Practical Strategies for Minimizing Stark Law Risk

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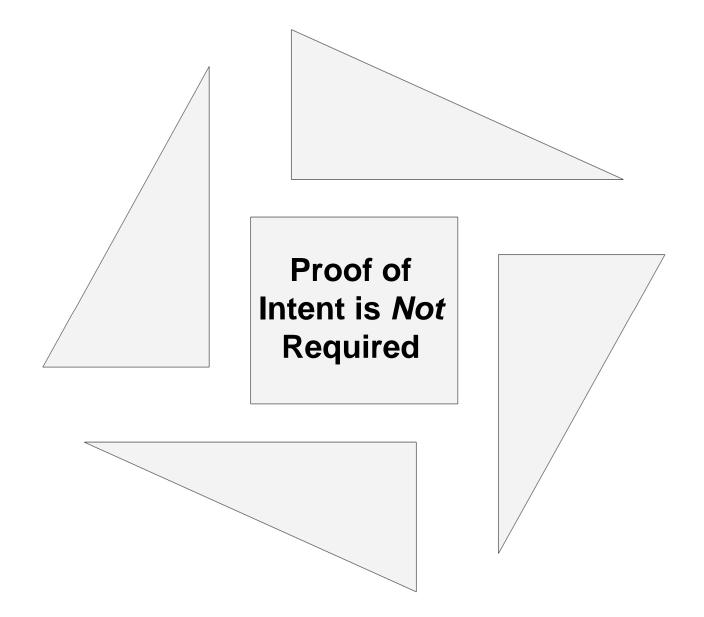
Overview

- Real estate complexities
- Non-monetary compensation and medical staff incidental benefits
- Commercial Reasonableness and Fair Market Value
- Medical Directorships/Administrative Roles
- Clinical Practice Acquisitions
- Technical Violations Defensive Options
- Stark reviews and the self-referral disclosure protocol
- Physician integration challenges related to Comanagement and Purchased Services Agreements
- Various Risk Reducing Operational Recommendations

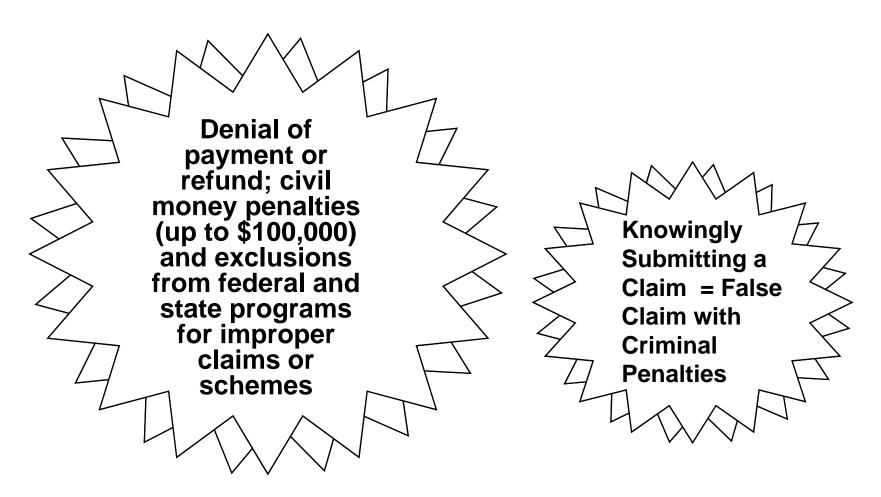
Stark Act 42 U.S.C. 1395nn

- The Stark II Act prohibits a physician from making a *Referral*
 - to an *Entity*
 - for the furnishing of a Designated Health Service
 - for which payment may be made under Medicare or Medicaid
 - > if the physician (or an immediate family member)
 - has a *Financial Relationship* with the entity
- Unless an exception applies

Stark II Act



Penalties



Avoiding a False Claim

- The False Claims Act, 31 U.S.C. § 3729 et seq., establishes liability when any person or entity improperly receives from or avoids payment to the Federal government
- In summary, the Act prohibits:
 - Knowingly presenting, or causing to be presented to the Government a false claim for payment;
 - Knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or approved by the government;
 - Conspiring to defraud the Government by getting a false claim allowed or paid;
 - Falsely certifying the type or amount of property to be used by the Government;
 - Certifying receipt of property on a document without completely knowing that the information is true;
 - Knowingly buying Government property from an unauthorized officer of the Government, and;
 - Knowingly making, using, or causing to be made or used a false record to avoid, or decrease an obligation to pay or transmit property to the Government.

Real Estate Complexities: Office Space Rates

- Square foot measurement
- Real estate appraisals
- Gross lease v. triple net lease
- Payment of increases in operating expenses
- Tenant improvements
- Holdover Rent
- Exclusive use
- No percentage-based leasing arrangement
- No per click rental for referrals from lessor

Real Estate Complexities: Shared Space - Timeshares

Must allocate all costs to set FMV Rental Rate

- Rental of space (Half or Full Day Slots)
- Vacancy Rate (Project 20% vacancy?)
- Supplies
- > Utilities
- Staff (Registration, Nursing, etc.)
- > Equipment



Real Estate Shared Space

(Example)

Assume:

- \$18 gross per square foot rental (exclusive use)
- 30% projected vacancy (in suite)
- 1,000 square feet in suite
- Building has 6,000 square feet, with 1,000 square feet of common area used by the suite (5,000 square feet usable space)



Suite capable of being leased in half day increments (8:00 A.M. – Noon; 1:00 P.M. – 5:00 P.M.)

Furnished Shared Space

(Example)

- Furniture and equipment in suite determined to be leaseable at \$2,000 per year using independent third party leasing company.
- Miscellaneous medical/office supplies projected to be used in suite is approximately \$5,000 annually if suite leased 70% of the time.





Shared Space

Example - allocating vacancy and common areas costs

\$18 (exclusive use rate) + 30% (vacancy) = \$25.71 per square foot (\$18 ÷ .7 = \$25.71)

1,000 square feet (suite) \div 5,000 square feet (building not including common area) = 20% (percentage of suite's usable space in building's usable space)

1,000 square feet (common area) x 20% (suite to building)

= 200 square feet (common area allocated to suite)



Shared Space

Example

1,200 square feet (suite plus allocated common area)

$$x $25.71 = $30,852$$

\$30,852 + \$2,000 (furniture and equipment) + \$5,000 (medical/office supplies) = **\$37,852**

$$$37,852 \div 52 \text{ (weeks)} = $728 \text{ (weekly rate)}$$

 $$728 \div 5$ (business days in week) = \$146 (daily rate)

$$$146 \div 2 = $73 \text{ (half day rate)}$$



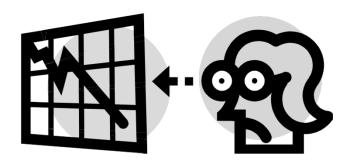
Shared Space

Example

Example becomes more complicated if:

- Part of suite is leased (as opposed to full suite)
- Staff is provided by landlord/hospital
- Specialized equipment is included but not used by all tenants
- Non-standardized supplies are used by a tenant





Time Share Issues

Time Share leases issues

- Specific Days, # of Days
- What is Exclusive Use? What must be used exclusively?
- Is Lease Required?
 - Hospital patients Can Hospital arrange for specialists to see Hospital's patients in Hospital space?
 - > If Hospital schedules the patient but does not bill providerbased can Hospital charge the physician the technical fee?

What is a Financial Relationship?

Remuneration is defined (42 CFR§ 411.351) as:

"any payment **or other benefit** made directly or indirectly, overtly or covertly, in cash or **in kind** ..."



(Applies to Compensation Relationships)

Compensation (defined as *any benefit*), not including cash or cash equivalents (i.e., gift certificates that may be redeemed in whole or in part for cash), may not exceed an aggregate of \$380 per year per physician as long as:

- > Benefit is not determined based upon volume or value of referrals.
- > Benefit is not solicited by physician or anyone affiliated with their practice.
- > Maximum cannot be aggregated to make a larger gift to a group.

The \$380 limit applies to calendar year

The \$380 limit is updated annually.

See: www.cms.hhs.gov/PhysicianSelfReferral/

See: http://www.kriegdevault.com/info/stark-act

- 1. If a hospital inadvertently exceeds the annual limit, the hospital will still be deemed to be in compliance if i) the value of the excess is no more than 50% of the limit, and ii) the physician returns the excess by the end of the calendar year or within 180 consecutive calendar days, whichever is *earlier*. NOTE: Can only be used once every 3 years.
- 2. Hospitals can hold 1 formal medical staff event per year without including the cost in this exception.

Allocation example:

- \$1,000 oil painting to 5 physician group
- Stark inflates the value to \$5,000 as \$1,000 must be allocated to each physician
- Cannot allocate 1/5 to each physician



"[F]ree CME could constitute remuneration to the physician depending on the content of the program and the physician's obligation to acquire CME credits."

Phase II, page 16114

Preamble, on Page 16112 of Phase II, stated that "[the Medical Staff Incidental Benefits Exception] was not intended to cover the provision of tangential, off-site benefits, such as *restaurant dinners or theater tickets,* which must comply with the exception for non-monetary compensation up to \$355." (emphasis added)



Medical Staff Incidental Benefits Exception

Items or services used on the hospital's campus may be given to members of its medical staff if:

- > Item or service is provided to *all* members in the same specialty without regard to volume or value of referrals.
- Item or service is provided only during periods when the medical staff members are making rounds or involved in other services that benefit the hospital and its patients.

Medical Staff Incidental Benefits Exception

 The item or service is reasonably related to the delivery of medical services at the hospital.

Each item or service is less than \$32 per

Free For

Physicians/

benefit

Medical Staff Incidental Benefits Exception

- The exception specifically recognizes that "internet access, pagers, or two-way radios, used away from the campus *only to access* hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web-site or in hospital advertising, will meet the single "*on campus*" *requirement*...." (emphasis added)
- But not access to a third party internet site e.g. for CME



Tracking Non-Monetary Compensation

The OIG assumes that DHS providers track the non-monetary compensation given to each referring physician.

[Organization Name]

Non-Monetary Physician Gift/Benefit*and business Meal ** Tracking Form

Reason For Form: Gift/Benefit*		□ Business Meal**	
Recipients (Gift/Benefit) Attendees (Business	Meal):		
Gift/Benefit Description or Location of Bu			
Reason for Gift/Benefit or Business Meal:			
Value of Gift/Benefit or Business Meal:			
If Gift/Benefit, how value determined:			
Signed by:	Title		Doto
Signed by:Print:			Date:
Gift/Benefit CFO/Designee approval ***: Date:			
*Defined as any non-monetary benefit, including golf, etc., even if some business is conducted du washes, flowers, and other gifts, even if such items ** Modest meal at a local restaurant provided to a primary and mateiral purpose of which is to discuentier meial is a Gift/Benefit. ***Finance approval signifies that with this Gifts/Benefits during the current fiscal year.	ring such social e have a logo. Physician (not inc ass legitimate busin	eluding spouses) during a b ness issues. If any spouse i	s, hats, jackets, car usiness meeting the s in attendance, the

Officer Approval Section for Gifts/Benefits:

By affixing my signature, I attest that consistent with [Organization Name] policies and procedures, the above referenced Gift/Benefit will be offered, regardless of wehther these individuals refer patients to [Organization Name] for services (and, if applicable, to all similarly situated physicinas), and the Gift/Benefit being offered does not in any way take into account the volume or value of the Physicians' referrals to [Organization Name]. It is also my understanding, as of the date noted below that the Physician(s) noted above have not, and will not with the above-noted Gift/Benefit, received Gifts/Benefits that exceed \$300 during the fiscal year in which the Gift/Benefit was given.

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Who Tracks Non-Monetary Compensation?

Compliance Department

Legal Department

Finance Department (Accounts Payable)

Medical Staff Office

"What do you mean by FMV?"

- In the healthcare context, there are essentially 3 basic views on the meaning of FMV:
 - "Person on the street" perspective
 - > Professional appraisal perspective
 - Legal/regulatory perspective
- Unfortunately, these 3 basic views frequently conflict.
- Parties can get "dazed and confused" when these 3 competing views meet to complete a transaction.

"The Street" View of FMV

- "What everyone is getting paid in the market"
- "What the hospital down the street is paying"
- "Incremental cost plus a profit margin"
- "What's in a survey book"
- "What it's worth to one party to the transaction"

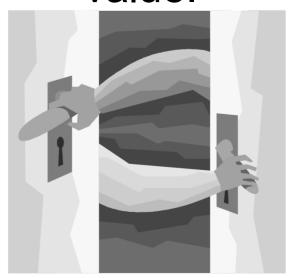


Professional Appraisal View of FMV

- Based on the "hypothetical-typical" buyer concept
- FMV contrasts with investment value or strategic value
- Determination of FMV is based on 3 approaches to value:
 - > Cost
 - > Income
 - > Market
- Formal body of knowledge and professional standards governing the appraisal practice for real estate and business valuation ("BV")
- No current body of knowledge or standards for compensation valuation ("CV")

Legal/Regulatory View of Fair Market Value

According to the Stark Act, *fair market value* is "the value in arm's-length transactions, consistent with the general market value."



Legal/Regulatory View of Fair Market Value

"General Market Value" means the price that an <u>asset</u> would bring as a result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the <u>compensation</u> that would be included in a service agreement as a result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

42 C.F.R. § 411.351

Legal/Regulatory View of FMV

 Stark regulations state that the definition of FMV "is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies."

Stark example: Exclusion of market comparables between parties in position to refer.

Stark example: FMV can be established by "any method that is commercially reasonable."

OIG Anti-kickback statute example:
 Footnote 5 to Advisory Opinion 09-09 cautioning the use of the Discounted Cash Flow (DCF) method for an ASC valuation

Avoid the FMV Definition Pitfall

 The "Street" perspective of FMV is generally not reliable for healthcare regulatory purposes but may provide useful information.



- Regulatory definition of FMV may limit or qualify FMV methods used in professional appraisal practice.
- FMV as determined under professional appraisal standards may be more rigorous than the regulatory requirements.

Avoid the FMV Definition Pitfall

- Learn to identify and navigate through the different views of FMV as they arise in negotiating transactions and compliance reviews.
- Recognize that appraisal professionals do not give regulatory advice, but only their opinion as to the determination of FMV, which may or may not take into account regulatory considerations.

What Is Commercially Reasonable?

To be commercially reasonable, both the **SERVICES** and **PAYMENT** must be commercially reasonable.



What Is Commercially Reasonable?

The following services may not be commercially reasonable:

- Two medical directors over a department when only one is needed.
- Paying the physician for questionable consulting services.
- Renting a piece of equipment full-time when only used once a month (assuming rental for one day is less than full-time rental).
- Purchase of physician's medical office building with no intention to use building.

Medical Directorships/Administrative Services

- Time documentation see Exhibit _____.
- Hourly compensation administrative vs. clinical benchmark data.
- Monthly stipend payments compliance risk increases.
- Appropriate oversight of performance of administrative duties.

Physician Practice Acquisition

- Obtain appropriate practice valuation –
 use blending of asset, market, and income
 approaches.
- Do not value practice based on medical records.
- Post-acquisition compensation must be consistent with business valuation.
- Post-acquisition ancillary revenue streamcan this be paid to physicians?

Technical Violations

- Use 6 month holdover period (personal service, rental of office space and equipment exceptions).
- Use delayed signature rule (30-days intentional, 90-days inadvertent).
- Use temporary non-compliance rule-must be compliant for at least 180 days and brought back into compliance within 90days of temporary non-compliance.

Technical Violations

(Cont.)

- Was physician an employee?
- Does physician refer DHS?
- Did non-compliant arrangement end outside of the reopening period [4 years]?
- Can multiple documents create the "written arrangement signed by the parties"?
- Was the issue a mere contract violation, but not a Stark Law violation (i.e., late payments).

Technical Violations

(cont.)

- Was there a mutual mistake (unintentional overpayments)?
- State Law defenses?

- What is a Stark audit/review?
 - > Attorney-client protections
- Conducting the audit/review:
 - >The DHS entity should first identify all financial arrangements that it has with referring physicians.

- When to do an audit/review
 - Must be committed to taking corrective actions, including disclosures and repayments
- Why do an audit/review?
 - > See the slide on the use of the SRDP below

Sources for Identifying Physician Financial Arrangements

- Legal Department
- Accounting Department
- All Operational Departments Medical Staff Office

- Accounts Payable Tax Department
- Marketing- Business Development
- Compliance Department Education-Research-GME

 All documents regarding each financial arrangement need to be produced for review.

 A document production checklist is included as <u>Exhibit A</u>.

Exhibit A

HOSPITAL DOCUMENT PRODUCTION ON CHECKLIST FOR STARK LAW REVIEW

The following is a list of documents that are required to be copied and assembled in the order as they appear on this checklist. The documents will be reviewed by LAW FIRM L.L.P. If the document is located and copied, place a "\" before the description of the document. If the document is either not applicable, or could not be located, insert "N/A" in the space before the document description.

Contract Party:				
Cont	ract Type: Leases in MOB Employment – Medical Administration Employment – Teaching	☐ Leases – other than MOB ☐ Employment - Clinical ☐ Independent Contractor – Medical Administration		
	 ☐ Independent Contractor – Clinical ☐ Physician Recruitment ☐ Other 	☐ Independent Contractor – Teaching ☐ Hospital-Base Group		
List and Description of Documents				
Executive copy of Contract and all Amendments Fair Market Value documentation supporting the financial arrangement in the Contract Minutes of meeting where contract was discussed and approved List of all payments made to and from contract party related to the Contract Legal review of Contract (both internal and external) Time sheets submitted by contract party Productivity data if any portion of compensation is based upon productivity The following documents apply only to Recruitment Arrangements Community need analysis For income guarantees, financial documentation relied upon for payment of income guarantee, including incremental expenses Documentation relied upon supporting the reasonableness of amount of income guarantee or forgivable loan If contract does not specify, state where physician moved from, and when:				
	Relocated from:	State		
	Date physician relocated:			
If you have any questions or comments regarding the assembly of the documentation, contactat Law Firm LLP at 555-555-555. Created By: Robert A. Wade Partner, Krieg D				
		4101 Edison Lab		

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As part of Exhibit A, the relationship owner needs to identify the type of arrangement in order that the attorney can identify the applicable Stark exception.

Leases in MOB

- Leases other than MOB
- Employment specifying services:
 - administrative teaching research clinical

clinical

- Independent Contractor specifying services:
 - administrative
- teaching
- research
- Physician Recruitment
- Hospital-Based Group
- Other

Some organizations use a CARTS certification when the contract is created- certifying the purpose as Clinical, Administrative, Research, Teaching and/or Strategic

From Exhibit A, documentation regarding the financial arrangement should be produced.

- Executed copy of Contract and all Amendments
- Fair Market Value documentation supporting the financial arrangement in the Contract
- Minutes of meeting where Contract was discussed and approved
- List of all payments made to and from contract party related to the Contract
- Legal review of Contract (both internal and external)
- Timesheets submitted by contract party
- Productivity data if any portion of compensation is based upon productivity

After all documentation regarding each financial arrangement has been assembled, each financial arrangement must be analyzed for Stark Law compliance. The Stark Contract Review Form attached as Exhibit B can be used to evaluate and create an inventory listing each financial arrangement.

Exhibit B

Issue	File Complete	Reviewer Comments
Executed Copy and all Amendments		Agreement Name: Term:
FMV Documentation Supporting Arrangement		Compensation: Time: FMV Justification:
Meeting Minutes with Discussion and Approval		Committee Minutes:
List of Payments To and From Party		Aggregate Amounts: 2007: 2008: 2009:
Legal Review		
Timesheets Submitted		51

After each financial arrangement is analyzed (and if a concern is raised outside of an audit/review), the DHS entity will either need to determine if the financial arrangement conforms with all components of an applicable Stark exception, or corrective action needs to occur.

Types of Corrective Action:

Prospective Actions

- Written agreement needs to be developed or modified.
- Financial terms need to be modified to be consistent with commercial reasonableness/fair market value.

<u>Actions Related to Prior Services</u>

- Items required to be paid need to be charged to physician (i.e., increases in operating expenses).
- Additional documentation of compliance with a Stark exception needs to be collected.
- The "period of disallowance" needs to be determined.
- Possible repayment or self-disclosure will need to be made.

Overview of the SRDP Protocol

- Introduction and Discussion of Protocol
- Cooperation with OIG and the Department of Justice
- Instructions Regarding Submission
- Verification
- Payments
- Cooperation and Removal and Timeliness of Disclosure
- Factors Considered in Reducing Amounts Owed

So, Go Ahead & Self-Disclose!!



Why use the SRDP?

- Suspected Whistleblower
- Sale/Purchase Transaction
- Revenue Integrity
- Change in Management
- Financing Requirement
- Governance Requirement
- Overpayment Has Been Identified
 - Consider other compliance options?

Introduction and Discussion of Protocol

- Purpose is to resolve actual or potential violations of the physician self-referral law
- Separate from the advisory opinion process- MUST ADMIT A VIOLATION HAS OCCURRED
- Disclosure must be made in good faith
- Cannot appeal settlement
- Application of Reopening Rules

Instructions Regarding Submission

- Financial Analysis
 - "Look Back" Period
 - Total amount actually or potentially due and owing
 - Description of the methodology used including estimates
 - Summary of auditing activity and documents used

Quantification of Potential Overpayment

Providers need to:

- Determine commencement and ending of period of time during which financial arrangement fell out of compliance
- <u>Utilize the 6-month</u> holdover period, where applicable (personal services arrangements and rental of space and equipment exceptions)
- If financial arrangement was with a group practice, identify each physician in the group practice
- Determine when any applicable physician "referred" to the DHS entity during the period of disallowance
 - > Referring physician
 - Admitting physician
 - Attending physician
 - > Consulting physician
- Especially for the consulting category, determine if items or services ordered by "tainted" physician impacted the reimbursement received

Quantification of Potential Overpayment

Assuming provider diligently quantifies the potential overpayment during the "lookback" period with due diligence, 60-day reporting period does not commence until the amount of the overpayment has been *determined*.

Factors Considered, Reducing Penalty and Repayment Amounts

CMS may consider the following factors in reducing the amount due:

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of the disclosing party
- Effectiveness of compliance program, especially if compliance program resulted in discovery of potential Stark infraction

Nature and Extent of Improper / Illegal Practice

Some of the sub-factors CMS will weigh include:

- Commercially reasonable? Fair market value?
- Takes into account volume or value of referrals?
- History of program abuse?
- Set in advance?
- Presence, strength of preexisting compliance program?
- Length, pervasiveness of noncompliance?
- Steps taken to correct noncompliance?

Reducing Penalty and Repayment Amounts: Additional Factors

- Timeliness of self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of disclosing party

PHYSICIAN INTEGRATION:

CO-MANAGEMENT and PURCHASED SERVICE AGREEMENTS (PSAs)

Services:

- Hiring and Firing
- Recruitment
- Marketing
- On-site Management
- Selecting and Ordering of Equipment and Supplies
- Policies and Procedures
- Coding

- Billing
- Utilization Management and Review
- Capital and Operating Budgets
- Discharge Planning
- Quality Review
- Compliance
- Purchasing

Because the compensation for comanagement services establishes a "financial arrangement" between the hospital and the physicians, and because the physicians will refer inpatients or outpatients to the hospital, the Stark Law is implicated.

Stark Law

 Co-management arrangements should comply with either the personal service arrangements exception or the fair market value exception.

- Fair Market Value and Commercially Reasonable Compensation
- Fair market value and commercial reasonableness will be determined based upon the extent to which the *physicians* are providing *management services* above and beyond simply treating patients within the department.

Fair Market Value Compensation:

- There are three primary compensation methodologies, including:
 - > Hourly Compensation
 - Percentage of Gross or Net Collections
 - A Combination of Hourly Compensation and Percentage of Gross or Net Income
- Ultimately, the amount of compensation paid to the physicians must be documented to be reasonable in light of the management services provided by the physicians.

Commercial Reasonableness:

- What is the physician group's experience in providing management services
- Are management services needed/need documented?
- Will the management services replace hospital services and reduce hospital costs?
- Is the engagement of the physician group for management services one of the best solutions?
- Will the physician group bring in a new service line or new management methods?

PSA AGREEMENTS

- Is a PSA appropriate if the location will not be provider-based?
- Are the physicians seeing hospital patients?
 - Can the hospital pay physicians to see their own patients?
 - Can the hospital pay physicians to see charity care or low reimbursement patients?
- Is the PSA necessary to retain this type of physician services in the community?

Selection of Physician Group/Groups

 Careful consideration must be made when selecting the physician group to provide comanagement services to make sure that such selection is not intended to induce future or reward future or past referrals.

Practical Strategies for Avoiding Non-Compliance Arrangements

- Educate everyone involved with physician financial arrangements regarding Stark Law risks.
- Use contract management data base.
- Designate at least one person in organization to monitor expiration dates of financial arrangements with referring physicians.
- Determine whether Evergreen Clauses should be used.
- Establish fair market value/commercial reasonableness documentation process.
- Use third party valuations or defensibility opinions when warranted (i.e., compensation above the 75th percentile).

Practical Strategies for Avoiding Non-Compliance Arrangements

(Cont.)

- Use tracking system for non-monetary compensation.
- Designate at least one person within organization to review and approve of all medical director time studies prior to payment.
- Accounts payable should assure that, where applicable, a written and executed agreement exists *prior* to paying any referring physician.
- Establish Stark Law alliance between compliance, legal and finance departments.
- Make sure real estate manager understands Stark Law restrictions related to office leasing arrangements – especially part time arrangements.

Practical Strategies for Avoiding Non-Compliance Arrangements

(Cont.)

- If potential violation is discovered, establish process to cease billing for services referred by tainted physicians until applicable exception is met.
- Review executives' expense accounts for non-monetary compensation issues.
- Conduct periodic Stark Law compliance reviews to insure that the financial terms of arrangements have been met.
- If productivity compensation is paid, make sure productivity is accurately reported (i.e., tracking personally performed wRVUs vs. RVUs ordered for ancillary services or wRVUs generated by mid-level providers).