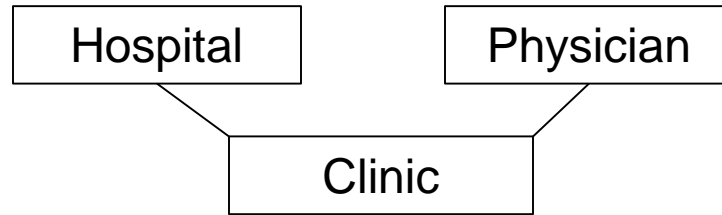


Structuring Innovative Hospital/Physician Joint Ventures and Other Arrangements

January 15, 2020

Fredrikson
& BYRON, P.A.

Hospital Investment in Clinic



Stark Law

- The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:
 - (b) In-office ancillary services.

Stark Law

- (3) They are billed by one of the following:
 - (i) The physician performing or supervising the service.
 - (ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.
 - (iii) The group practice if the supervising physician is a “physician in the group practice” (as defined at § 411.351) under a billing number assigned to the group practice.

Group Practice

- Single legal entity. For purposes of this subpart, a group practice is a physician practice that meets the following conditions:
- The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations...

Group Practice (More)

- A group practice that is otherwise a single legal entity may itself own subsidiary entities.

What About Antikickback?

- Likely will not meet small entity safe harbor
- Meet as many requirements as possible—no sweetheart deal
- Intent key to analysis

Corporate Practice Doctrine

- State laws differ
- Hospital authority
- No lay governance
- Associated PC
- Nonprofit exception

Class B Shares

- Rights and preferences set forth in resolution
- Profit and loss in JV operations
- Preferred? Convertible? Withdrawal?
- Governance

Partnership

- Partnership is both an entity and the aggregation of the partners' activities
- Must bill in name of practice
- Some complication re single entity test
- Careful of corporate practice rules

Participating Debt

- Returns on debt based on profit and loss
- Stark law considers certain debt to be ownership
- No sweetheart deals

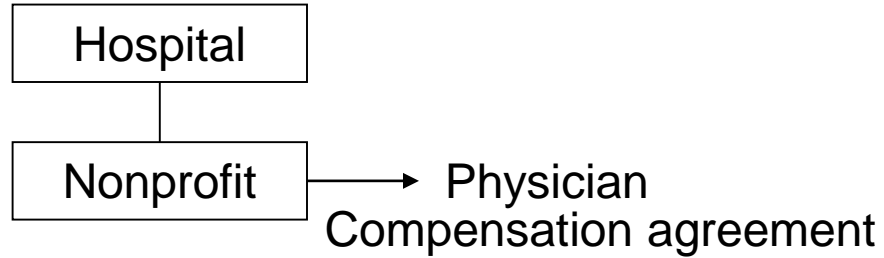
Examples

- Hospital wants to work with clinic to establish a new clinic location
- Hospital wants to bring clinic into system, but clinic wants to retain independence

Lessons Learned

- Investment in clinic is an underused strategy
- Many forms and approaches
- Don't do this at home

Nonprofit Entities



- Nonprofit LLC or PLLC

Corporate Practice

- Typically less rigid for a nonprofit
- Some states allow a nonprofit PC
- Some states permit a nonprofit to practice a profession

Technical Service Ventures

- Hospital can generally participate in unlicensed activities

Multipart Financial Relationships

- Nonprofits can typically make distributions to other nonprofits
- Physicians and other private persons can receive reasonable compensation

Reasonable Compensation

- Generally, what private parties would pay/receive for similar services
- Not based on referral relationship
- Key off of outside survey information
- May pay for management or for professional services

Stark Law Opportunity

- Membership in a nonprofit is not ownership
- May be able to structure such an arrangement in an urban area

Taxable or Exempt

- Exempt entities are subject to IRS rules on private inurement, private benefit and intermediate sanctions
- Taxable nonprofits much less regulated
- Exempt entities may fundraise

Examples

- Hospital joint venture with nonprofit health plan
- Dental provider operating low-income clinics
- Hospice establishing related palliative care clinic

Lessons Learned

- Use of a nonprofit entities may be a Stark Law strategy
- Nonprofits may also work where corporate practice is an issue

ASC Joint Ventures

ASC Joint Ventures

- What are the critical terms?
- Which laws are relevant?

Regulatory Issues

- **Applicable Federal Laws**
 1. Antikickback Statute
 2. Stark
 3. Antitrust
 4. Tax Exemption Laws
- **State Laws**

AKS and ASC Safe Harbors

- 1. Surgeon-Owned ASCs
- 2. Single-Specialty ASCs
- 3. Multi-Specialty ASCs
- 4. Hospital/Physician ASCs

ASC Safe Harbors-Key Elements

- Not be related to volume or value of referrals
- No loans or loan guarantees by other investors
- Distributions directly proportional to the amount of investment

ASC Safe Harbors-Key Elements (cont.)

- Ancillary services
 - directly and integrally related to primary procedures performed at the ASC
 - none may be separately billed to Medicare
- Must treat Medicare patients in a nondiscriminatory manner
- Patients must be fully informed of the physician's ownership

One-Third Tests

- For Single-Specialty ASCs:
 - At least 1/3 of each physician investor's medical practice
 - Income from all sources for the previous fiscal year or
 - Previous 12 month period must be derived from the
 - Physician investor's performance of ASC procedures
- For Multi-Specialty ASCs:
 - 1/3 Income Test, and
 - At least 1/3 of the ASC procedures performed by each
 - Physician investor for the previous fiscal year or previous
 - 12 month period must be performed at the ASC

ASCs and Stark

- ASC services are not Stark DHS

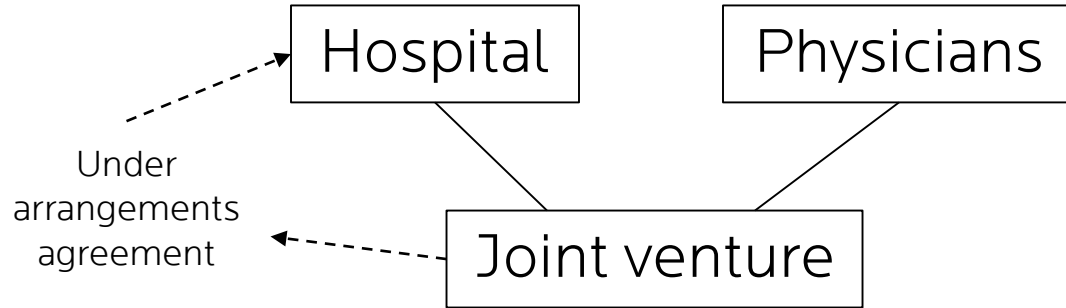
ASCs and Antitrust

- Payor Contracting
- *Copperweld* analysis

Closing thoughts on ASCs

- Investor Selection
- Valuation Issues
- Co-Location
- Hotels
- Outpatients vs. ASC
- Myths

Under-Arrangement Deals



Opportunity

- Joint venturing a hospital service
- Hospital-based department or entity rules make this generally impossible
- Under arrangements rules are simple

Exception to Prohibition on Physician Ownership in Hospitals

In general, a hospital-based department owned in part by a physician is treated as a physician-owned hospital

This prohibition may be repealed

Stark Issues

- Ownership by a referring physician only permitted in rural areas
- Where the hospital is purchasing the service under arrangements, the exceptions for compensation arrangement must be met.

Direct and Indirect Compensation

- Service arrangements can be per-click
- Lease arrangements cannot
- The fee structure should separate these elements
- Fair Market Value should be supported analytically

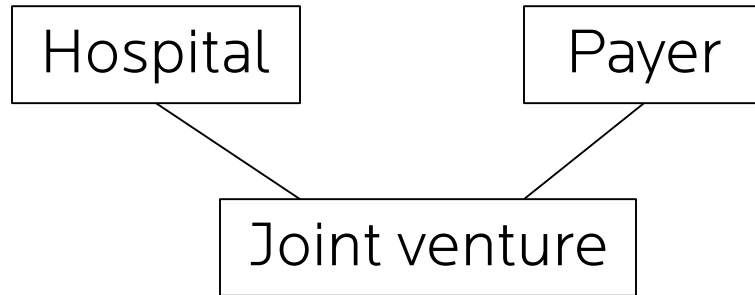
Antikickback

- Intent based
- Concept of commercial reasonableness

Lessons Learned

- Under arrangements is an approach that can still permit joint venturing in certain circumstances.

Hospital Payer Co-ownership



What Are “Aligned Incentives”

- Total Cost of Care Adjustments
- Payer’s incentive is to reduce medical cost
- Provider’s incentive is to reduce cost, but not cost of own services

“Aligned Incentives”

- Capitation
- Payer is incented to pay cap that is less than FFS pay structure
- Provider incented to reduce cost, especially of other providers in pool

Payer Responsibility for Provider's Economic Results

- Most alignment arrangements don't do this
- Payer ownership of part or all of provider
- Contract that approximates financial results of ownership

Ownership Issues

- Exemption—*Redlands* analysis
- Corporate Practice
- Conflict of Interest
- Choice of Entity
- Governance—preserving separate interests

Network Arrangements

- Insurance laws
- Antikickback and Stark issues
- Network distributions
- Participation of other providers

Examples

- Hospital and Payer co-ownership of clinic services operations
- Development of network contract

Professional Service Agreements

- What are they?
- Why do we use them?
- What are the critical terms?
- Which laws are relevant?

What is a Professional Service Agreement?

- Agreement between two health care providers for the provision of medical services
- Examples:
 - Hospital/specialists
 - Primary care group/specialists
 - Hospital/physician group

Why Do We Use Professional Service Agreements?

- Streamline the billing process
- Expand services to patients
- Greater flexibility and potentially lower costs

Critical Terms

- Term
- Termination Rights
- Exclusivity
- Payment
- Noncompetition
- Nonsolicitation/No-hire Clauses
- Performance Standards

Regulatory Issues

- Applicable Federal Laws
 1. Medicare Reassignment Rule
 2. Tax Exemption Laws
 3. Antikickback Statute
 4. Antitrust
 5. Stark
- State Laws

Medicare Reassignment

- Non-employee physician can reassign right to receive payment, as long as:
 - Joint and several liability
 - Access to billing records

Tax Exemption

- Tax-exempt hospitals (or clinics) must operate exclusively for charitable purposes.
- IRS intermediate sanction rules create penalties for excess benefit transactions (overpayments) which apply to recipient and responsible persons.

Tax Exempt Bonds

- Exclusive agreements or management agreements must meet requirements of IRS “permitted arrangements” rules

AKS Safe Harbor for Personal Services Agreements

- To fall within the safe harbor, the agreement must meet the following 7 requirements:
 1. In writing
 2. Covers all services to be provided
 3. If the services will be provided on a periodic, sporadic, or part-time basis, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals
 4. Term is at least one year
 5. Compensation is set in advance, consistent with FMV, and does not take into account referrals between the parties
 6. Agreement does not involve the promotion of illegal activity
 7. Services cannot exceed those reasonably necessary to accomplish legitimate business purpose

Stark Exception for Personal Service Arrangements

- Very similar to AKS Safe Harbor
- Must meet the following conditions:
 1. In writing
 2. Specifies and covers all services to be provided
 3. Term must be for at least one year
 4. Services cannot exceed those reasonable and necessary to achieve legitimate business purpose
 5. Compensation must be set in advance, not exceed FMV, and not take into account referrals between the parties
 6. Services cannot involve illegal activity

Group Practice Definition

- In Office Ancillary Exception
- Must be a “group practice” – one requirement is that “substantially all of the patient care services of the physicians who are members of the group (that is, at least 75% of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. . . .” 42 CFR 411.352(d).



Group Practice Definition

- “If the group’s business includes providing professional services to another entity, which, in turn, pays the group for those services, it is our view that these are services that should count as services a physician provides through the group. We are, therefore, interpreting the requirement that substantially all of a physician’s services be provided through the group and be billed “under a billing number assigned to the group” and amounts so received treated as receipts of the group to include any physicians’ professional services billed by a group under any group billing number regardless of the payer of the services, provided the receipts are treated as receipts of the group. In other words, the phrase “billed under a billing number assigned to the group” . . . does not refer exclusively to Medicare or Medicaid billing numbers.” 66 FR 905 (Jan. 4, 2001).

State Laws

- Antikickback Laws
- Anti-Referral Laws
- Fee-Splitting Laws

Antitrust

- Sufficient clinical and/or financial integration for joint pricing?
- Exclusivity and market power?

Closing PSA Thoughts

- Hospitalists
- Emergency Department
- Neonatalists
- Overhead (billing)
- Valuation
- Hospital-based clinics

Gainsharing/Co-Management Arrangements

- What are they?
- Why do we use them?
- What are the critical terms?
- Which laws are relevant?

Regulatory Issues

- **Applicable Federal Laws**
 1. Tax Exemption Laws
 2. Antikickback Statute
 3. Stark
 4. False Claims Act
 5. Civil Monetary Penalties
- **State Laws**

AKS Safe Harbors

- Personal Services and Management Agreement Safe Harbors
 - compensation must be “set in advance”

Civil Monetary Penalties

- Prohibits hospitals from making, and physicians from receiving, direct or indirect payments as an “inducement to reduce or limit medically necessary services” to Medicare patients.

Practical Considerations/Safeguards

- No stinting, steering or cherry-picking
- No payments for changes in volume/referrals
- No payments for quicker-sicker discharge
- No reward for changes in payor mix, case mix
- Must be FMV

Closing Thoughts on Co-Management/Gainsharing

- FMV
- Lessons Learned
 - governance
 - change in market/regulatory landscape

Options, Covenants and Other Rights

- Option to Buy
- Right of First Refusal
- Covenant to Not Sell
- Other Agreements...