

# **PHYSICIAN-HOSPITAL JOINT VENTURE MODELS FOR CARDIOVASCULAR SERVICES**

***Planning, Legal and  
Structuring Considerations***

Robert L. Cohen  
Kutak Rock LLP

# Table of Contents

Joint Venture, Strategy and Planning Steps	3-8
Summary of Joint Venture Models and Regulatory Issues	9-14
Overview of Specific Joint Venture Models	15
Equity Joint Venture (Service Line and Hospital)	16-20
Leasing Models	21-24
Under Arrangements	25-31
Clinical Co-Management	32-37
Legal Appendix	38-80
Sample Joint Venture Work Plan and Timeline	81-84
Kutak Rock LLP and Robert Cohen Background Information	85-87

# Joint Venture Planning

# Strategic Reasons for a Physician Joint Venture Strategy

- Develop common incentives to grow the business
- Defensive strategy to retain portion of the revenue stream and/or preempt the competition (responding to “market realities”)
- Vehicle for entry into new markets
- Offer a new delivery model to the community
- Mechanism for innovative care management and delivery programs
- Serve as a platform to build broader trust and respect
- Physician recruitment strategy

# Implications of a Joint Venture Strategy

- ❑ Planning and deal execution are key to developing a sustainable partnership
- ❑ Successful deal execution often depends upon coordination of management, outside consultants and legal counsel
- ❑ Preparation should encompass:
  - Assessment of physician objectives
  - Business planning, determining project feasibility
  - Review of structuring options, including areas of legal risk and reimbursement analysis
  - Organization of “deal” process

## Implications of a Joint Venture Strategy (cont.)

- ❑ Key elements are sharing of control and financial risk/reward
- ❑ Typically involve extensive negotiations over ownership, governance and management terms
- ❑ Other key terms include physician investor eligibility requirements and redemption terms (typically dictated by legal analysis), rights of first refusal (for transfers and upon unwind or dissolution) and non-compete provision

# Critical Questions

- Choice of “partners”
- Alternatives for physician investment in the market
- Location and services mix; real estate issues
- Legal and financial feasibility of proposed arrangements
- Financial impact to hospital
- Capital requirements and financing options
- Who will manage the venture
- Timeline and cost for implementation

# Timeline for Joint Venture Formation

1-2 months

- Determine physician interest level and objectives
- Determine services to be included in joint venture
- Develop preliminary business plan and financial projections, including hospital impact analysis
- Assess legal, reimbursement regulatory and tax requirements
- Preliminary site and facility planning

2-4 months

- Form physician/hospital steering committee to agree on legal structure and business terms
- Prepare and refine term sheet
- Plan for corporate and regulatory approvals; continue site and facility planning
- Obtain necessary valuations of hospital contributed assets
- Finalize projections and financing options

2-3 months

- Draft definitive agreements (Operating Agreement, Lease, Asset Contribution Agreement, Management Agreement)
- Prepare Private Placement Memorandum (PPM) and plan for physician offering
- Complete offering; organize initial owner and board meetings and close on transaction agreements
- Accept physician subscriptions

# Joint Venture Models

# Summary of Legal Models

- ❑ Various structures in which hospitals and physicians may align to provide technical services
- ❑ Ownership Models
  - Equity joint venture
  - Under Arrangements joint venture
  - Leasing company joint venture
- ❑ Contractual Models
  - Leasing Arrangements (full-time or time-share)
  - Purchased Services Agreement (“Under Arrangements”)
  - Gainsharing/Clinical Co-management/Pay for Performance

# Regulatory Constraints and Sources of Risk

- ❑ Stark Law – applies to broad categories of services, including substantially all diagnostic imaging and hospital services (these services are called “Designated Health Services” or “DHS”). Intent generally not at issue; financial relationship of referring physicians with entity providing DHS must fit within an exception
  - Current Stark Law exceptions apply to investment in ASCs, services provided by group practices, transactions in a rural market, investment in a whole hospital, employment contracts, personal services agreements, leases and recruitment agreements
- ❑ Anti-Kickback Statute – Intent is a critical issue. OIG has issued safe harbors for investment interests in ASCs and investment entities, certain compensation arrangements, employment and leasing; satisfaction of safe harbors helpful but not required and many transactions will not comply with a safe harbor
- ❑ Civil Monetary Penalties Law (Prohibiting Payments to Physicians to Reduce or Limit Services to Program Beneficiaries)

## Regulatory Constraints and Sources of Risk (cont.)

- ❑ IRS Requirements for Tax-Exempt Organizations
- ❑ IRS Requirements for Tax-Exempt Bond-Financing
- ❑ Antitrust issues, particularly ability of hospital participants to negotiate with payors on behalf of the venture
- ❑ Medicare reimbursement rules
- ❑ Securities Law rules applicable to physician investment in a venture
- ❑ State Laws (CON, licensure, self-referral, corporate practice of medicine, other civil and criminal statutes such as consumer and insurance fraud laws). Example, recent Illinois Attorney General investigation and complaint against physician imaging turnkey lease arrangements

# Factors That Impact Selection of Model

- ❑ Type of physician investors (referring vs. non-referring)
- ❑ Are services DHS?
- ❑ Location
  - Rural vs. urban
  - On vs. off hospital campus
  - Medically underserved area
  - Same building as physician's office
- ❑ Reimbursement
  - Physician fee schedule
  - HOPPS
  - Commercial payor requirements

# Possible Impact of Stark III Regulations

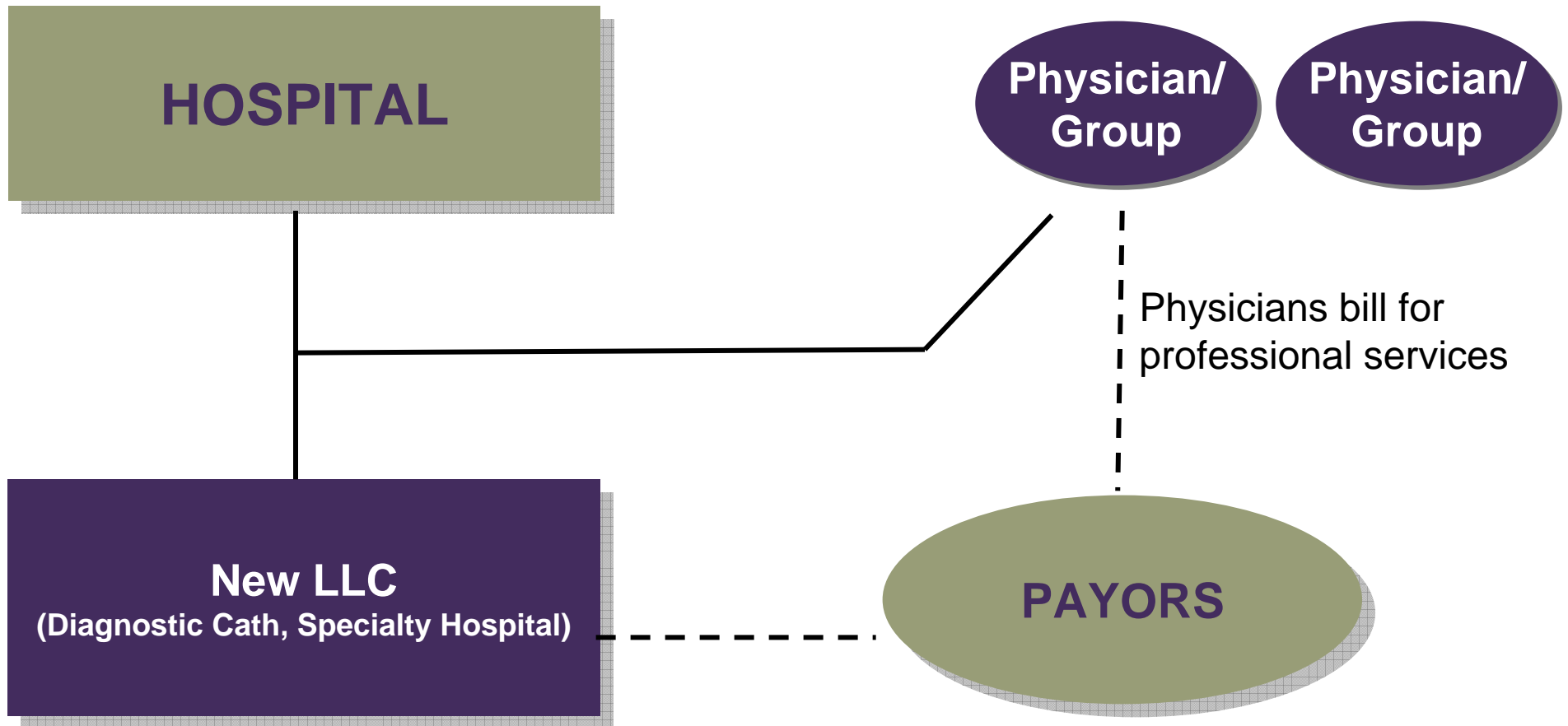
- ❑ Phase III regulations may be released within next few months
- ❑ Regulations may adopt MedPac recommendation to expand definition of physician ownership to include interests in an entity that derives a substantial proportion of its revenue from a provider of DHS
- ❑ Some limitation on hospital/physician under arrangements joint ventures likely
- ❑ Leasing structures may also be impacted where physicians have ownership interest in lessor
- ❑ Deals should be structured with “exit strategy” in case rules change
- ❑ CMS may continue to revise Stark regulations annually with physician fee schedule revisions

# Overview of Legal Structures

# Service Line or Hospital Equity Joint Venture

- ❑ Service is provided by a new entity that is co-owned by physicians and hospital—typically a limited liability company (LLC) or limited partnership (LP)
  - New entity will have its own tax ID number that is separate from hospital or physicians
- ❑ Example is Cardiac Cath Lab (in states that allow non hospital-based cath labs) with a hospital and cardiologists as investors
- ❑ Must be able to obtain state license, if applicable, and to enroll as Medicaid and Medicare provider or supplier
- ❑ Will separately contract with commercial payors
- ❑ Venture may employ staff or lease from hospital or from third party

# Equity Joint Venture



JV bills for technical service rendered by JV

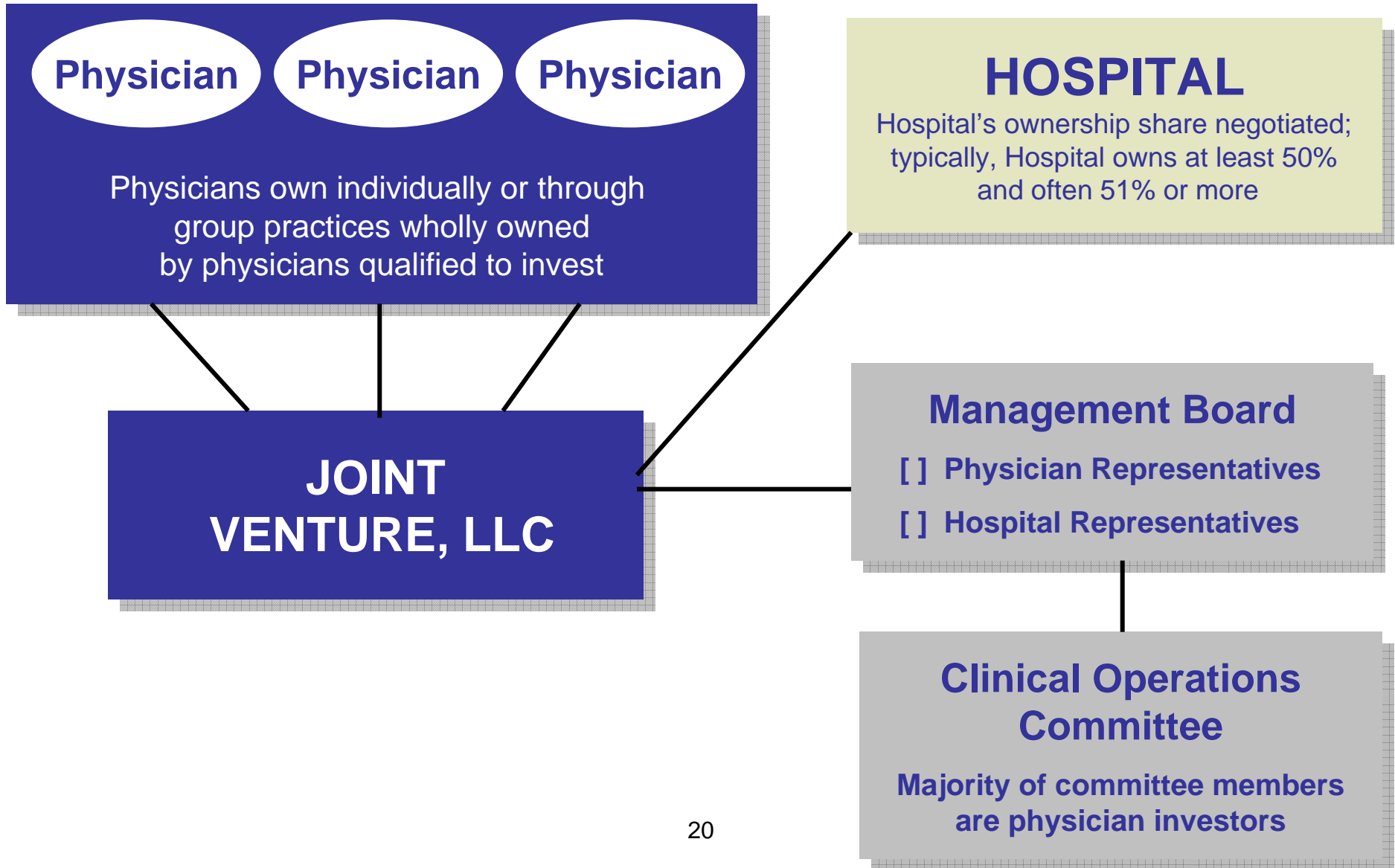
# Joint Venture Legal Structure

- ❑ LLC or limited partnership structure limits potential financial exposure while avoiding double taxation
- ❑ Properly structured venture permits hospital to treat its portion of revenue stream as tax-exempt
- ❑ In LLC structure, physicians and hospital elect a Management Board, with hospital and physician owner representation, as the governing body of the LLC. Typically, a physician-controlled Clinical Operations Committee would oversee clinical matters
- ❑ Distributions are proportionate to ownership and not based on referrals

# Joint Venture Deal Terms

- Hospital/physician ownership split
- Physician investor eligibility requirements
- Hospital tax exemption requirements
- Governance provisions
- Dispute resolution
- Equity transfer terms
- Redemption terms
- Unwind for legal or tax reasons
- Noncompete provisions
- Rights of first referral (transfer; dissolution)
- Management/staffing arrangements

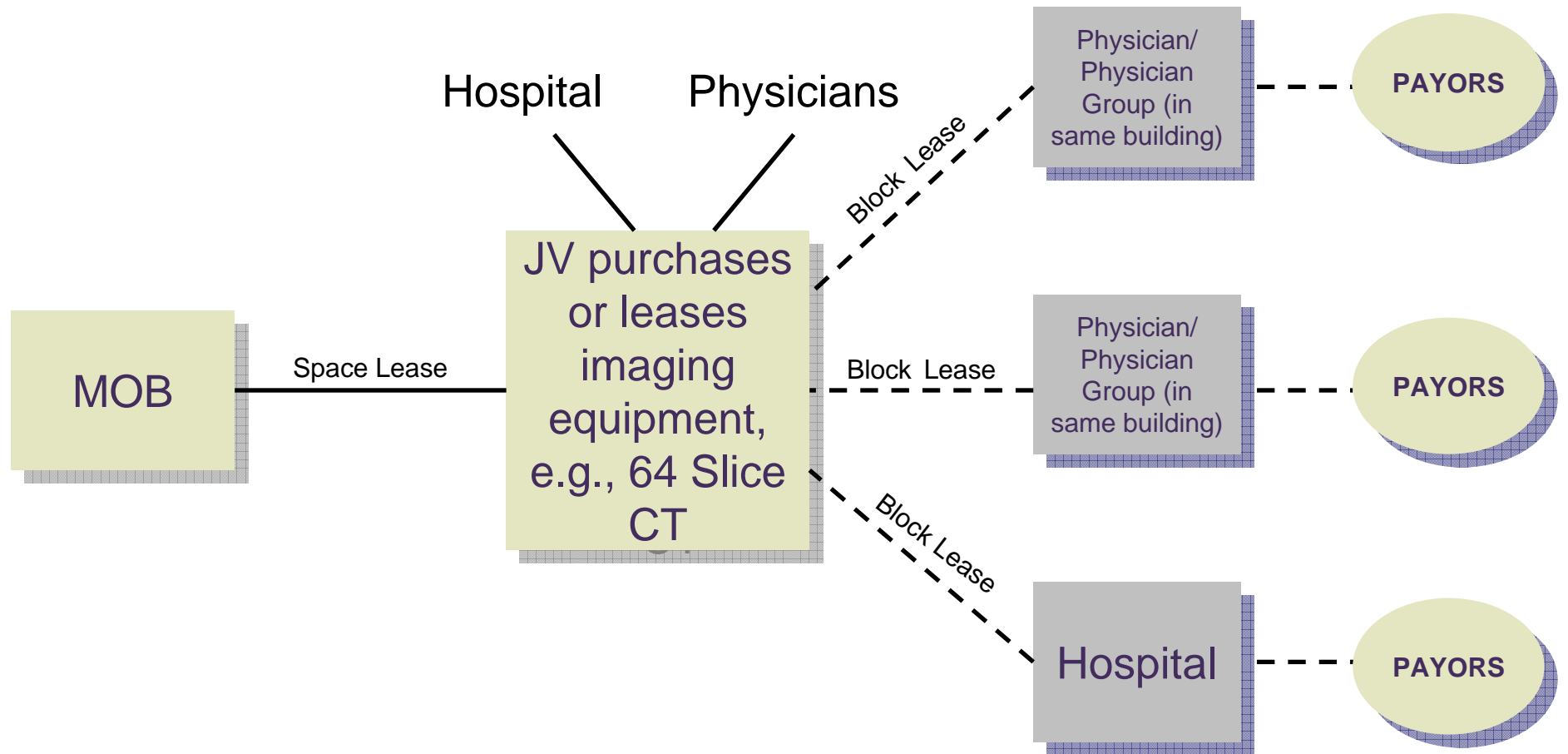
# Joint Venture Legal Structure



# Leasing Model

- ❑ Hospital and physicians form JV to acquire imaging equipment
- ❑ Hospital and physicians have exclusive use of imaging equipment during defined blocks of time (subject to exceptions for emergency cases)
  - Fixed, fair market value lease rates
  - Multiple parties may lease exclusive blocks
- ❑ Each lessee bills for the technical component of imaging service performed on its patients during its block lease time
- ❑ Each lessee provides or contracts separately for the professional interpretations of imaging services performed during its lease time

# Leasing Model



# Time Share Lease Structure

## Operational/Financial Considerations

- ❑ Fixed-time blocks for use of equipment (blocks must be fixed for at least a year)
- ❑ Lease rate based on fair market value opinion (maintenance costs included in lease rate)
- ❑ Space (and possibly staff) leased by hospital to physician groups under separate agreement

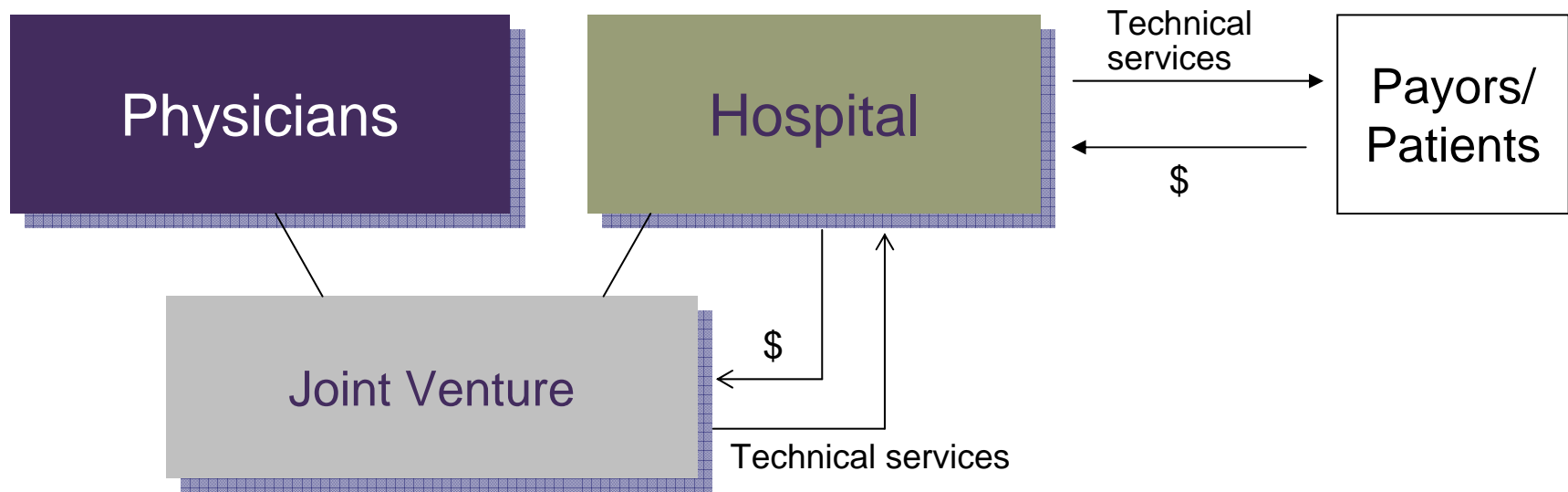
# Time Share Lease Structure Legal Considerations

- ❑ Stark
  - Time share lease of equipment structured to satisfy compensation exception to Stark; similar exception available for space and staff leases. However, Stark III regulations may impact whether physicians may own interest in the leasing company
  - Arrangement must be structured to meet the in-office ancillary services exception to Stark so physicians can bill for services
- ❑ Anti-Kickback Statute
  - Safe harbor compliance possible with fixed rate/fixed block lease
  - Limits but does not eliminate legal risk
- ❑ Provider-based requirements
  - Exclusive use by hospital during hospital lease period required to treat the time-share lease as a provider based service of the hospital

# Under Arrangements Joint Venture

- ❑ Hospital and physicians form JV to acquire imaging equipment and operate the imaging service for hospital
- ❑ JV is responsible for providing equipment/equipment maintenance, technologists and other staff, and supplies and may provide space
- ❑ Hospital provides and bills for the technical component of the imaging service as a provider-based service of the hospital
- ❑ Hospital purchases the technical component of the imaging service from the JV for a fair market value fee
- ❑ Hospital contracts for professional interpretation (may be covered under exclusive radiology contract) and physicians bill separately for professional component

# Under Arrangements Joint Venture



Hospital is the provider of technical services

Payors pay Hospital

Hospital pays joint venture on fee schedule basis for technical services

## Example: Cath Lab or 64-Slice CT Venture “Under Arrangements” Structure

- ❑ Hospital and physician groups jointly form JV entity (“Newco”), a company that provides management and operations for cath lab services (diagnostic and interventional) and/or 64-Slice CT services
- ❑ Hospital contracts with Newco to manage and operate cath lab/64-Slice CT services
- ❑ Newco operates in space provided by Hospital; Newco leases space from hospital/Newco funds site improvements
- ❑ Newco purchases or leases the equipment from a vendor
- ❑ Newco employs technicians and support staff, management, etc.

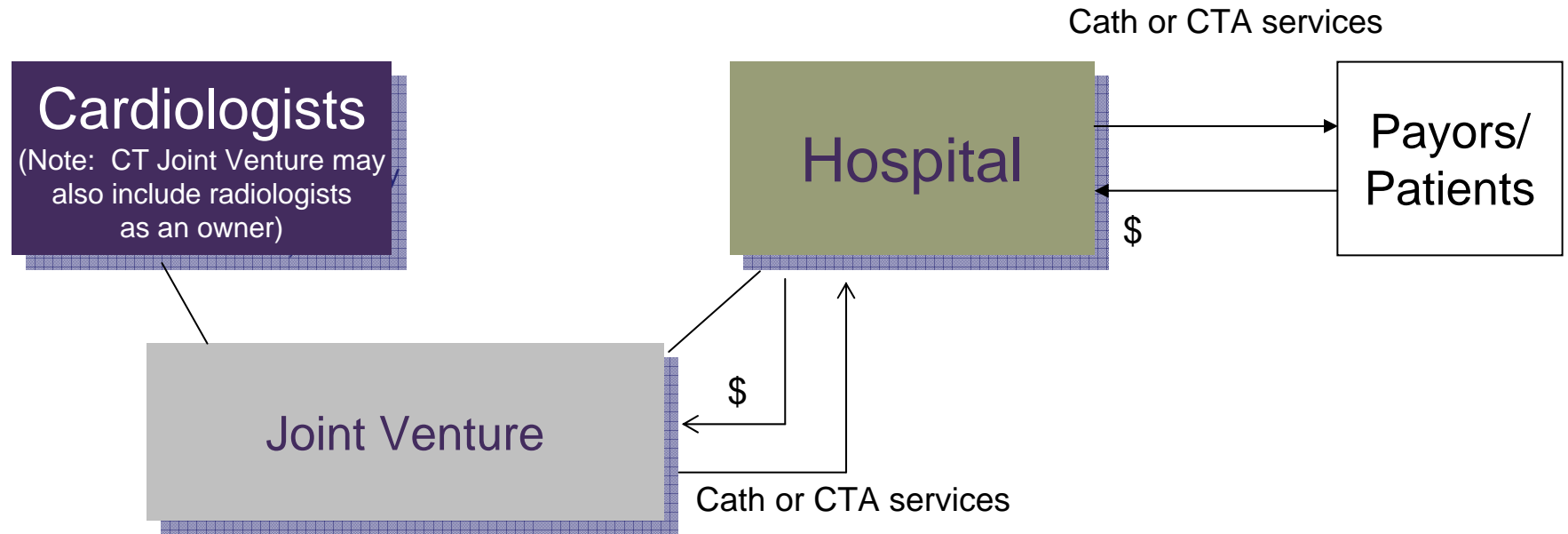
# Example: Cath Lab or 64-Slice CT Joint Venture “Under Arrangements” Structure

- ❑ Hospital pays Newco for services rendered according to a per service fee schedule or an annual fixed fee
- ❑ Fee arrangement must be supported by an independent valuation to determine fair market value
- ❑ Hospital is the provider of cath lab services
  - Patients registered as hospital patients
  - Hospital bills payors under its payor contracts
  - Hospital retains reimbursement less fees paid to Newco for services
- ❑ Newco operates in furtherance of hospital’s charitable purposes
  - Fee schedule discounted to account for charity care

## Example: Cath Lab or 64-Slice CT Joint Venture “Under Arrangements” Structure

- ❑ Newco is responsible for the costs of purchasing or leasing equipment, employing technical and support staff, supplies, etc.
- ❑ Newco profits are distributed to Newco’s owners
- ❑ Cardiologists bill professional fees; cardiologists may contract with radiologists to perform over-reads

# Example: Cath Lab or 64-Slice CT Joint Venture “Under Arrangements” Model



Joint venture owns/leases equipment and employs techs

Hospital is the provider of Cath Lab/CTA services

Payors pay Hospital

Hospital purchases Cath Lab/CTA service components from joint venture and pays joint venture on fee schedule basis

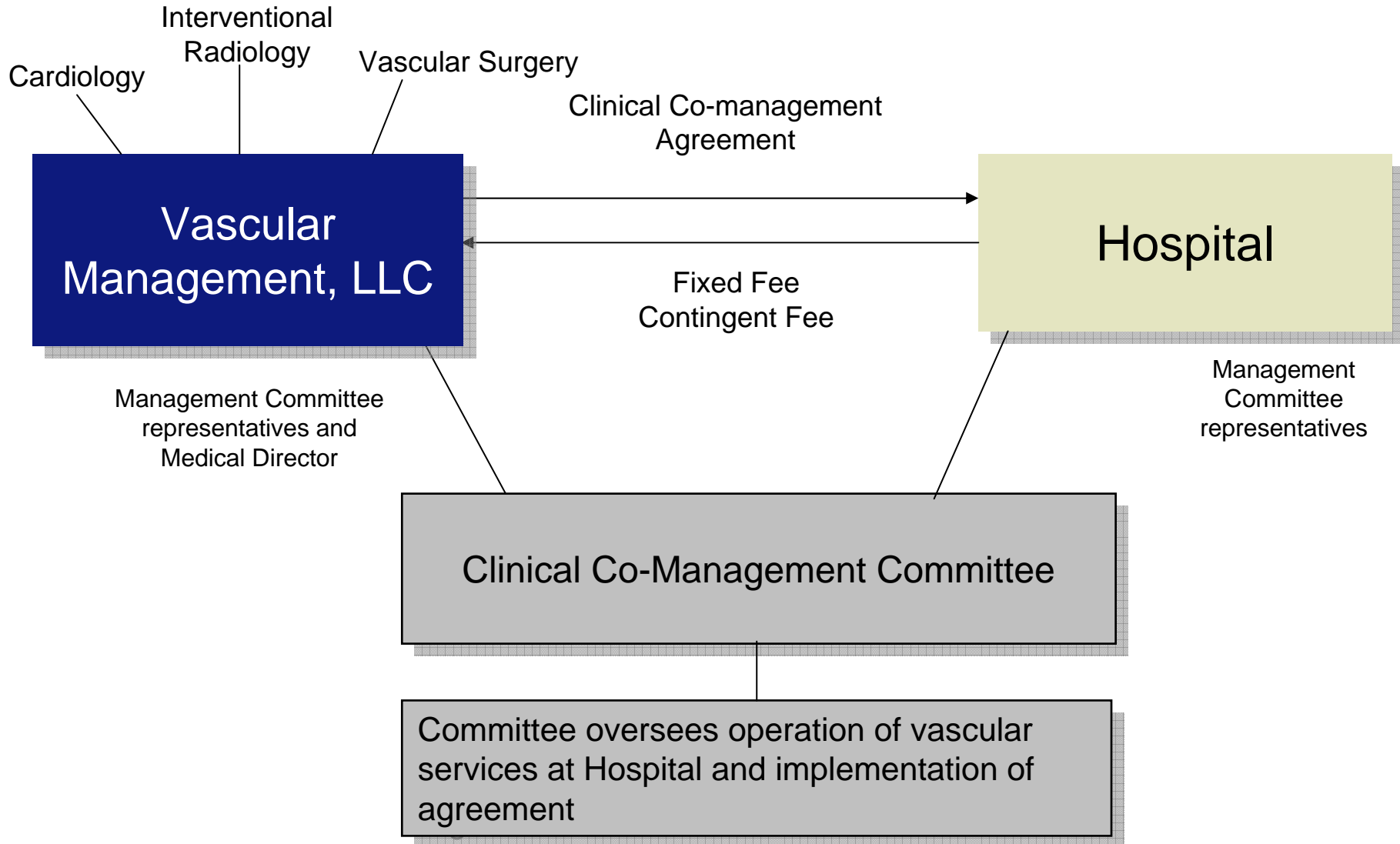
# “Under Arrangements” Structure Legal Considerations

- ❑ Stark
  - Ownership of joint venture not subject to Stark (no referrals of DHS to this entity) under current laws, but Stark III regulations may impact this exception
  - Purchased service agreement between hospital and joint venture structured to meet compensation exception to Stark; Stark allows “per unit” compensation
- ❑ Anti-kickback Statute
  - No safe harbor protection available
  - Key factors to minimize legal risk—New LLC is a “real company” providing new or expanded services; fee arrangement is FMV; investment and returns not based on referrals
- ❑ Medicare Requirements
  - Outpatient therapeutic services can be provided under arrangements only if furnished in the hospital or at a location (other than a rural health clinic or federally qualified health center) designated as a department of a provider
  - Entire hospital department cannot be contracted for “under arrangements”
  - CMS taking position that off-campus provision of services under arrangements by physician/hospital joint ventures violates provider based regulations

# Clinical Co-Management

- ❑ Physician Manager undertakes “hands on” administration and clinical/quality management of a hospital department or program (beyond typical medical director duties)
- ❑ Management provided pursuant to management contract with a physician group or with a physician or hospital/physician joint venture
- ❑ Manager enters into a management agreement with the hospital to provide agreed-upon clinical management and administrative services
- ❑ Compensation may include fixed compensation and incentive compensation based on achievement of quality goals (but not budgetary goals unless part of a permissible gainsharing program)

# Example: Clinical Co-Management for Vascular Service Line



# Financial Terms of Agreement

- Components of compensation may include (to be negotiated):
  - Base compensation for administrative/medical director services
  - Hourly compensation for committee service
  - Incentive compensation based on meeting quality-based targets as specified in the Agreement
  - Reimbursement of expenses

# Financial Terms--Incentive Compensation

- ❑ Permissible measures for incentive compensation:
  - Achievement of quality goals
  - Achievement of operational efficiency goals that do not result in reduction of care to patients
  - New program development
- ❑ Budgetary goals cannot be included unless part of a permissible gainsharing program, which would require an OIG advisory opinion

# Performance Measures

- ❑ Actual performance measures will be identified working with independent consultant who will provide “baseline assessment” of current program and identify benchmarks to use in establishing performance standards and incentive measures under the Agreement
- ❑ Incentive measures can be based on improvement or on achievement of specified targets
- ❑ Incentives can be structured, if desired, to provide for partial payment at certain levels of performance and greater payment at higher levels

# Hospital Reserve Powers

- Hospital maintains certain reserve powers, including:
  - approval of budgets and strategic plans
  - approval of contracts and expenditures in excess of specified limits (to be specified in Clinical Co-Management Agreement)
  - approval of any actions that might, in the reasonable judgment of Hospital, jeopardize its tax-exempt status

# Legal Appendix

# Legal Considerations

- ❑ Stark Law
- ❑ Anti-kickback Statute
- ❑ Tax-exempt issues (impact on exempt status, tax treatment of income from the venture, private use of bond-financed space or equipment)
- ❑ Reimbursement
- ❑ State law (licensure, anti-self referral, CON, if applicable)
  - Example: Illinois AG recently joined in challenge to certain turnkey leasing arrangements as shams based on State fraud and deceptive business practices statutes
- ❑ Securities law (applicable to physician investment)
- ❑ Antitrust (impact on payor contracting)

# Stark Law

- ❑ Unless exception applies, law prevents a physician from referring designated health services (“DHS”) to an entity, or the entity from billing for the DHS, if the physician has a financial relationship with the entity
- ❑ DHS are services “ancillary” to the physician service, including
  - Diagnostic imaging services (other than interventional radiology)
  - Inpatient and outpatient hospital services
- ❑ Financial relationships include ownership and compensation

# Stark Law Exceptions

- Examples:
  - “In-office ancillary exception” for referrals within a physician practice
  - Personal services agreements, equipment leases and space leases structured to meet specified requirements
  - Exception for ownership of certain rural entities
  - Referrals by radiologist for diagnostic radiology or by radiation oncologist for radiation treatment pursuant to a consultation
  - Ownership of a hospital if the physician is authorized to perform services at the hospital and the investment is in the entire hospital
- Exceptions generally require fair market value compensation

# Stark Law Exceptions-Imaging

- ❑ A physician who refers imaging services cannot own an interest in an imaging center and comply with Stark unless:
  - The physician is a radiologist;
  - The imaging center is part of the physician's group practice;
  - The imaging center is located in rural area;
  - The imaging center is a publicly traded entity;
  - The imaging center does not treat Medicare patients; or
  - The imaging center provides Medicare services only "under arrangements" to a hospital

# Joint Ventures in Rural Areas

- ❑ Physician ownership of “rural provider” not subject to Stark
- ❑ A “rural provider” is
  - Located in a rural area
  - Provides “substantially all” (at least 75%) of its DHS to residents of a rural area
- ❑ A “rural area” is an area not classified as an MSA (less than 50,000 population)
- ❑ Exception allows any type of physician to own an interest in an imaging service and refer Medicare patients without violating Stark

# Under Arrangements Joint Ventures

- ❑ Under arrangements joint venture analyzed as compensation arrangement between hospital and JV
- ❑ Compensation arrangement
  - Must be consistent with fair market value
  - Must not consider volume or value of referrals or other business generated by physician
- ❑ Stark allows “per use” or “per service” compensation if:
  - Compensation formula set in advance
  - Compensation consistent with fair market value
  - Compensation per unit does not vary based on referrals

# Leasing Models

- ❑ Lease of space/equipment for imaging services must comply with lease exceptions to Stark
  - Exclusive use during lease period
  - Time-share leases allowed as long as exclusive use during block
- ❑ Rental rates
  - Must be consistent with fair market value
  - Must not consider volume or value of referrals or other business generated by physician
  - May be “per hour” or “per service”
- ❑ Physician lessee must comply with in-office ancillary service exception (unless rural)

# In-Office Ancillary Services Exception

- ❑ Physician group must be a bona fide “group practice” under Stark
- ❑ Imaging services must be performed or supervised by a physician in the group practice
- ❑ Imaging services must be furnished in
  - A “centralized location” for imaging services (used by the group on a full-time basis); or
  - In the same building (same postal address) in which members of the group practice perform physician services unrelated to the imaging services
- ❑ Imaging services must be billed by the group practice
- ❑ This exception allows physician groups to compete with hospital in the provision of imaging services

# Same Building Test

- ❑ Where use is by a solo practitioner, or by a group less than full-time, one of three tests must be met:
  - The office is normally open for medical services at least 35 hours per week and group physicians regularly furnish physician services to patients (including some non-DHS services) there at least 30 hours per week;
  - The patient receiving the DHS usually receives physician services from group physicians at the office, the office is normally open for medical services at least 8 hours per week, and the referring physician regularly furnishes physician services to patients (including some non-DHS services) there at least 6 hours per week; or
  - The referring physician is present and orders the DHS during a patient visit on the premises *or* a group physician is present while the DHS is furnished; the group's office is normally open for medical services at least 8 hours per week; and a group physician regularly practices medicine and furnishes physician services to patients (including some non-DHS services) there at least 6 hours per week

# Possible Impact of Stark III Regulations

- ❑ Phase III regulations may be released within next few months
- ❑ Regulations may adopt MedPac recommendation to expand definition of physician ownership to include interests in an entity that derives a substantial proportion of its revenue from a provider of DHS
- ❑ Some limitation on hospital/physician under arrangements joint ventures likely
- ❑ Leasing structures may also be impacted where physicians have ownership interest in lessor
- ❑ Deals should be structured with “exit strategy” in case rules change
- ❑ CMS may continue to revise Stark regulations annually with physician fee schedule revisions

# Anti-Kickback Statute

- ❑ Unlike Stark Law, the Anti-Kickback Statute is an intent-based statute that is not limited to physician ownership or DHS
- ❑ Elements of the offense
  - Knowingly and willfully
  - Offer, pay, solicit, or receive
  - Remuneration
  - In return for referring, purchasing, leasing, ordering, or arranging for
  - Any item or service that is reimbursed under a federal health care program

# Anti-Kickback Statute

- ❑ Parties on both sides of a transaction may be in violation
  - Violation to offer or pay
  - Violation to solicit or receive
- ❑ Remuneration
  - Any payment or benefit between parties in a position to make referrals may violate the statute
  - Concern with joint ventures with referral sources is whether the financial arrangement creates prohibited remuneration
- ❑ Law is potentially relevant to contracts and arrangements, including joint ventures, between referral sources and referral recipients

# Anti-Kickback Statute Safe Harbors

- ❑ OIG has published safe harbors to protect certain financial relationships between referring parties
- ❑ Most joint ventures will not fully satisfy all elements of a safe harbor
  - Does not make transaction illegal, but must analyze facts
- ❑ Potential safe harbors for imaging joint venture models include:
  - Small entity investment
  - Small entity located in medically underserved area
  - Personal services and management contracts
  - Space/equipment rental

# Small Entity Investment Safe Harbor

- ❑ Potentially applicable to all hospital/physician joint venture entities
- ❑ Safe harbor has two 40% tests that are difficult to satisfy:
  - No more than 40% owned by referral sources
  - No more than 40% of total revenues generated from investors
  - Hospital generally considered a referral source as well as referring physician investors, but can mitigate with safeguards
- ❑ Other elements include:
  - 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

# MUA Safe Harbor

- ❑ Potentially applicable to hospital/physician joint venture entities located in a medically underserved area (MUA)
- ❑ Does not contain the troublesome 40% tests of the small entity investment safe harbor
- ❑ No more than 50% owned by referral sources
  - Hospital generally considered a referral source as well as referring physician investors, making this element difficult to satisfy, but can mitigate risk with safeguards
- ❑ 75% of revenues derived from service to persons who reside in MUA

# Personal Services/Management Contracts Safe Harbor

- ❑ Potentially applicable to under arrangements transactions
- ❑ Safe harbor requires aggregate compensation to be set in advance
  - Eliminates any form of “per unit” compensation from satisfying the safe harbor
  - Fixed fee compensation may satisfy the safe harbor
- ❑ Compensation must be consistent with fair market value
  - Independent valuation recommended, especially for “per unit” fee arrangements

# Space/Equipment Lease Safe Harbor

- ❑ Potentially applicable to leasing models
- ❑ Safe harbor requires aggregate compensation to be set in advance
  - Eliminates any form of variable lease rate (percentage lease, “per use” lease, hourly rate lease)
  - Fixed lease rates may satisfy the safe harbor
  - Exclusive use, “time share” lease arrangements are typically fixed rate leases that may be structured to satisfy the safe harbor
- ❑ Compensation must be consistent with fair market value
  - Independent valuation recommended

# Contractual Joint Venture Risk with Leasing Models

- ❑ “Turn key” lease arrangements may be characterized as a “contractual joint venture” that poses Anti-Kickback Statute risk
- ❑ Physician practice expands into ancillary business (e.g., CT/MRI) by contracting with an existing provider to supply key components of the technical service to the practice
- ❑ Arrangement allows practice to bill for technical services
- ❑ Factors increasing risk include:
  - “Turn key” arrangement
  - Physician could otherwise refer to supplier
  - Other referrals between parties
  - Disproportionate profit to physicians
- ❑ Anti-kickback Statute risk reduced if arrangements are structured to fall within safe harbors

# Factors That Mitigate Anti-Kickback Statute Risk

- ❑ Investment terms and opportunity the same for all investors and not referral-based (but do not have to offer to all physicians)
- ❑ Obtain independent valuation of all financial arrangements
- ❑ Venture provides new, improved, or expanded services and does not merely replicate existing hospital services
- ❑ Substantial capital investment by investors in proportion to ownership that is not financed by the venture or any investor
- ❑ Investment returns based solely on ownership percentage, not referrals
- ❑ Parties articulate and document the legitimate business purposes for the venture
- ❑ Venture functions as a “stand alone” business enterprise
- ❑ Hospital takes steps to mitigate risk that it is a referral source to the venture

# Tax-Exempt Status Considerations

- ❑ Special considerations for tax-exempt hospitals that enter into joint ventures with for-profit partners
- ❑ With ancillary service venture, the issues will generally be limited to UBI rather than a threat to tax-exempt status
- ❑ Sufficient hospital control is required to ensure revenue stream to hospital is tax-exempt:
  - Conservative position: hospital control including majority board representation
  - Alternative structure: 50/50 board representation with hospital reserve powers to ensure venture operates to further charitable purposes

# Tax-Exempt Status Considerations

- ❑ Venture must further charitable purposes:
  - Venture participates in Medicare/Medicaid and provides indigent care
  - Venture maintains open medical staff, if applicable
- ❑ Financial arrangements on arm's-length terms and at fair market value
- ❑ Arrangements with for-profit parties should be for limited terms and should be terminable for cause over objections of interested parties

# Tax-Exempt Status Considerations

## Valuation

- ❑ Transfer of hospital assets, including existing hospital business, must be appropriately valued
- ❑ Venture should compensate hospital for value of transferred assets
- ❑ Valuation methodology will emphasize discounted cash flow, taking into account relevant assumptions, including alternatives for physician investment that may cause shift in volume

# Tax-Exempt Status Considerations

## Private Use

- ❑ Joint ventures using bond-financed facilities or equipment will constitute an impermissible private use unless space or equipment can be allocated to funds reserved for non-exempt use
- ❑ Under arrangements transaction may address private use issue if compensation and term complies with Revenue Procedure 97-13
  - Compliance with 97-13 would require a short-term contractual arrangement (generally 2 years or less) if compensation is “per unit”

# Reimbursement Considerations

- ❑ Must determine how the provider of applicable technical services will be reimbursed from Medicare and third party payors
- ❑ Hospital-based reimbursement models
  - Under Arrangements Joint Venture
  - Hospital lease of imaging equipment
- ❑ Physician fee schedule reimbursement models
  - Freestanding diagnostic imaging center
  - Physician provision of technical services/lease of imaging equipment
- ❑ Commercial payor considerations
  - Reimbursement differential for hospital-based vs. freestanding/physician office
  - Credentialing requirements for freestanding/physician office
  - Multiple imaging modality requirements for freestanding/physician office

# Reimbursement Implications of Deficit Reduction Act of 2005

- ❑ Historically, freestanding imaging providers have received higher reimbursement than hospital-based imaging services
- ❑ Effective January 1, 2007, Medicare reimbursement to freestanding imaging providers capped at hospital-based rate
- ❑ Medicare also taking steps to reduce reimbursement for imaging services
  - Multiple imaging procedure discount

# Highmark and Other Commercial Payors

- ❑ Taking steps to reduce the number of freestanding imaging providers on their panels and/or reimbursement rates
  - May require accreditation of the imaging facility by ACR or other accreditation agencies
    - Higher standards and costs
    - Survey for compliance
  - May require imaging provider to offer multiple imaging modalities to gain access to network
  - May impose minimum hourly requirements for offering imaging services
  - Multiple procedure discounts
- ❑ Deterrent or prohibiting factor to some freestanding or leasing models to provide imaging services

# Hospital-Based Reimbursement “Under Arrangements” Requirements

- ❑ Medicare imposes certain requirements on hospital purchasing services “under arrangements” to ensure hospital exercises professional responsibility over the services
  - Admit patients pursuant to hospital admission policies
  - Hospital retains control over medical records of patients
  - Plans of care and certifications obtained from physicians
  - Medical necessity reviewed by hospital’s utilization review committee
- ❑ Hospital may not act solely as a billing agent

# Hospital-Based Reimbursement Provider-Based Status Requirements

- ❑ Joint ventures may qualify for provider-based status if located on the hospital's main campus
  - Model limited to rural areas or imaging ventures with radiologists
- ❑ Venture must satisfy requirements for provider-based status
  - Operate under hospital's license (unless state law requires a separate license)
  - Clinical services integrated with hospital
  - Financial operations integrated with hospital
  - Services held out to public has hospital services
  - Comply with requirements for hospital outpatient departments, including EMTALA and 72-hour rule

# Interplay Between “Under Arrangements” and Provider-Based Status Requirements

- ❑ CMS blurring any distinction between venture providing services to a hospital “under arrangements” and a provider-based joint venture
- ❑ Safest approach: limit “under arrangements” joint ventures to location on hospital campus and comply with both regulations
  - Submit attestation to CMS
- ❑ “Under arrangements” joint venture located off-campus subject to risk of not qualifying for hospital-based reimbursement
  - Violates on-campus requirement for provider-based joint ventures
  - Management contract rules prohibit third party from providing patient care staff
  - May be able to structure hospital service as IDTF

# Physician Fee Schedule Reimbursement Medicare Enrollment Options

- ❑ If an imaging provider is not hospital-based, must enroll in Medicare as a freestanding imaging provider
- ❑ Options include
  - Independent Diagnostic Testing Facility (IDTF)
  - Physician practice
  - Portable x-ray supplier
- ❑ Enrollment as IDTF is required if
  - Imaging provider operates independently from a physician's office or hospital
  - Substantial portion of business involves diagnostic testing for outside patients
- ❑ Ventures between hospitals and radiologists can typically avoid IDTF enrollment and enroll as a radiology group practice if radiologists are personally providing interpretations on-site at imaging center

# Physician Fee Schedule Reimbursement IDTF Hurdles

- ❑ New supplier standards for IDTF's effective January 1, 2007
  - Must maintain appropriate physical facility with phone number
  - Testing equipment located at physical site (excluding portable equipment) and appropriately calibrated and maintained
  - Comprehensive liability insurance
  - Must not directly solicit patients
  - Appropriately credentialed technical staff on site
  - Medical records storage and retrieval
  - Subject to CMS unannounced on-site inspections

# Physician Fee Schedule Reimbursement Potential IDTF Changes

- ❑ CMS Transmittal 187 incorporates new IDTF standards into CMS manuals
  - Rescinded because manual provisions went further than new regulatory standards
- ❑ If adopted in the future these standards could
  - Prohibit IDTF's from sharing space with other Medicare suppliers
  - Prohibit IDTF's from sharing equipment
  - Require technologists to be full-time employees of the IDTF
  - Broaden the scope of services required from the IDTF's supervising physician

# Medicare Reassignment Rules Purchased Diagnostic Tests

- ❑ A physician group or IDTF may purchase the technical component of a diagnostic test from another Medicare supplier and bill Medicare for the test
  - The purchasing supplier must provide the professional interpretation of the test
- ❑ Physician group may not mark up the charge for the technical component. The physician group must accept the lowest of:
  - Medicare fee schedule amount
  - Amount charged by supplier
  - Physician group's actual charge
- ❑ Risk with “turn key” lease arrangements

# Medicare Reassignment Rules

## Purchased Interpretations

- ❑ A physician group or IDTF may purchase the professional interpretation of a diagnostic test from another Medicare provider
  - Test must be initiated by a physician that is independent of the supplier of the technical component of the test or the physician providing the professional interpretation
  - Physician providing the interpretation does not see the patient
  - The entity that bills for the professional interpretation must perform the technical component of the test

# Medicare Reassignment Rules

## Contractual Arrangement Reassignment

- ❑ Professional interpretations may be subject to a contractual arrangement with a physician who reassigns to the IDTF or physician group to right to bill for the professional interpretation
  - In IDTF, the interpretation is not required to be performed on the premises of the IDTF
  - In a physician group, the interpretation must be performed in the group practice's facilities in a manner that complies with the in-office ancillary services exception to Stark
- ❑ Proposed rules may further restrict contractual arrangement reassignments
  - Prevent physician groups from contracting with independent contractors to provide interpretations that are billed globally by the groups

# Professional Interpretation of Imaging Studies

## Legal and Reimbursement Considerations

- ❑ Shared interpretations commonly come up in context of coronary computerized tomography angiography (CCTA) studies
- ❑ Concerns about these shared interpretation arrangements have been raised from the following perspectives
  - Stark law
  - Federal anti-kickback statute
  - Federal false claims act
  - Medicare reassignment rules

# Shared Interpretations – Commonly Used Models

- ❑ Global billing model
  - Hospital bills globally for CCTA
  - Distributes FMV fee per exam to cardiologist/radiologist
  - Concerns: Reassignment and false claims
- ❑ Alternative professional billing
  - Cardiologist and radiologist each interpret a portion of the CCTA
  - Each takes turn in billing for professional component
  - Concern: False claims
- ❑ Supplemental reading between hospital and radiologist
  - Cardiologist reads cardiac portion
  - Hospital pays radiologists flat fee per exam to read non-cardiac portion
  - Reports of components are merged and cardiologist bills for services
  - Concern: Kickback and false claims
- ❑ Supplemental reading between cardiologists and radiologists
  - Cardiologist reads cardiac portion and pays radiologist flat fee per exam to read non-cardiac portion
  - Reports are merged and cardiologist bills for services
  - Concerns: Stark, reassignment and false claims

# Shared Interpretations – Reactions to Concerns

- ❑ Designate one group of physicians to perform and bill for the entire interpretation
  - Problem arises in finding physicians who are appropriately qualified to read both the cardiac and non-cardiac portions of the CCTA study
  - If not qualified to read both portions of the study, could pose, among other things, professional liability concerns
- ❑ Attempt to structure a compliant “split interpretation” arrangement
  - Primary read arrangement
  - QA arrangement

# Shared Interpretations – Primary Read Arrangements

- ❑ Cardiologist responsible for performing primary CCTA reads
- ❑ Cardiologist enters into a contractual arrangement with a radiologist under which the radiologist first performs preliminary read of non-cardiac portion of the study and reports results of preliminary read to cardiologist
- ❑ After receiving radiologist's report, cardiologist reads entirety of CCTA study and generates a report and bills for the interpretation

## Shared Interpretations – QA Arrangements

- ❑ Either cardiologists or radiologists are designated as the primary group responsible for performing and billing the entire CCTA study
- ❑ The non-primary group enters into a contractual arrangement with the primary group under which:
  - The non-primary group provides quality assurance review of the portion of the CCTA studies with which group is most qualified
  - The non-primary group generates a report to the primary group that indicates it is a secondary read of a previously interpreted study
  - The primary group compensates the non-primary group at a fair market value rate for its services

# Shared Interpretations – Other Reactions

- ❑ Some have chosen to adopt shared interpretation models that may be technically non-compliant assuming that concerns are too remote to generate scrutiny
- ❑ If you elect to adopt a potentially non-compliant interpretation model, you may want to consider obtaining the consent of the carrier to the shared interpretation model
- ❑ Bear in mind however that approaching the carrier will not remove all concerns associated with the model (e.g. Stark law concerns)

# Other Legal Issues

- Other common legal issues that may be relevant include:
  - State anti-kickback and anti-self-referral laws (typically similar to federal provisions, but many states have specific requirements or limitations that must be considered)
  - State Certificate of Need requirements may limit ability to provide new service, particularly in joint venture setting
  - Physician pension plans may be impacted by affiliated service group rules
  - Securities laws may impose disclosure requirements where a joint venture is created, particularly if some investors are less involved in the formation or operation of the venture

# Joint Venture Work Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<b>Organizational Matters</b>				
<p>Engage financial consultant for financial feasibility analysis</p> <p>Engage valuation firm to opine on fair market value lease rate or fee schedule, as applicable</p> <p>Engage legal counsel to advise on structuring options and provide legal analysis</p>	<ul style="list-style-type: none"> <li>The feasibility process will conclude with a decision on whether or not to proceed with the joint venture subject to board approval</li> </ul>	Hospital		<p>Feasibility analysis will include an assessment of the financial feasibility of the proposed venture based on key assumptions, including working capital requirements, equipment and other start-up costs, joint venture volumes, reimbursement to the joint venture and to physicians for professional services, space lease expense, staffing, supplies and other expenses</p> <p>The feasibility analysis will also include discussion of legal structuring options and a recommendation on same</p>

# CTA Joint Venture Work Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<b>Establish Legal Structure of Joint Venture Entity</b>				
<p>Prepare initial Term Sheet based on Planning Committee's recommended legal structure</p> <p>Planning Committee to review Term Sheet. Legal counsel to revise Term Sheet per recommendations of the Planning Committee</p>	<p>2<sup>nd</sup>/3<sup>rd</sup> Planning Committee meetings.</p>	<p>Legal Counsel</p>		<p>Term sheet will summarize legal structure, ownership, governance, transfer, redemption and other key deal terms for joint venture entity and terms of agreements between joint venture, hospital and/or physician owner</p> <p>Assume transaction counsel, hospital counsel and physician counsel will discuss in advance of Planning Committee meeting(s) to identify open points</p>
<p>Planning Committee to review Term Sheet. Legal counsel to revise Term Sheet per recommendations of the Planning Committee</p>	<p>Detailed review of Term Sheet at 2<sup>nd</sup>/3<sup>rd</sup>/4<sup>th</sup> Planning Committee meetings</p>	<p>Planning Committee/ Legal Counsel</p>		

# Joint Venture Work Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<ul style="list-style-type: none"> <li>• Draft Operating Agreement, Purchased Services Agreement (if under arrangements structure), Time Share Lease Agreement (if time share lease structure), other transaction documents</li> <li>• Review securities law requirements for physician investment</li> <li>• Prepare private placement memorandum (PPM) for physician offering, if required for securities law purposes</li> </ul>	Plan for approval by 4 <sup>th</sup> /5 <sup>th</sup> Planning Committee meetings, assuming substantial review and negotiation by legal counsel prior to meetings	Legal Counsel  Planning Committee		Planning Committee to discuss open points at 4 <sup>th</sup> /5 <sup>th</sup> meeting(s)
<b>Obtain Necessary Board and Regulatory Approvals</b>				
Present to Hospital Board	Prior to closing on legal documents	Hospital		

# Joint Venture Work Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<b>Formation and Capitalization</b>				
Form joint venture entity with initial Board of Managers and officers		Legal Counsel		
Commence physician offering period if required. Close on offering if applicable; physician investors and Hospital to make capital contributions to new venture entity in exchange for ownership interests. Close on transaction documents		New LLC		
Appoint physicians and Hospital representatives to Management Board of New LLC.		New LLC		
<b>Post Closing</b>				
		New LLC		
Commence facility development/operations planning				

# Overview of Kutak Rock LLP

- ❑ National law firm with offices in 15 cities
- ❑ Extensive health care practice with focus on physician-hospital joint ventures
- ❑ Counsel in recent joint venture transactions in over 40 states, including cardiovascular, advanced diagnostics, surgery, endoscopy, radiation therapy, cancer and whole/specialty hospitals
- ❑ Recent projects include multi-specialty ASCs, endoscopy centers, vascular center with diagnostic and treatment components, joint venture diagnostic cath and CT; “under arrangements” agreement for diagnostic and interventional cath; clinical co-management agreements for cardiac and vascular service lines; joint venture and time share lease for 64 slice CT; specialty heart hospital

# Joint Venture Experience

- ❑ Kutak Rock is a national firm with a full-service health care practice
- ❑ Counsel in joint venture transactions in over 40 states involving multiple health care service lines, including:
  - Imaging
  - Cardiology
  - Vascular
  - Cancer
  - Endoscopy
  - Nuclear medicine
  - ASC
  - General and specialty hospitals
  - LTACH

# Robert Cohen Background

- ❑ Chairperson of healthcare practice of Kutak Rock LLP for over 15 years
- ❑ Practice focus on physician/hospital joint ventures, with emphasis on project management and facilitation of planning and deal-structuring process between hospital and physician participants
- ❑ Transaction counsel in numerous venture projects, including cardiology, vascular, cancer treatment, imaging, ambulatory surgery and endoscopy
- ❑ Business experience as founder of ambulatory center development and management company
- ❑ Contact: [robert.cohen@kutakrock.com](mailto:robert.cohen@kutakrock.com) (402.231.8738)