . . for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than **five years, or both.**”

Stark vs. AKS

Stark Law

- Regulated by CMS
- Prohibits referrals where a financial relationship exists
- Civil penalties only
- Strict liability
- Applies only to physicians
- Mandatory Exceptions

Anti-Kickback Statute

- Regulated by the OIG
- Prohibits payments intended to induce referrals
- Criminal + Civil
- “Intent”
- Applies to anyone who attempts, accepts or gives kickbacks
- “Voluntary” Safe Harbors

Hot Topics – “Stand in the Shoes”

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Meaning of SITS

- When determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician refers Medicare patients for DHS, the referring physician stands in the shoes of:
 - (1) Another physician who employs the referring physician;
 - (2) His or her wholly-owned PC;
 - (3) **A physician's medical practice that employs or contracts with the referring physician** or in which the physician has an ownership interest; OR
 - (4) A group practice of which the referring physician is a member or independent contractor.
- **If a physician “stands in the shoes” of his physician practice, then any** compensation arrangements with the practice and an entity - for example, a hospital - would be analyzed as direct compensation arrangements vis-à-vis the physician.
- As such, the compensation arrangement would have to meet a direct compensation exception under the Stark Law regulations at 411.357 in order for the physician to make any designated health services (DHS) referrals to that hospital.

Impact of SITS

- Impact – indirect-to-direct issue – compensation must now be set in advance for the term of the agreement and the term of the agreement must be for at least one year.

November 2009 SITS Clarification

- Exceptions under 411.355 (Ownership/Comp) and 411.357 (Comp) prohibit compensation that takes into account the **volume or value of referrals or other business generated** by the referring physicians
- With SITS, the relevant referrals and other business generated between the parties are referrals and other business generated between the entity furnishing DHS and the physician organization, not just the owner physician.

Hot Topics – Per Click & Percentage Leasing Arrangements

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Stark Law Special Rules on Compensation

- Previously, CMS set out special rules on compensation -
 - **“Set in advance”** defined as when the aggregate compensation, which can be a per unit-of-service or percentage methodology, is set out in writing and in sufficient detail so that it can be objectively verified prior to the furnishing of items/services
 - Per unit-of-service is deemed not to take into account the volume or value of referrals if the per unit-of-service based compensation is FMV at the inception of the arrangement and does not vary during the course of the arrangement in any manner that takes into account DHS referrals
 - **Unit based comp is deemed not to take into account “other business generated between the parties”** provided that the compensation is FMV for items/services actually provided and does not vary during the course of the arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for personally performed services)

Stark Law Special Rules on Compensation

- In FY 2009 IPPS Final Rules, CMS revised several exceptions to prohibit the use of percentage-based compensation formula and per unit-of-service arrangements in the context of equipment and space leases

Revised Rule Related to Per-Click/Percentage

- These exceptions now prohibit compensation arrangements that use a formula based on either:
 - (i) a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed/business generated in the office space or by the use of equipment; or
 - (ii) per unit-of-service rental charges for equipment or space, to the extent that such charges reflect services provided to patients referred between the parties
- **SO although the special rules on compensation still exist, CMS found the percentage and per unit compensation arrangements problematic in lease arrangements**

Permitted Lease Arrangements as of October 1

- As long as the arrangement meets the space or equipment rental exception, the following are acceptable:
 - Block time leases
 - Beware – small blocks of time or very extended periods of time
 - Flat fee leases
- Arrangements with physicians whose ordering of services are **not “referrals” under the Stark Law are also acceptable** – e.g., radiologists for diagnostic radiology, radiation oncologists for radiation therapy and pathologists for clinical diagnostic lab tests and pathological examination services, when provided pursuant to a “consultation”
- “Tools of the trade” interpretation

Hot Topics – “Under Arrangements”

**Relationships:
Revision of the Definition of “Entity”**

What is an “Under Arrangements” Relationship?

- Under the Medicare payment rules, certain providers, e.g., acute care hospitals, can provide services to their patients directly or **“under arrangements” with a third party** and bill Medicare for those services.
- **Third parties that provide “under arrangements” services to hospitals include a broad range of entities.**

Treatment of “UA” Relationships Under Revised Stark Regulations

- Effective October 1, 2009, CMS broadened the definition of “entity.”

- New definition:

“Entity” means “(i)...the person or entity that has performed services that are billed as DHS; or (ii)...the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned ...

Impact of Revised Definition of “Entity”

- As of October 1, 2009 –
 1. Hospital and physician-owned entity need to meet a compensation exception AND
 2. **the physician’s ownership in the third-party service provider (e.g., lab) must meet a Stark Law ownership exception in order for the physician to refer patients for inpatient or outpatient services/DHS provided by the third-party service provider “under arrangements” to the hospital for which the hospital bills.**

Colorado Heart Institute, LLC v. Johnson

- Physicians and physician-owned entities (cath labs) brought suit in the D.C. District Court to stop the change to the regulatory **definition of “entity.”**
- The case did not survive the jurisdictional challenge (April 2009)
 - Found the Medicare Act § 405(h) precluded review under the general federal question jurisdiction and required that the claim be exhausted through the administrative claims process before it could be heard in federal court.

“Under Arrangements” Example: Cath Lab

- Physician A has an ownership interest in a cardiac catheterization laboratory (“Cath Lab”) that provides services “under arrangements” to Hospital’s inpatients and outpatients pursuant to an agreement between the Hospital and the Lab
- **Prior to October 2009, only Hospital was considered the “entity” under the Stark Law**
- Cardiac catheterization is not itself a DHS, so, prior to October 2009, **Physician A’s referrals to the Cath Lab did not need to meet a Stark Law ownership exception.**
- In the past, Physician A needed to meet a Stark Law direct or indirect compensation exception in order to refer patients to the Hospital
- Effective October 1, 2009 – **Cath Lab is an “entity” because it “performs”** the inpatient/outpatient services billed under arrangements
 - Need to meet direct/indirect compensation exception in order to refer patients to Hospital AND
 - Need to meet ownership exception for Physician A to refer patients to Cath Lab for the outpatient/inpatient services/DHS billed by the Hospital

Under Arrangements & Lithotripsy

- Lithotripsy was the subject of specific litigation in which a court decision held that it was not a designated health service (DHS) subject to the Stark Law.
- Because of its special status, physician-owned entities **providing lithotripsy services in “under arrangements”** relationships are not DHS entities and do not need to meet a Stark Law ownership exception for the lithotripsy arrangement.
- **However, the “under arrangements” contract still** constitutes a financial relationship, which would require that the parties meet a relevant compensation exception for the referral of OTHER DHS, e.g., inpatient/outpatient hospital services.

What is “perform”?

- **No definition**
- **But CMS stated that a service is “performed” if the physician or physician organization:**
 1. Does the “medical work” for the service; AND
 2. Could bill for the service, but the physician or physician organization has contracted with the hospital and the hospital bills for the service instead.
- **CMS also stated that entity does not “perform” DHS if it only –**
 - Leases or sells space/equipment
 - Furnishes supplies not separately billable
 - Provides management or billing services
 - Provides personnel
- **NOTE: Although CMS “assume[s] that health care providers have restructured their arrangements to come into compliance with the new rule by the October 1, 2009 effective date,” on November 25, 2009, CMS solicited comments to determine if further guidance may be beneficial in interpreting the 2009 IPPS final rule changes.**

“Under Arrangements” Example: Leasing Company

- Physician B has an ownership interest in a leasing company that provides equipment for use by Hospital and the services of a technician to monitor the equipment.
- **Prior to October 2009, the leasing company was not an “entity” as it was only providing the equipment and tech, not billing Medicare for any service.**
- **Prior to October 2009, the Hospital was the DHS “entity” under the Stark Law.**
- Effective October 1, 2009, is the equipment leasing company **considered the DHS “entity”?**
- CONSIDER –
 - Do the equipment and tech constitute an entire DHS, e.g., MRI?
 - If not, what services is the tech performing?
 - Are the services part of a DRG and by themselves not separately billable, e.g., perfusion?
 - **Can you use “tools of the trade”?**

Compliance Tools

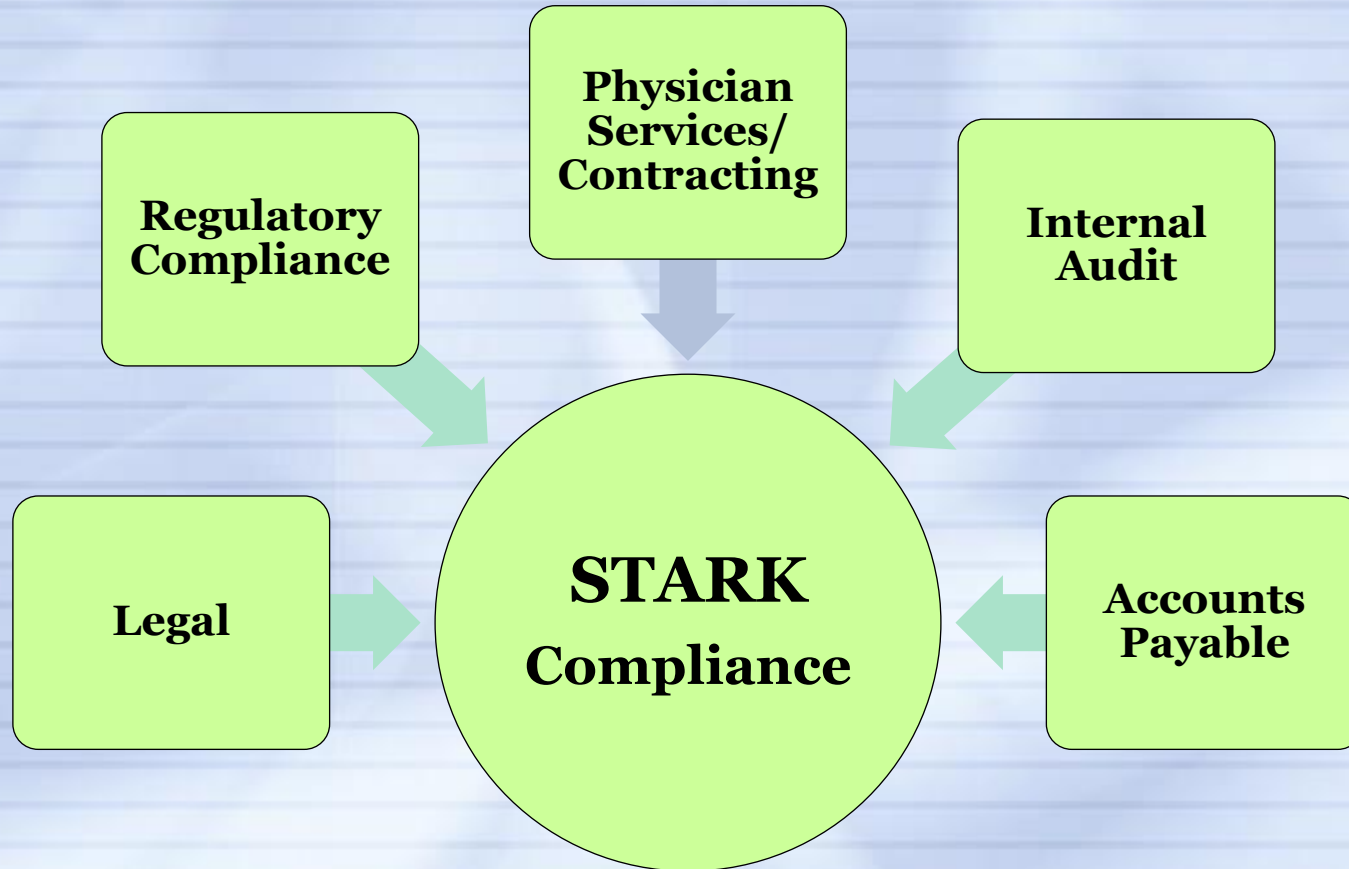
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Reminders – Strict Liability & Penalties

- Unlike AKS, the Stark Law is not intent-based
 - if your arrangement falls under it, it must meet an exception.
- Not Criminal
- Subject to Various Penalties –
 - Civil Monetary Penalty (CMP) up to \$15,000 for each service plus 2 times the reimbursement claimed
 - CMP up to \$100,000 for circumvention (e.g., cross-referral) schemes
 - Exclusion
 - Boot-strapped False Claims Act penalties

Stark Compliance – Not Just Legal’s Responsibility



Stark Compliance – Not Just Legal’s Responsibility

- Key Controls:
 - Governance and Oversight
 - Policies, Procedures, and Workflows
 - Interdisciplinary Collaboration/Communication
 - Corrective Action Process
 - Auditing and Monitoring/Tracking
 - Reporting
 - Training (Board, Management, and Staff)



Stark Compliance – Not Just Legal’s Responsibility

(1) Policy-Making Procedures:

- » Put policies in writing
- » Clearly delineate responsibilities
- » Collaborate with operations to ensure process and desired **controls are accurate and “doable”**
- » **Obtain Legal’s input**
- » Get Board approval (if necessary)
- » Operationalize (train and audit)

(2) Physician Contracting Process (Medical Directorships, Service Agreements, Lease Agreements):

- » All agreements in writing
- » Document fair market value (“FMV”)
- » **Document Legal’s approval**
- » Document business need
- » Enter into physician arrangements contracting database/tracking system

Practical Methodologies, Strategies, and Tools



Financial Relationships Tracking Database

Internal Contract ID	<input type="text"/>	Last Updated	<input type="text"/>	Physician First Name	<input type="text"/>	Physician Last Name	<input type="text"/>
Physician NPI/UPIN	<input type="text"/>	Member of Affiliated Group?	<input type="radio"/> Yes <input type="radio"/> No	Physician Owner/Investor	<input type="radio"/> Yes <input type="radio"/> No		
Immediate Family Member Owner/Investor	<input type="radio"/> Yes <input type="radio"/> No	Family Member First Name	<input type="text"/>				
Family Member Relationship	<input type="text"/>	Family Member Last Name	<input type="text"/>				

Contract Information	Compensation	Fair Market Value
Effective Date <input type="text"/>	DHS Provided <input type="radio"/> Yes <input type="radio"/> No	FMV Completed <input type="radio"/> Yes <input type="radio"/> No
Term Date <input type="text"/>	Type <input type="text"/>	FMV Approach <input type="text"/>
Auto-Renewal <input type="radio"/> Yes <input type="radio"/> No	Stark Exception <input type="radio"/> Yes <input type="radio"/> No	FMV Approach Description <input type="text"/>
In Writing <input type="radio"/> Yes <input type="radio"/> No	Type <input type="text"/>	FMV Documentation in File <input type="radio"/> Yes <input type="radio"/> No
Master Contract Location <input type="text"/>	Compensation Amount <input type="text"/>	FMV Notes <input type="text"/>
Financial Relationship <input type="text"/>	Compensation Payment Type <input type="text"/>	
Financial Relationship Description <input type="text"/>	Compensation Based on Volume or Value of Referrals <input type="radio"/> Yes <input type="radio"/> No	
Comments/Overall Contract Notes <input type="text"/>	Compensation Calculation Notes <input type="text"/>	



Practical Methodologies, Strategies, and Tools

- Stark/Anti-Kickback Database- “Industry best practice,” but what is reasonable and effective for your organization?
- Accountability, due diligence, and documentation are key, regardless of specific methodologies and tools/templates utilized.
- Experiences from Corporate Integrity Agreements (“CIAs”) and performing Independent Review Organization (“IRO”) services.
- The Fair Market Value (“FMV”) Challenge

Practical Methodologies, Strategies, and Tools

- **Conduct a baseline evaluation of “current state” as it relates to financial relationships and compliance.**
 - Are policies and procedures in place, current, and thorough?
 - Are oversight and audit processes sufficient and routine?
 - Do we have a consistent, defined approach for FMV determinations and documentation?
 - How effective are our tracking and reporting mechanisms?
 - **Do we have a “response protocol” should corrective actions be necessary?**
- Coordinate baseline review/evaluation and any audits related to financial relationships with legal counsel.

Practical Issues for Discussion

- Non-monetary compensation
- Timekeeping requirements
- Term and termination issues
- “Hold over” / “Temporary noncompliance”
- Mid-term revision of compensation arrangements

Wrap-Up/Questions

Thank You for Attending!
Enjoy the Institute!

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