Morgan Lewis

FAST BREAK: STARK LESSONS FOR PHYSICIAN PRACTICE ACQUISITIONS

Albert Shay, Eric Knickrehm, and Jake Harper

August 23, 2018

Agenda

- What is the Stark Law and what kind of arrangements does it apply to?
- What are common mistakes physician practices make with respect to Stark Law compliance?
- How can physicians and operational partners structure compensation arrangements to reduce compliance risks but remain competitive in the marketplace?
- What does enforcement of Stark Law violations look like and what are the ramifications for noncompliance?
- What should physicians, buyers, and investors consider when making a self-disclosure to CMS as a component of a practice acquisition?

WHAT IS THE STARK LAW AND WHAT KIND OF ARRANGEMENTS DOES IT APPLY TO?

Stark Law Prohibition

- Physician may not refer Medicare/Medicaid patients to a DHS entity if the physician or immediate family member of the physician has a financial relationship with the entity
- DHS entity cannot bill for the services
- Unless the financial relationship qualifies for an exception
- Strict liability statute; intent is irrelevant
- Proscriptive statute – if the statute applies, referrals are prohibited unless an exception applies

Financial Relationship

- Very broadly defined to include
  - Ownership or investment interest
  - Compensation arrangements
  - Direct and indirect financial relationship

Financial Relationship

- Ownership interests
  - Can be through:
    - Equity
    - Debt
    - "Other means"
  - Includes stock, shares, partnership interests, LLC memberships, and loans secured with an entity's property or revenue
  - Includes interest in an entity that holds an ownership or investment interest in any entity providing designated health services

Financial Relationship

- Compensation arrangement
  - Direct or indirect arrangement involving remuneration between a physician (or immediate family member) and an entity
  - Remuneration includes any payment or benefit, in cash or in kind

Designated Health Services

Clinical laboratory services	Radiology services
Physical and occupational therapy services	Durable medical equipment
Radiation therapy services	Outpatient prescription drugs
Parenteral and enteral nutrients, equipment, and supplies	Home health services
Prosthetics, orthotics, and prosthetic devices and supplies	Inpatient / outpatient hospital services

In Office Ancillary Services Exception

- The Stark law exception for **"in-office ancillary services"** protects both ownership and compensation relationships between a physician and his or her own group. This exception has a number of components and can be extremely complex to apply. Criteria relevant to this exception include
  - Who performs or supervised the provision of the service
  - Where the services are furnished – either in the "same building" the physician furnishes non-DHS services or a "centralized building" for the provision of DHS
  - What entity bills for the service
- Does the physician practice meet the Stark law definition of a "bona fide group practice" test which includes, among other things,
  - Requirements related to how income from DHS is distributed
  - Special rules for profit sharing and productivity bonuses
  - Meeting requirements that "substantially all" services billed by the group by provided by "members" of the group

In Office Ancillary Services Exception

- This exception essentially prohibits physicians from being paid directly for DHS that they order but do not perform personally; however, physicians are allowed to receive indirect benefit through productivity bonuses and profit sharing arrangements provided they are properly structured.
- There is also a *de minimis* exception, which may apply if Medicare revenue from DHS is insubstantial.
  - DHS revenues account for less than 5% of the group's total revenues; and
  - The allocation of those DHS revenues to each physician in the group constitutes less than 5% of each physician's total compensation from the group.

WHAT ARE COMMON MISTAKES PHYSICIAN PRACTICES MAKE WITH RESPECT TO STARK LAW COMPLIANCE?

Common Mistakes with Stark Law Compliance?

- Not knowing which services are DHS
- Improperly Structured Productivity Compensation Plans or Profit Shares (e.g., Eat What You Kill)
  - Does not exclude DHS revenue from net collections
  - If DHS revenue is pooled and distributed to physicians in the group, does not distribute in a manner that is compliant.
- Not maintaining compliance with requirements of group practice definition
  - Loose affiliations of multiple legal entities rather than a single legal entity that functions as a unified business.
  - Physicians in the group do not provide substantially all (75%) of their patient care services through the group and billed through a billing number assigned to the group.

HOW CAN PHYSICIANS AND OPERATIONAL PARTNERS STRUCTURE COMPENSATION ARRANGEMENTS TO REDUCE COMPLIANCE RISKS BUT REMAIN COMPETITIVE IN THE MARKETPLACE?

Compliant But Competitive Compensation Arrangements

- Exclude DHS from Net Collections but Distribute It in a Compliant Manner to Physicians in the Group Practice
  - "Safe Harbor" Distribution Methods
    - Per Capita Distributions
    - A physician's percentage ownership in the group practice entity
    - Distribution attributable to services which are not DHS (e.g., commercial payor collections)
    - Distribution based on total patient encounters or work RVUs
- For larger groups, developing multiple "pods" for distribution of DHS revenues may be an option
  - Permits groups to distribute DHS revenues using differing distribution methodologies, however, at least 5 physicians must be in each "pod" and DHS distributed within each pod must still be done in a compliant manner.
  - Groups can develop separate pods based on geography, service line (e.g., pathology, radiology, etc.), or other mechanisms.

Compliant But Competitive Compensation Arrangements

- Incorporating a Mandatory Referral Provision into Physician Compensation Arrangements
  - Groups may include provisions in physician employment agreements requiring physicians to refer their patients for health care services to the group unless one of the following exceptions exists:
    - The patient expresses a preference for a different provider/supplier;
    - The patient's insurer requires a different provider/supplier; or
    - It is in the best medical interests of the patient, in the independent medical judgment of the Physician, that the patient receives health care services from another provider/supplier.

WHAT DOES ENFORCEMENT OF STARK LAW VIOLATIONS LOOK LIKE AND WHAT ARE THE RAMIFICATIONS FOR NONCOMPLIANCE?

Stark Law Enforcement and Ramifications for Noncompliance

- Overpayment Refund Obligations
  - Providers must report & return overpayments within 60 days of either identification of the overpayment
- Civil sanctions
  - Denial of payment
  - Refunds of amounts collected
  - Civil Monetary Penalties for knowing violations on a per service basis.
  - $100,000 for each arrangement or "scheme"
- Potential False Claims Act liability
  - Up to $23,863 for each bill/claim submitted
  - 3x amount claimed
  - Program exclusion

Stark Law Enforcement and Ramifications for Noncompliance

- **$2 million dollar settlement by Family Medicine Centers of South Carolina LLC (FMC), Its Co-Owner, and Its Laboratory Director for Alleged False Claims Act Violations**
  - Government alleged that the Stark Law was violated by FMC's incentive compensation plan that paid FMC's physicians a percentage of the value of laboratory and other diagnostic tests that they personally ordered through FMC, which FMC then billed to Medicare.
  - Dr. Serbin, FMC's co-owner and chief executive, allegedly initiated this program and reminded FMC's physicians that they needed to order tests and other services through FMC in order to increase FMC's profits and to ensure that their take-home pay remained in the upper level nationwide for family practice doctors.
  - Settlement included not just the group practice entity, but also its principal owner/CEO as well as the laboratory director.

Stark Law Enforcement and Ramifications for Noncompliance

- **$1 million dollar settlement by two California urologists to settle false claims act allegations related to radiation therapy referrals**
  - Government alleged alleged that Drs. Apaydin and Worsham knowingly caused eight urologists to violate the Anti-Kickback Statute and the Stark Law by having them enter into lease agreements with an affiliated facility where image-guided radiation therapy (IGRT) services were performed under which the lessee urologists could bill for, and thereby profit from, their referrals of IGRT performed at the facility.
    - The 8 lessee urologists entered into a separate settlement agreement with the government where they agreed to pay $900,000 to settle the allegations.
  - The Government also alleged that Drs. Apaydin and Worsham violated the Stark Law by improperly billing Medicare for their own IGRT referrals to the facility, as that facility and the group practice were separate entities and their financial arrangements did not comply with any exceptions to the Stark Law.

WHAT SHOULD PHYSICIANS, BUYERS, AND INVESTORS CONSIDER WHEN MAKING A SELF-DISCLOSURE TO CMS AS A COMPONENT OF A PRACTICE ACQUISITION?

Self-Disclosure Considerations in Physician Practice Transactions

- **A Stark Law compliance issue is identified during the course of regulatory diligence in a transaction. Now what?**
  - Be cautious and deliberate in all communications and distribution of information between buyer and seller.
    - Counsel for both Buyer and Seller should carefully discuss the potential non-compliance issue so that Seller's counsel can determine whether there is non-compliance.
    - All parties must be mindful of the Medicare overpayment rule and the obligations that attach once there is credible information of a potential overpayment.
  - If reasonable diligence determines there has been non-compliance with Stark Law requirements the obligations of the Medicare overpayment rule would apply, including a 6-year lookback period and 60-day refund requirements.
- **So…What's Next?**

Self-Disclosure Considerations in Physician Practice Transactions

- The determination of how to handle Stark Law non-compliance will ultimately remain with the Seller, although Buyers can influence potential steps for resolution.
- A common step is for Seller to submit a voluntary self-disclosure under the CMS Self-Referral Disclosure Protocol (SRDP)
  - Seller's counsel would typically prepare the self-disclosure filing and permit Buyer's counsel an opportunity to review and comment on the self-disclosure materials.
  - Once filed, it may take several years for CMS to communicate regarding any settlement.
  - Settlement amounts are usually a percentage of the overall overpayment identified in the self-disclosure and are determined on a case-by-case basis. However, it would be atypical for any settlement to be in excess of 10% of the overall overpayment identified.
- Buyer and Seller can include appropriate special indemnification and escrow amounts in a purchase agreement to account for Stark Law liability and collaborate in addressing the underlying issues that caused the noncompliance.

QUESTIONS

Thanks!

Al Shay
Partner
Washington, DC
+1.202.739.5291
albert.shay@morganlewis.com
Click Here for full bio

Al focuses his practice on counseling healthcare companies of all types on regulatory, fraud and abuse, Stark law, Medicare reimbursement, and transactional matters. Al devotes a substantial portion of his practice to corporate compliance issues, including internal and government investigations, and has experience representing clients before regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS), the US Department of Health and Human Services' Office of Inspector General, and the Provider Reimbursement Review Board.

Thanks!

Eric Knickrehm
Associate
Washington, DC
+1.202.739.5859
Eric.knickrehm@morganlewis.com
Click Here for full bio

Eric focuses his practice on healthcare transactional matters as well as regulatory counseling and compliance. He advises private equity funds, practice management companies, physician group practices, healthcare trade associations, pharmacies, and post-acute care providers on a wide variety of healthcare regulatory issues.

Join us next month!

Please join us for next month's webinar:

"*Fast Break*: Telehealth and Medicare's New Virtual Check-in"

Featuring Jake Harper

- Tuesday September 25 3:00 PM (EST)