Summary of Presentation

- Overview of joint venture models and strategy
- Summary of reimbursement and legal considerations
- Summary of deal terms
Types of Joint Ventures

- Clinical laboratory services
- Physical therapy services
- Durable medical equipment
- Pharmacy services
- Radiology and other imaging services
- Cardiovascular joint ventures
- Ambulatory surgery centers

Degree of Physician/Hospital Economic Alignment

- Integrated Salary
- Employment
- Leasing Arrangements
- Co-Management
- Equity Joint Venture
- Integrated Salary Employment
### Degree of Physician/Hospital Economic Alignment

#### Leasing Arrangements

**Description:**
Contractual arrangement in which a hospital or physician rents space, equipment, and/or personnel from the owner of the asset(s) or employer of personnel

**Strengths:**
- Short-term, flexible relationship
- No capital commitment from lessee
- Lessee gains access to facility/equipment and associated technical fees without depreciation risk
- Lessor enjoys stability of rental fees
- Potential recruitment tool

**Weaknesses:**
- Complex process to establish and verify fair market value
- Under increasing regulatory scrutiny
- Economics for physician lessors often less attractive than other financial arrangements

**Applicability:**
- Hospitals and physicians with small local market share
- Hospitals and physicians with limited capital
- Hospitals lacking medical staff support for geographic expansion

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#### Co-Management

**Description:**
Contract between hospital and select physicians under which physicians agree to provide management services for a particular service line

**Strengths:**
- May facilitate efficiency and quality improvements
- May protect share, reduce physician defections

**Weaknesses:**
- Rarely able to eliminate administrative FTEs
- Moderate legal costs and measured legal risk
- Highest revenue, busiest physicians unlikely to participate
- Has not consistently stemmed defection past the 3-5 year mark

**Applicability:**
- Hospitals with potential physician competitors who are somewhat risk-averse
- Hospitals with potential physician competitors who desire “control” more than income support
Degree of Physician/Hospital Economic Alignment

**Equity Joint Venture**

**Description:**
Legal entity including hospital, physicians (and potentially a third party) that invests in and jointly owns clinical infrastructure; risk and profit of partners distributed in direct proportion to equity and governance.

**Strengths:**
- High level of income support to physicians
- Opportunity to expand hospital capacity at reduced capital cost
- “Incubator” for cost savings practices

**Weaknesses:**
- Loss of technical revenue to hospital
- High start-up and legal costs
- Potential political problems with excluded physicians, as well as included physicians should the venture sour
- Lifespan at mercy of reimbursement shifts and recapitalization hurdles

**Applicability:**
- Local markets where ORs are at capacity
- Markets with low hospital market share
- Growth markets outside hospital’s primary service area
- States without strong CON protections
- Hospitals seeking to recruit new surgeons

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**Integrated Salary Employment**

**Description:**
Hospital that directly employs physicians – may include anywhere from a few physicians to the entire medical staff.

**Strengths:**
- Physician protection from private-practice costs
- Income stability for physicians and hospitals in highly competitive markets
- System expansion through practice capitalization
- Physician recruitment edge

**Weaknesses:**
- Potentially very expensive
- Hospital tendency to employ poor-performing physicians
- Complexity of structuring the “right” compensation plan for each physician

**Applicability:**
- Rural and indigent areas, other areas of shortage or historic recruitment difficulty
- States with declining Medicaid rates or rising malpractice costs
- Markets with predominantly small private practices
- Intensely competitive markets
Potential Advantages of an Alignment Strategy

- Defensive strategy to retain portion of the revenue stream and/or preempt the competition
- Develop common incentives to grow the business
- Offer a new delivery model to the community
- Can be a mechanism for innovative care management and delivery programs
- Serve as a platform to build broader trust and respect in other areas
- May aid in bringing new or improved services to the community
- Physician recruitment vehicle

Basic Joint Venture Models

- Hospital-Based Joint Venture
  - Hospital
  - Physicians
  - Professional Service
  - Technical Service
  - Payors

- Non-Hospital Based Joint Venture
  - Hospital
  - Physicians
  - Bill Technical and Professional Globally
  - Payors
Joint Venture Legal Issues

- Reimbursement analysis
- Stark Law
- Anti-kickback Statute
- Tax-exempt status/intermediate sanctions
- Limitations on use of bond-financed facilities
- State law (licensure, CON, anti-self referral)
- Securities law requirements (applicable if physician offering)
- Antitrust

Reimbursement Analysis

- What type of health care entity (state licensure and Medicare certification) fits with proposed services?
  - Ambulatory Surgical Center ("ASC")
  - Independent Diagnostic Testing Center ("IDTF")
  - Specialty hospital
  - Hybrid
    - Per CMS, ASC and IDTF may not concurrently share the same space
  - Provider-based department (C.F.R. § 413.65)
    - On-campus [in hospital or within 250 yards of main building] joint ventures may qualify as provider-based departments. Cannot have off-campus provider-based joint venture. Exceptions for rural areas.
Reimbursement Analysis

- What services can be billed by possible health care entities?
  - ASC can only bill for surgical procedures on Medicare-approved list
  - IDTFs can only bill for diagnostic, and not therapeutic, services
  - Hospitals can bill for all types of hospital inpatient and outpatient services

Stark II 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 Self-Referral Prohibition

Entity v. Not an Entity

“Entity” means the entity that submits a bill for DHS to Medicare under its provider number.

Currently, a physician may hold ownership in a company that simply leases equipment and/or sells services back to the physician since that company doesn’t bill Medicare for DHS. If the company doesn’t bill Medicare, it isn’t an “entity” to which the physician would be making prohibited referrals.

Bad Model
Good Model

5 Primary Stark Exceptions

- Rental of Office Space or Equipment
- Personal Services
- Indirect Compensation Arrangement
- Whole Hospital Exception
- Bonafide Employment Arrangement
Rental of Office Space and Equipment Exception

(Applies to Compensation Relationships)

- Payments made by lessee to lessor for use of equipment and premises is not prohibited compensation if:
  - Lease is signed in writing, and specifies premises and equipment to be leased;
  - Space and equipment rented does not exceed that which is reasonable and necessary for legitimate business purposes of lease and is used exclusively by lessee when being leased by lessee;

- Term of lease is for at least one year;
- Rental charges over term of lease are set in advance, consistent with fair market value, and not determined in a manner that takes into account volume or value of referrals or other business generated between parties; and
- Lease would be commercially reasonable even if no referrals were made between parties.
- Hold over month-to-month following a term of at least one year, assuming all other provisions of the exception are met, continuing on a month-to-month basis for up to 6 months on the same terms and conditions will meet the rental of office space and equipment exceptions.
Rental of Office Space and Equipment Exception

(Applies to Compensation Relationships)

If use is not full-time, lessee must be exclusive user of space/equipment when lessee is using/leasing space/equipment.

- Group A Group A
- Permitted

- Group A Group B
- Not Permitted

Rental of Equipment

(Applies to Compensation Relationships)

- Can charge per use fee ("per click") as long as charge does not reflect payment for professional services.
### Personal Services – Management Arrangement

(Appplies to Compensation Relationships)

- The arrangement is in writing, signed by the parties, and specifies the services covered by the agreement
- The arrangement covers all services to be provided by physician to entity
- The aggregate services contracted for do not exceed those reasonable and necessary for the legitimate business purposes of the arrangement
- The term is at least one year
  - If parties terminate during the term they may not enter into the same or substantially the same arrangement during the first year of the original term
- The compensation is set in advance and, except for physician incentive plans, does not take into account the volume or value of referrals or other business generated between the parties
- The services do not involve the counseling or promotion of an unlawful business arrangement or other activity

### “Group Practice” Definition

- Must meet definition for In-Office Ancillary Exception
“Group Practice” Definition

• To qualify as a group practice, the professional services must be performed:
  – Personally by another physician who is in same “group practice” as referring physician; or
  – Under personal supervision of referring physician or another physician who is in same group practice.

Criteria of Group Practice

• Group practice means a group of two or more physicians legally organized as a partnership, professional corporation, faculty practice plan or similar association where:
  – Each physician in group provides substantially the full range of services that physician routinely provides (including medical care, consultation, diagnosis or treatment);
  – Professional services provided through joint use of shared office space, facilities, equipment and personnel;
Criteria of Group Practice

• **Substantially** (75%+) of each physician’s patient care services are provided through group (Must be able to document through time cards, personal schedules, etc.);
  – Must meet within 12 months of formation or 12 months of new physician relocating (25 miles+) to join group.
• All services are billed under group’s billing number;
• All income is treated as receipts of group;
• Overhead expenses and income from practice are distributed in accordance with **previously determined methods**; and

Criteria of Group Practice

• No physician who is member of group may directly or indirectly receive compensation based on volume or value of referrals by physician. (However, physician may be paid share of overall profits or productivity bonus based on services personally performed or services incident to such personally performed services.)
In-Office Ancillary Exception

(Applied to Ownership and Compensation Arrangements)

Must answer 3 questions:

Who?

How?

Where?

In-Office Ancillary Exception

(Applied to Ownership and Compensation Arrangements)

- A Centralized Building, which means all or part of a building that is owned or leased on a full-time basis by a group practice including a mobile vehicle, van or trailer where some or all of the group practices DHS is provided.
### In-Office Ancillary Exception

**Where Are Services Provided?**

#### “Same Building” Requirement

**Full-Time Office**

- Open to patients 35 hrs/wk
- Referring physician or group members regularly provide physician services (some unrelated to DHS) at least 30 hrs/wk.
- Meant to describe buildings that are the principal place of practice for the referring physician or his/her group.

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**Part-Time Office #1**

- Office where patient usually receives physician services.
- Open to patients 8 hrs/wk.
- **Referring physician** provides physician services (some unrelated to DHS) at least 6 hrs/wk.
- Meant to describe building where the referring physician practices medicine at least 1 day per week and that is a principal place where the physician’s patients receive physician services.
In-Office Ancillary Exception

Where Are Services Provided?
“Same Building” Requirement
Part-Time Office #2

- Open to patients 8 hrs/wk.
- Referring physician or group member furnishes physician services (some unrelated to DHS) at least 6 hrs/wk.
- **Referring physician** must be **present and order** DHS during patient visit or **group member** must be **present** while DHS is furnished.
- Meant to describe building where the referring physician (or group practice) practices medicine at least 1 day per week and the DHS are ordered during the patient visit or the physicians are present during the furnishing of the DHS.

Who May Provide Service?

- DHS must be personally furnished by:
  - Referring physician
  - Group practice member
  - Individual supervised by referring physician or another physician in the group practice.

NOTE: Physician “in the group practice” includes independent contractors
In-Office Ancillary Exception

How are Services Billed?

• DHS must be billed by:
  – Performing/supervising physician.
  – Performing/supervising physician’s group practice.
  – Group practice if supervising physician is an independent contractor “in the group practice.”
  – Entity wholly-owned by performing/supervising physician or by group practice under a number assigned to the entity, the physician or the group practice.
  – Third-party billing company acting as agent of any of the above.

In-Office Ancillary Exception

How are Services Billed?

DME

• How is equipment used by patient?
• Durable medical equipment (“DME”), like canes, crutches, walkers, blood glucose monitors, can be subject to in-office ancillary exception if:
  – the DME is required by the patient to depart from the physician’s office, or is a blood glucose monitor;
  – it is furnished in the same building as the patient-physician encounter; and
  – the DME is furnished personally by the physician, a physician in the same group practice, or an employee of the same group practice.
Indirect Compensation Arrangement Definition:
An indirect compensation arrangement is any series of ownership or compensation arrangements if the aggregate compensation arrangement closest to the referring physician varies based upon the volume or value of referrals. For example:

A → B → C → D

DHS Entity

Indirect Compensation Arrangement Exception
(Applies to Compensation Relationships)

Each component of the compensation that is closest to the referring physician (in the example below, the compensation between company B and C) must be fair market value.
Stark Phase III

“Stand in the Shoes”

- 42 CFR 411.354 (c) (ii) - A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.

Stark Phase III

“Stand in the Shoes” continued

Pre-Phase III View

Physician

Group

Hospital

$ Indirect

Phase III View

Physician Organization

Hospital

$ Direct
Stark Phase III

“Stand in the Shoes” continued

• Implemented due to CMS’s concern that arrangements between DHS entities and group practices are often viewed as outside the application of the Stark Law
  – For example, an arrangement that did not meet the Stark Law's definition of a direct compensation arrangement and that also failed to meet one of the prongs of the indirect compensation arrangement definition may allow a physician to make referrals to the entity for the furnishing of DHS without violating the Stark Law’s referral prohibition.

• Phase III definition applies to new arrangements or renewals entered into after September 5, 2007.
• Grandfather provision for arrangements that were “properly structured to comply with the indirect compensation arrangements exception”

Whole Hospital

(Appplies to Ownership Relationships)

– Hospital Ownership
  • An ownership or investment interest in a hospital, in the case of a DHS furnished by the hospital, does not constitute a financial relationship if
    – The referring physician is authorized to perform services at the hospital
    – The hospital is not a specialty hospital
    – Ownership is in the entire hospital and not merely a distinct part or department of the hospital

– Specialty hospital is defined as a hospital in one of the 50 states or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following:
  • Patients with a cardiac condition
  • Patients with an orthopedic condition
  • Patients receiving a surgical procedure
  • Is not Psychiatric hospitals, Rehabilitation hospitals, Children’s hospitals, Long-term care hospitals
Bonafide Employee

(Applies to Compensation Relationships)

- Requirements for Exception
  - The employer and physician (or immediate family member) have a bona fide employment relationship
  - Employment is for identifiable services
  - Remuneration for the employment is consistent with fair market value and, except for certain permitted productivity bonuses, does not take into account the volume or value of referrals
  - Agreement would be commercially reasonable even if no referrals were made to the employer
- Because personally performed DHS are not referrals under the statute, employed physicians can be paid in a manner directly correlating to their own personal labor but are not permitted to receive payment for generating referrals of DHS performed by others

Stark Law Proposed Changes in 2008 Medicare Physician Fee Schedule

- “Under arrangements” and definition of “entity”: CMS proposed that the definition of “entity” include both the entity performing the DHS and the entity that submits the claim for the DHS

![Diagram showing Hospital, Physician Group, DR. and Referral relationship]
Anti-Kickback Statute

- Unlike Stark Law, is an intent-based statute not limited to physician ownership or DHS
- Prohibits offer, solicitation, payment or receipt of remuneration if intent is to induce referrals of patients or other business paid for in whole or in part by a federal program
- Potentially relevant to contracts and arrangements, including joint ventures, involving referral sources
- Issue is whether return on investment constitutes an improper inducement for referral
- Hospital may be considered a referral source due to employment or other arrangements with physicians or due to other facts (e.g., discharge planning, marketing)

1989 OIG Fraud Alert on Joint Ventures

- OIG identified suspect features of a joint venture, including:
  - Investors chosen because they are a referral source
  - Disproportionate investment opportunity to physicians expected to make more referrals
  - Tracking of referrals by venture
  - Loss of investment interests of physicians threatened if referral targets not met
Anti-Kickback Statute

- OIG has published safe harbors to protect certain ventures
- May decrease degree of Anti-kickback Statute risk by:
  - Meeting small investment interest safe harbor requirements as closely as possible
  - Limiting investment to physicians who are in a position to personally perform venture services (analogy to requirements of ASC safe harbors)

Anti-Kickback Statute

- Small investment interest safe harbor:
  - Investment interests offered to investors on same terms which are not related to previous or expected volume of referrals
  - No more than 40% of the value of the investment interests are held by referral sources or parties providing items or services to the venture
  - No more than 40% of the gross revenues of the venture are from referrals or other business generated from investors
  - The venture does not loan funds to or guarantee a loan for a referral source investor for purposes of making an investment in the venture
  - Payments to investors are directly proportional to the amount of their capital investment
Underserved Area Safe Harbor

- Similar to small investment interest safe harbor, except:
  - Referral sources and parties furnishing items and services to the venture may own up to 50% of the venture
  - No limit on percentage of business from investors
- Venture must be located in a Medically Underserved Area (MUA)
- At least 75% of business must be from persons residing in an MUA or members of medically underserved populations

Hospital Tax-exempt Status Considerations

- Jeopardy to tax-exempt status
- Venture income as unrelated business taxable income
- Valuation issues
- Tax-exempt bond-financing considerations
Tax-Exempt Status Considerations

- Venture must further charitable purposes:
  - Venture participates in Medicare/Medicaid and provides indigent care
  - Venture maintains open medical staff
  - Financial arrangements on arm’s-length terms and at fair market value
  - Primacy of charitable over profit-making purposes

- Defensible governance structure: 51/49 board representation with hospital control as necessary to ensure on-going exempt operation
  - Hospital reserve powers ensure venture operates to further charitable purposes
  - Hospital approval required for material decisions (not just supermajority vote on key decisions)

- Management arrangements with for-profit parties should be for limited term and should be terminable for cause over objections of interested parties

Joint Venture Models

- “Per Click”
- Block Time Model
- Ambulatory Surgery Center
- Clinical Co-Management
- “Under Arrangement”
- Whole Hospital
Per Click Model

- “Per click” = No business risk
- “Turn-key” arrangement
- Limited involvement in performance of technical or professional components
- Patients scheduled in any available time slot
- No minimum # of procedures or minimum # based on historical usage
- May qualify for in-office ancillary exception – Must meet same building or centralized building requirement
- May meet office space/equipment leasing safe harbors under Anti-Kickback Statute
- Most suspect model due to no risk on physician
- Must be exclusive user when leasing on per-click basis
### Per Click Model

- In Phase III (page 51033), CMS stated “that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the Anti-Kickback statute.”

### Purchased Diagnostic Tests

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42 C.F.R. § 414.50
Purchase Diagnostic Tests

- Anti-markup provision applies
  - to the technical component of a purchase diagnostic test
  - to any anatomic pathology diagnostic testing service furnished in space that i) is utilized by a physician group practice as a “centralized building” as defined by the Stark Act (See Slide 32), and ii) does not qualify as a “same building” under the Stark Act (see Slides 33-35).

Block Time Model
Block Time Model

- Block time = real business risk
- Physician leases specified time block
- Pay regardless of procedure volume
- May qualify for in-office ancillary exemption
- May meet office space/equipment leasing safe harbors under Anti-Kickback Statute
- Must be exclusive user during block time

Ambulatory Surgery Centers

- Ambulatory surgery centers are not designated health services entities.
- No Stark issue.
### Ambulatory Surgery Center ("ASCs") Safe Harbor

- **Four Types of ASCs:**
  1. Surgeon-owned ASCs
  2. Single-specialty ASCs
  3. Multi-specialty ASCs
  4. Hospital/physician ASCs

### ASC Safe Harbor

**Surgeon-owned ASCs:**

To qualify for this Safe Harbor, the following seven factors must be met:

1. All investors must be general surgeons or surgeons engaged in the same surgical specialty.
2. The investment terms must not be related to previous or expected volume of referrals to be generated from investor.
3. At least one-third of surgeons/investors' medical practice income from all sources must be derived from surgeons' procedures.
4. The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
5. The return on investment must be directly proportional to the amount of capital investment.
6. All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
7. The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
### ASC Safe Harbor

**Single-specialty ASCs:**
To qualify for this Safe Harbor, the following seven factors must be met:

1. All investors must be physicians engaged in the same medical practice specialty.
2. The investment terms must not be related to previous or expected volume of referrals to be generated from investor.
3. At least one-third of surgeons/investors’ medical practice income from all sources must be derived from surgeons’ procedures.
4. The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
5. The return on investment must be directly proportional to the amount of capital investment.
6. All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
7. The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.

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### ASC Safe Harbor

**Multi/specialty ASCs:**
To qualify for this Safe Harbor, the following eight factors must be met:

1. All investors must be physicians who are in a position to refer patients directly to the ASC and perform procedures on such referred procedures.
2. The investment terms must not be related to previous or expected volume of referrals to be generated from investor.
3. At least one-third of surgeons/investors’ medical practice income from all sources must be derived from surgeons’ procedures.
4. At least one-third of the procedures performed by each physician must be performed at the ASC.
5. The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
6. The return on investment must be directly proportional to the amount of capital investment.
7. All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
8. The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
ASC Safe Harbor

Hospital/physician ASCs:
To qualify for this Safe Harbor, the following Nine factors must be met:
1. At least one investor must be a hospital and all of the remaining investors must be physicians who meet the requirements of the surgeon-owned ASC, single-specialty ASC or multi-specialty ASC. (Still must meet one-third tests.)
2. The investment terms must not be related to previous or expected volume of referrals to be generated from investor.
3. The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
4. The return on investment must be directly proportional to the amount of capital investment.
5. All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
6. The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
7. The ASC may not use space or equipment owned by the hospital unless such space/equipment meets the Equipment/Leased Space Safe Harbor.
8. The hospital investor may not include any cost related to the ASC on its cost report or any other claim for payment from Medicare/Medicaid.
9. The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the ASC.

Clinical Co-Management

Physician Group

Management Services

Fair Market Value Compensation

Hospital Service Line
Clinical Co-Management

- Clearly defined management services to be provided by physician group
- Compensation methodology should be documented to be fair market value
  - Hourly Rate v. Annualize Compensation
  - Incentive compensation based upon quality indicators

Under Arrangement Ventures

Entire services treated as a hospital service and billed by the hospital. The venture’s sole payment is a fee paid by the hospital, usually on a “per service” basis.
Under Arrangement Ventures

Coverage and Payment Conditions

- Payment to the hospital discharges the beneficiary’s liability. Hospital must retain responsibility for the service and exert significant degree of control.
  - Hospital registers patients
  - Hospital maintains complete medical record on patient
  - Hospital credential physicians who provide the service
  - Hospital’s utilization review and quality assurance programs apply to the service
  - Hospital’s governing body responsible for the services furnished under arrangement

Under Arrangement Ventures

Coverage and Payment Conditions

- Hospital may directly bill the Medicare program for these services at APC rates
- Agreement with venture must prohibit venture from billing anyone other than hospital for the services
“Under Arrangements” Services

- Hospital may directly bill the Medicare program for these services (at APC rates)
- Agreement must prohibit supplier from billing anyone other than hospital for the services
- Agreement between hospital and joint venture must ensure hospital standards are met:
  - Credentialing
  - Medical staff membership and clinical privileges for physicians providing services
  - Medical records standards
  - Physician supervision
  - Transfer agreement and protocols

Whole Hospital

- Not an “Entity” – 42 C.F.R. § 411.356(c)(3)
- No Stark Prohibition
- Moratorium Lifted
- Subject to Congressional Debate
  - Quality
  - Impact on “Safety Net” Hospitals
  - Treat Lower Acuity Patients – Higher referred to Community Hospitals