

Cardiovascular CT Imaging

Legal Considerations and Structuring Options

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Summary of Presentation

- Overview of legal issues
- Discussion of structuring options
 - Within group practice
 - Arrangements involving other parties
 - Joint venture arrangements
 - Contractual arrangements
- Example of work plan and timeline for CTA joint venture formation

Overview of Legal Issues

- Stark Law
 - Antikickback Statute
 - Tax-exempt Status/Unrelated Business Taxable Income (UBTI)*
 - Tax-exempt Bond Financing
 - Antitrust
 - Securities Law Requirements
 - Reimbursement (certification, place of service, conditions of coverage, purchased diagnostics rule)
 - Certificate of Need/Licensure
 - Employment Law/Pension
 - Other state laws (e.g., fraud and abuse)
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- *Applies to tax-exempt hospitals only

Stark Law

- Restricts Medicare and Medicaid referrals of designated health services (“DHS”) by physicians to entities with which they or an immediate family member have a financial relationship
- DHS includes broad categories of items and services, including inpatient and outpatient hospital services and most ancillary services (e.g., radiology and other noninvasive imaging services, including CTA)

Stark Law

- If a physician or an immediate family member has a financial relationship (including an ownership interest) in an entity that provides DHS, an exception must apply or the physician cannot refer DHS to the entity
- There are exceptions for rural providers and for intrapractice referrals known as the “in office ancillary services exception”
- There are also exceptions for various compensation relationships (e.g., leasing). (Note that the Stark Law permits “per click” compensation for purposes of such exceptions, but “per click” compensation does not qualify for an Antikickback Statute safe harbor)

Stark Law “In-Office Ancillary” Exception

- CTA services can be provided by physician groups meeting Stark definition of “group practice” (or by solo practitioners) if in-office ancillary exception requirements met:
 - Services must be performed or supervised by a “physician in the group practice”
 - 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 DHS (hourly tests for use must be met)
 - Services must be billed by the group practice
- “Physician in the group practice” can be an independent contractor if independent contractor performs the services on-site

Proposed Changes to “Centralized Location” Requirement

- Proposed changes aimed at curbing “pod laboratory” arrangements
- Centralized building space must be at least 350 square feet
 - 350-square-foot requirement would not apply if there are no more than three group practices in the same building sharing the same “physician in the group practice”
- Space must permanently contain equipment used to perform at least 90% of DHS each calendar year
- CMS is considering, but not yet preparing, a requirement that the group practice staff the space with a non-physician employee or independent contractor who performs services for the group in the space at least 35 hours per week

“Same Building” Rules

- To comply with “same building requirement”, one of the following three tests must be met:
 - 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 eight hours per week, and the referring physician regularly furnishes physician services to patients (including some non-DHS services) there at least six 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 office is normally open for medical services at least eight hours per week; and a group physician regularly practices medicine and furnishes physician services to patients (including some non-DHS services) there at least six hours per week

Antikickback Statute

- Unlike Stark Law, the Antikickback 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

Antikickback Statute

- Parties on both sides of a transaction may be in violation
 - Violation to offer or pay
 - Violation to solicit or receive
- Remuneration
 - Not limited to traditional kickback schemes or bribes
 - Any payment or benefit between parties in a position to make referrals may violate the statute
- Law is potentially relevant to contracts and arrangements, including joint ventures, between referral sources and referral recipients

Antikickback Statute Safe Harbors

- OIG has published safe harbors to protect certain financial relationships between referring parties
- Joint venture models – possible safe harbors include:
 - Small entity investment
 - Small entity located in underserved area
- Several safe harbors protect certain types of compensation arrangements (personal service and employment arrangements, space and equipment leases)
- Compensation must be “set in advance” and at fair market value to satisfy safe-harbor requirements
 - “Per click” services arrangements do not meet safe harbor because aggregate compensation is not set in advance (but can qualify for Stark Law exception)

Hospital Tax Issues

- Tax-exempt Status/Unrelated Business Taxable Income (UBTI)
 - Tax-exempt participant in joint venture should ensure that venture operates in a charitable manner; will require certain controls by hospital participant
 - Example: if joint venture is a time-share lessor, documents should require use of leased facilities to be consistent with Medicare/Medicaid/charity care policies
 - All arrangements should be consistent with fair market value (failure to meet this requirement may expose physicians to “intermediate sanctions” excise taxes)
 - Use of tax-exempt facility by joint venture or private lessee constitutes a “private use,” which could jeopardize tax treatment of the hospital’s bonds

Antitrust

- Competitors cannot divide markets or fix prices
 - Competitors should not use venture to share pricing information
- Majority owner of joint venture may be able to negotiate on behalf of venture with managed care plans
 - Joint venture providers often have 51% hospital ownership to take advantage of hospital's market power
- Other antitrust issues (e.g., tying, refusal to deal) potentially present, depending on facts and circumstances

Reimbursement

- Deficit Reduction Act
 - Reimbursement for imaging services furnished in physician office and diagnostic testing facility capped at amount paid to hospital for same services effective January 1, 2007
 - Consequently, hospital reimbursement for imaging services will be at least as good as physician office or independent diagnostic testing facility (“IDTF”) reimbursement and possibly better
 - Change results in substantial percentage declines in reimbursement from 2006 Medicare payment rates for a number of services, including CTA
- Payors in some states (e.g., Highmark in western Pennsylvania) will not reimburse physician office imaging unless part of multimodality imaging center with full-time radiologists
- IDTF reimbursement
 - Must be certified by Medicare as IDTF
 - Limited by Medicare to reimbursement for diagnostic studies
 - Paid by Medicare under physician fee schedule
 - Private payor reimbursement will be pursuant to provider agreements

Professional Billing— Overread Arrangements

- Possible legal risk from overread arrangements with radiologists is that Medicare rules for professional component billing require that the physician reported as providing the interpretation be responsible for interpreting the entire image
- Overread or lack of overread arrangement could impact malpractice liability exposure

Other Legal Issues

- Other common legal issues that may be relevant include:
 - State antikickback, fee splitting and anti-self-referral laws (often 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

CTA Models: Overview

- Direct provision of service by group
 - Full-time
 - As time-share lessee (generally requires that CTA be located in building where cardiologists maintain office practice)
 - Under “shared expense” model practices share expenses of CTA that each uses separately on first-come, first-served basis (generally requires that CTA be located in building where cardiologists maintain office practice)
 - As provider of service obtained from an imaging supplier under a purchased services arrangement (generally federal health care program business is excluded under this model because purchased services cannot be marked up)
- Contractual, non-joint venture model
 - Purchased services agreement (“under arrangements” contract whereby physician group provides service to a hospital)
- Joint venture models
 - Time-share leasing company
 - Purchased services agreement (“under arrangements” contract whereby joint venture provides service to a hospital)
 - IDTF joint venture (in rural areas only)
 - Ownership of space or equipment leased to and used by another provider on a full-time basis

Direct Provision of CTA by Group Practice

- Unless rural exception applies, in-office ancillary services exception must be met to provide Medicare services
 - If full-time, CT does not need to be in same location as physician practice
 - If time-share lessee or party to a shared expenses arrangement, Stark Law hourly requirements for office use must be met

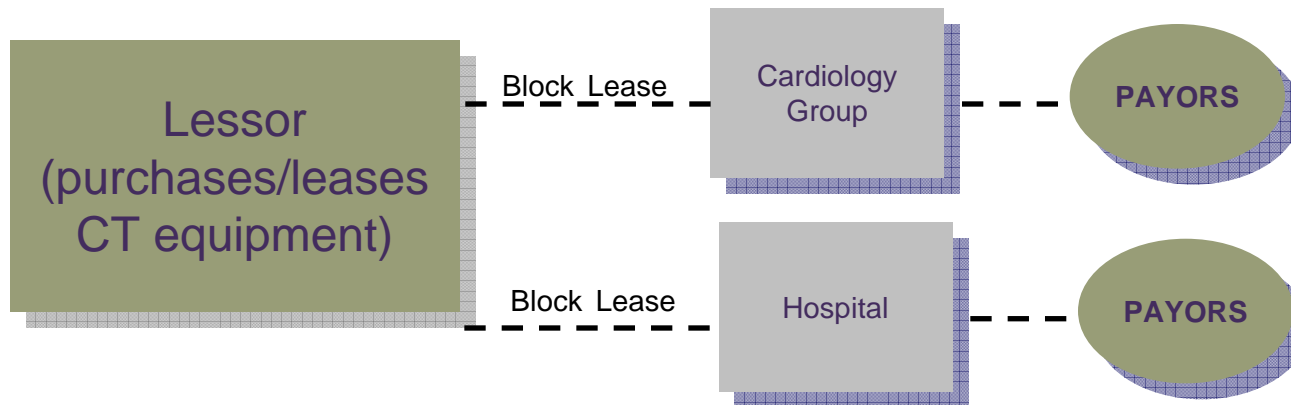
Direct Provision of CTA by Group Practice

- Medicare reimbursement
 - Physician must supervise diagnostic test according to required level of supervision
 - Direct supervision, which is generally required, means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. However, the physician is not required to be present in the room when the procedure is performed
 - Physician must provide primarily to own patients and not have a substantial portion of business be imaging or must also enroll as IDTF for nonpatients

Time-Share Lease Structure

- Equipment (e.g., 64-slice CT) and in some cases space and personnel are leased on a part-time basis to physicians, physician groups and/or a hospital
- Example of CTA time-share lease structure
 - Lessor leases or acquires CT equipment
 - Lessees have exclusive use of CT during defined blocks of time (subject to exceptions for “off peak” times and emergency cases) at a fixed fair market value lease rate. Cardiologists lease space and may lease staff from venture or, as applicable, hospital on part-time basis
 - Each party bills for the technical component of CTA performed on its patients during block lease time

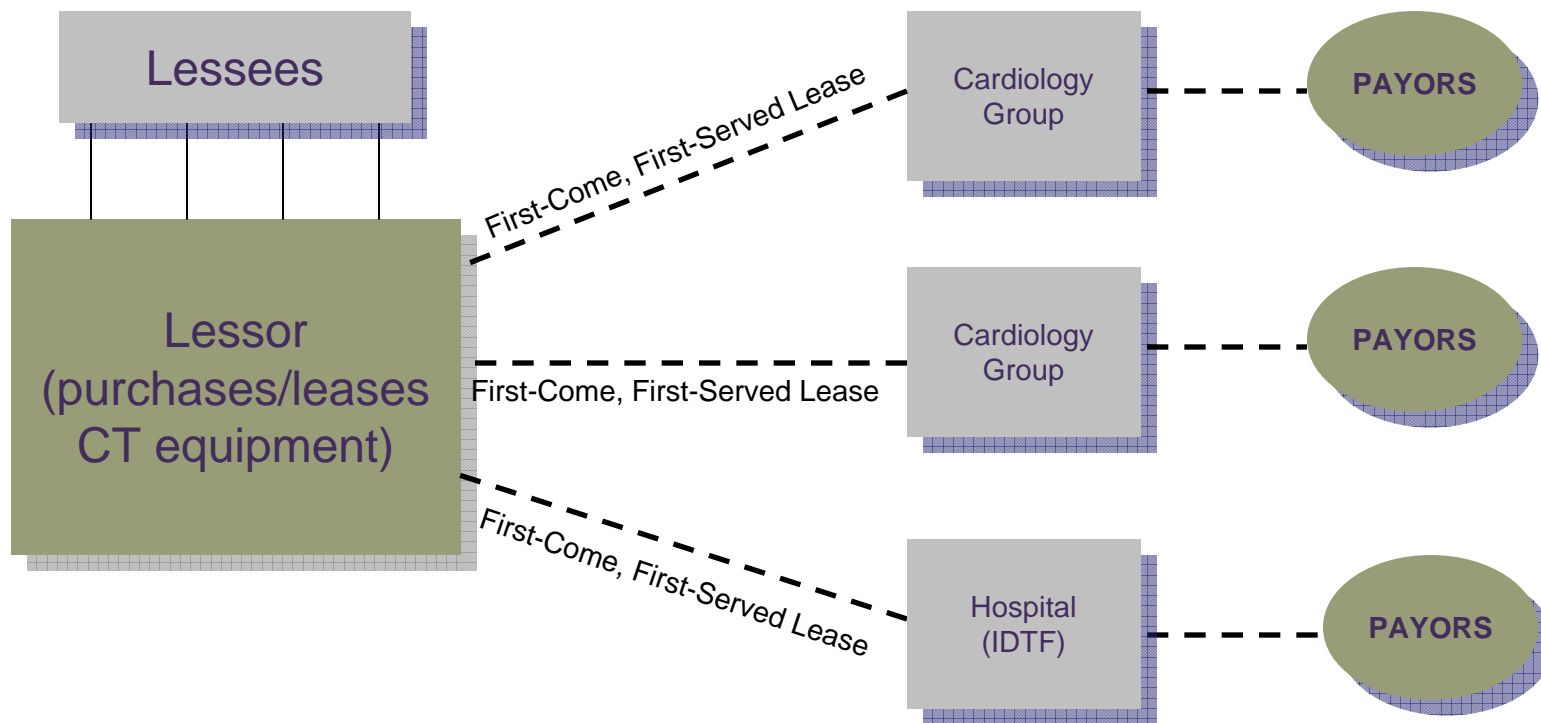
Example of CTA Time-Share Lease Structure (Block Leases)



Shared Expense Arrangement

- Variant of time share lease with first-come, first-served use rather than fixed blocks
- Costs allocated among the parties on a commercially reasonable basis generally consistent with actual use
- If hospital participates, it must do so as an IDTF

Example of CTA Shared Expense Arrangements



Time-Share Lease Structure Legal Considerations

- Stark
 - Time-share lease of equipment can be structured to satisfy compensation exception to Stark; similar exception available for space and staff leases
 - Arrangement must be structured to meet the in-office ancillary services exception to Stark so physicians can bill for Medicare CTA
 - Any incidental financial transactions (billing fee, leased employees, etc.) must be reviewed for Stark compliance
- Antikickback Statute
 - Safe-harbor compliance possible with fixed-rate/fixed-block lease
 - Limits but does not eliminate Antikickback Statute risk (per Advisory Opinion 04-17)

Time-Share Lease Arrangement Purchased Diagnostics Rule

- Medicare-purchased diagnostic test rule caps payment to a physician for a purchased diagnostic test at the lowest of the purchase price, the physician's actual charge, or the Medicare physician fee schedule amount
- There is some risk that a lease arrangement could be characterized as a purchased diagnostic test where the practice leases space, equipment and personnel

Time-Share Lease Arrangement Purchased Diagnostics Rule

- Risk of recharacterization is reduced if:
 - Lessee is sufficiently at risk (e.g., rental is fixed)
 - Arrangement is not “turnkey” lease (i.e., some services provided directly by lessee)
 - Lessee practice’s physicians:
 - oversee leased personnel furnishing services to group’s patients
 - establish clinical and operational protocols
 - provide any required personal supervision for services to group’s patients

Time-Share Lease Arrangement “Contractual Joint Venture” Risk

- OIG Advisory Opinion 04-17 reflects OIG concern with so-called “contractual joint ventures” where physicians bill for services obtained contractually (e.g., through lease of imaging components) from an entity that could provide the services directly
- Factors increasing risk:
 - Lessor is established provider of imaging service
 - Physicians bear little financial risk
 - “Turnkey” arrangements
- According to OIG, even if all arrangements were within safe harbors, group’s profit would not be protected
 - This aggressive position may not be upheld if litigated

Time-Share Lease Structure

“Contractual Joint Venture” Risk

- Leasing structures present some degree of risk of contractual joint venture recharacterization and/or purchased diagnostic services recharacterization. To reduce these risks, alternatives are:
 - Most conservative position: structure to fall within Antikickback Statute safe harbors (requires blocks of time and fixed fees that are predetermined no more frequently than annually)
 - More aggressive model: first-come, first-served usage (pricing needs to be analyzed based on specific facts)
 - First-come, first-served structure cannot be used for hospital lessee unless billed on IDTF
- Fair market value opinion for lease rates recommended
- Parties will need to negotiate terms of staff and space lease from hospital to cardiology group, if applicable

Time-Share Lease Arrangement Advisory Opinion 04-08

- Physician group-owned LLC would lease space, equipment, and therapist services to group physicians and other physicians in the same building
- Each lessee would pay the same amount regardless of usage but would have unlimited use of the center on a first-come, first-served basis
- OIG viewed potential that some physicians might pay more or less than fair market value for services actually used as potential remuneration for referrals
- Guidance indicates that “first-come, first-served” structure involves some Antikickback Statute risk when lessor and lessee have referral relationship

“Under Arrangements” Model

- Hospital contracts with a third party (which could be an independent entity, a physician group, a physician joint venture, or a hospital/physician joint venture) for services
- Hospital bills for the technical services and pays the service provider a fee, typically on a per-service basis
- Hospital is treated as the provider of technical services
- Hospital retains portion of reimbursement to cover its costs, including QA and billing, and provide for a reasonable profit margin consistent with fair market value pricing

“Under Arrangements” Model— Legal Considerations

- Hospital licensure
 - Hospital must be able to operate the CTA service under its hospital license consistent with state licensure laws
- Medicare conditions of participation
 - Hospital must retain administrative control over services
 - Patient admissions, patient records, physician certifications
 - QA, UR

“Under Arrangements” Model— Legal Considerations

- Valuation issues
 - Valuation of fee schedule for purchased service agreement
- Must structure to avoid private use of tax-exempt bonds, if applicable (e.g., limit term of contract to three years, terminable without cause or penalty at end of second year, or allocate to funds reserved for nonexempt use)
- Must review applicable state law requirements

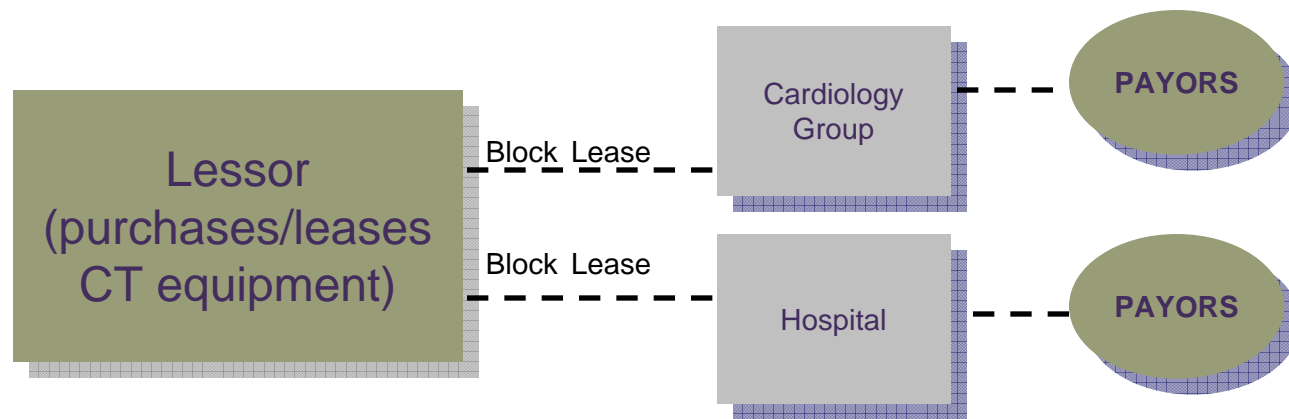
Joint Venture Models— Time Share Lessor

- Time-share lessor venture
 - Venture leases some or all of space, equipment and personnel to physicians, physician groups and or hospital; lessees bill for services
 - Lessor could be physician joint venture, physician/hospital joint venture, hospital or independent third party
 - Where parties form joint venture entity to acquire and lease equipment in time-share structure, recommended structure is generally limited liability company
 - Lessees may or may not include joint venture owners (Note: shared expense model contemplates that most or all lessees are owners)

Joint Venture Models— Time Share Lessor

- If hospital leases a time block, hospital must be able to treat the time-share lease as a provider-based service of the hospital unless hospital use is treated as IDTF; provider-based status requires exclusive use by hospital during hospital lease period
- Lessor may also act as IDTF; to reduce Antikickback Statute risk in this setting:
 - arrangements should be structured to meet Antikickback Statute safe-harbor requirements (requires blocks of time and fixed fees that are predetermined no more frequently than annually); or
 - lessees should agree to not refer to the IDTF

Joint Venture Time-Share Lease Structure



- If CT is in hospital, hospital would also lease space and staff on a block time basis to cardiology group
- Hospital would have contractual right to use equipment during other lessees' blocks if needed for an emergency case (rental payments can be adjusted to reflect emergency uses)

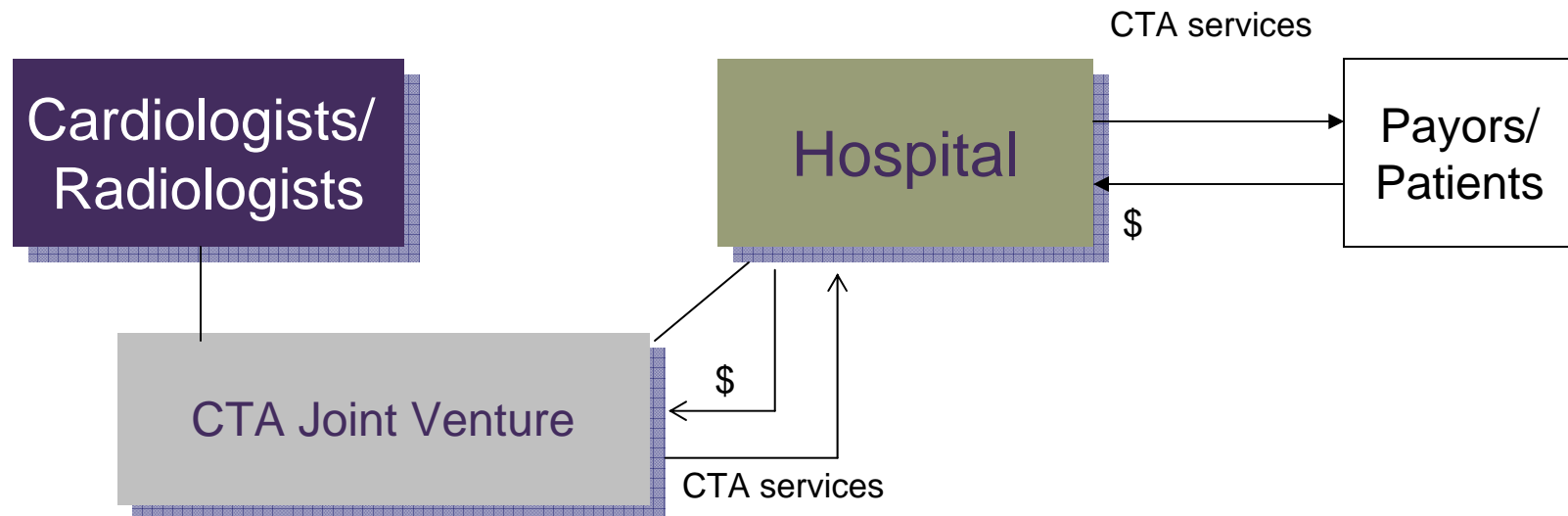
“Under Arrangements” Joint Venture

- CTA “under arrangements” joint venture example:
 - Physicians, or hospital and physicians jointly, form JV entity (“New LLC”), a company that provides technical component of outpatient 64-slice CT services
 - Hospital contracts with New LLC for the technical component of outpatient CTA services. (No requirement that services be provided in same building where physicians have offices)
 - New LLC operates in space provided by hospital or leases space from hospital
 - Pricing will reflect whether hospital or New LLC provides space
 - New LLC purchases or leases the equipment from a vendor
 - New LLC employs technicians and support staff, management, etc.

“Under Arrangements” Joint Venture

- CTA “under arrangements” joint venture example (continued):
 - Hospital pays New LLC 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
 - New LLC is responsible for the costs of purchasing or leasing equipment, employing technical and support staff, supplies, etc.
 - New LLC profits are distributed to New LLC’s owners
 - Cardiologists bill professional fees for CT interpretations
 - Cardiologists contract with radiologists to perform overreads

“Under Arrangements” CTA Joint Venture Example



Joint venture owns/leases equipment and employs techs

Hospital is the provider of CTA services

Payors pay hospital

Hospital purchases CTA services from joint venture and pays joint venture, typically on fee schedule basis

“Under Arrangements” CT Joint Venture—Legal Considerations

- Stark
 - Ownership of joint venture not subject to Stark (no referrals of DHS to joint venture entity)
 - Purchased service agreement between hospital and joint venture structured to meet compensation exception to Stark; Stark allows “per unit” compensation
- Antikickback Statute
 - No safe-harbor protection available
 - Key factors to minimize legal risk—New LLC is a “real company”; fee arrangement is fair market value

“Under Arrangements” Joint Venture Model—Legal Considerations

- Provider-based requirements
 - CMS concern with off-campus hospital outpatient diagnostic services provided under arrangement by a joint venture with hospital
- Tax Exemption Issues
 - If joint venture created, structure venture to avoid risk to hospital’s tax-exempt status
 - Hospital control to ensure ongoing charitable operation

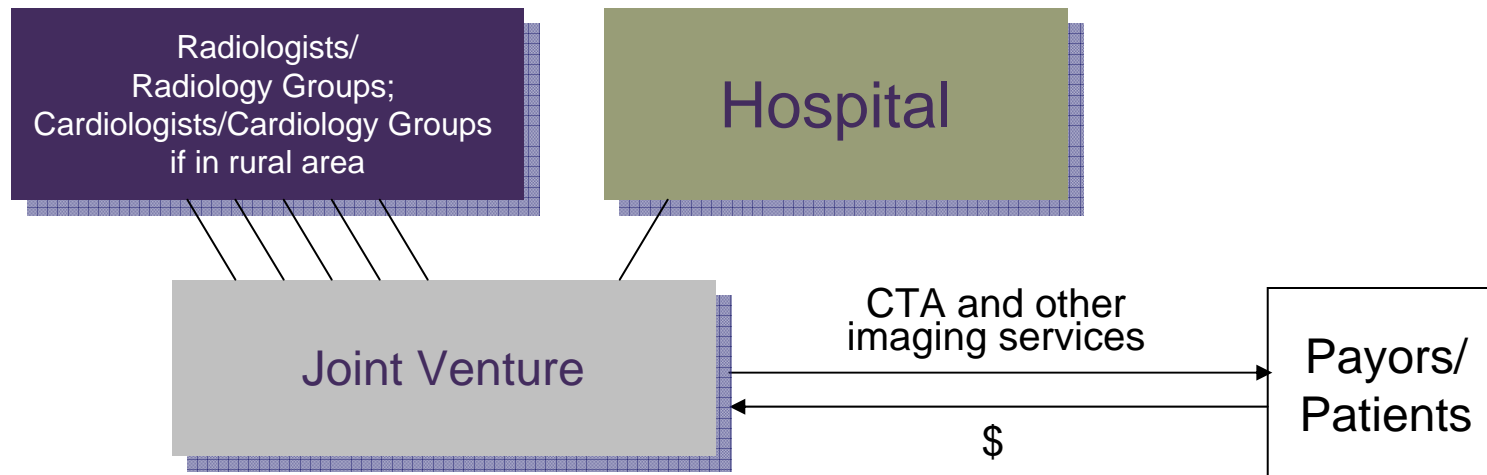
“Under Arrangements” Joint Venture Model—Operational Issues

- Hospital often best situated to lease staff to venture, but this increases Antikickback Statute risk, especially if leased staff only provide services back to hospital
- Risk is that arrangement may be viewed as, in substance, hospital providing services to itself, in which case the arrangement may be challenged as a mechanism to compensate physician participants for referrals

Other Joint Venture Models

- IDTF joint venture
 - If Medicare services provided and any ownership by referring physicians, Stark Law limits to rural areas
 - Radiologists generally not considered referring physicians for diagnostic radiology services furnished pursuant to a consultation
 - Even in rural areas, ownership by referring physicians may present substantial Antikickback Statute risk
- Venture to lease space or equipment full-time to another provider
 - Example: physicians form venture to purchase equipment and lease to hospital
 - Any profit retained by the lessor should be defensible as payment for additional risk undertaken or services provided
- Joint venture ownership may include cardiology groups, individual cardiologists, radiologists/radiology groups, and/or hospitals
 - Ownership by physicians who refer to cardiologist or radiologist owners generally presents significant Anti-kickback Statute risk unless returns to investors are not affected by referrals and are fair market value and may violate Stark Law requirements
 - Antikickback Statute and Stark Law analysis differs depending on type of venture

Example of Hospital/Physician IDTF Joint Venture



Joint venture is the provider of diagnostic imaging services

Questions and Discussion

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
Organizational Matters				
<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 (financial consultant and valuation firm may be same)</p> <p>Engage legal counsel to advise on structuring options and provide legal analysis</p>	<ul style="list-style-type: none"> The feasibility process will conclude with a decision on whether or not to proceed with the joint venture subject to board approval 	Financial Consultant/Legal Counsel		<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>

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<p>Establish Steering Committee with physician and hospital representatives to plan joint venture formation</p>	<p>First Steering Committee meeting will focus on proposed legal structure, timeline and preliminary financial projections.</p> <p>Expected time frame for completion is 60-90 days (3-5 Steering Committee meetings likely with telephone conferences, attorney meetings, etc. occurring between meetings.)</p>	<p>Representatives from cardiology practice(s); hospital representatives</p>		<p>Steering Committee work plan will include:</p> <ul style="list-style-type: none"> • Agreement on legal structure and terms, including legal structure and terms for joint venture entity and for physician investment in the joint venture; • Refinement and approval of financial projections; and • Review and approval of transaction documents.

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
Financial Projections and Valuation Opinion				
Financial consultant to prepare and deliver financial projections based on key assumptions as noted above. If leasing arrangement is contemplated, financial projections will be provided for joint venture company and physician lessees. Financial projections will be based on the valuation opinion in estimating the pricing of venture services or lease rate.		Financial Consultant		
Valuation company retained to deliver valuation opinion • Opinion will address valuation of contributed assets, if any, and pricing of block lease or under arrangements services block lease rate.		Valuation Company		
Present and review financial projections based on preferred legal structure with the Steering Committee	2 nd /3 rd Steering Committee meeting	Financial Consultant		
Determine management and staffing options for joint venture company	To be completed by 3 rd /4 th Steering Committee meeting and factored into revised financial projections	Steering Committee		

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
Establish Legal Structure of Joint Venture Entity				
Prepare initial Term Sheet Steering Committee to review Term Sheet. Legal counsel to revise Term Sheet per recommendations of the Steering Committee	1 st /2 nd Steering Committee meeting	Legal Counsel		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 cardiology practice. Assume transaction counsel, hospital counsel and physician counsel will discuss in advance of Steering Committee meeting(s) to identify open points.
Steering Committee to review Term Sheet. Legal counsel to revise Term Sheet per recommendations of the Steering Committee	Detailed review of Term Sheet at 2 nd /3 rd Steering Committee meeting	Steering Committee/ Legal Counsel		
Finalize Term Sheet	Goal is to finalize agreement on terms by 4 th Steering Committee meeting	Steering Committee/ Legal Counsel		

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
<ul style="list-style-type: none"> • Draft Operating Agreement, Purchased Services Agreement (if “under arrangements” structure), Time-Share Lease Agreement (if time-share lease structure), other transaction documents • Review securities law requirements for physicians investment. Prepare Private Placement Memorandum and Subscription Agreement for physician investor offering, if necessary • Commence planning for physician offering, if necessary 	Plan for approval by 4 th /5 th Steering Committee meeting, assuming substantial review and negotiation by legal counsel prior to meeting	Legal Counsel Steering Committee		Steering Committee to discuss open points at 4 th /5 th meeting
Finalize and obtain Steering Committee approval of final drafts of the Operating Agreement, other transaction documents, financial projections and PPM, if applicable	60-90 days from start of Steering Committee planning process	Legal Counsel/Steering Committee		
Steering Committee to agree on plan for physician offering, if offering is required		Steering Committee		
Obtain Necessary Board and Regulatory Approvals				
Present to hospital board	Prior to closing on legal documents or proceeding with physician offering	Hospital		Assume preliminary board approval has been obtained and board is updated on final terms

Example of CTA Joint Venture Action Plan and Timeline

ACTIONS	TIMELINE	RESPONSIBLE PARTY	STATUS	COMMENTS
Formation and Syndication				
Form joint venture entity with initial Board of Managers and officers		Legal Counsel		
Conduct physician investor meeting to commence offering and distribute PPMs, as necessary		New LLC		
Conclude offering and accept physician investor subscriptions, as necessary. Close on transaction documents. Physician investors and Hospital to make capital contributions to new venture entity in exchange for ownership interests		New LLC		
Appoint physicians and hospital representatives to Management Board of New LLC		New LLC		
Post closing				
		New LLC		
Commence facility development/operations planning				

Overview of Kutak Rock LLP

- National law firm with offices in 16 cities from coast to coast
- Extensive health care practice with focus on physician-hospital joint ventures
- Counsel in recent joint venture transactions in over 30 states, including cardiovascular, advanced diagnostics, surgery, endoscopy, cancer, whole and specialty hospital
- Recent cardiovascular projects include vascular center with diagnostic, treatment and research components, joint venture of diagnostic and interventional cardiac cath; clinical comanagement agreement for cardiac and vascular service lines; time-share lease and “under arrangements” joint ventures for 64-slice CT

Robert Cohen Background

- Chairperson of health care practice of Kutak Rock LLP for 15 years
- Practice focus on physician/hospital joint ventures, with emphasis on project management and facilitation of planning and deal-structuring process
- 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
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