

PHYSICIAN-HOSPITAL JOINT VENTURE AND AFFILIATION MODELS

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

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Summary of Presentation

- ❑ Overview of “partnering” models and strategy
- ❑ Planning and implementation steps
- ❑ Summary of reimbursement and legal considerations
- ❑ Review of specific transactions

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 healthcare 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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Potential Advantages of an Alignment 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

Planning Process

- ❑ Planning and deal execution are key to developing a sustainable partnership
- ❑ 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

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 venture
- Financial impact to hospital
- Capital requirements and financing options
- Who will manage the venture
- Timeline for implementation

Feasibility Analysis

- ❑ Volume assumptions based on physician interviews and hospital data
- ❑ Reimbursement assumptions: hospital rates vs. free-standing and inclusion in networks if free-standing
- ❑ Projected capital requirements (including value of “contributed” hospital business)
- ❑ Expense items
 - Facility costs
 - Staffing
 - Supplies
 - Management fee and billing expense
 - Other costs of operations

Summary of Models

- ❑ Ownership Models
 - Equity joint venture
- ❑ Contractual Models
 - Leasing Arrangements (full-time or time-share)
 - Purchased Services Agreement (“Under Arrangements”)
 - Clinical Co-management

Legal Issues

- Reimbursement analysis; provider-based rules
- 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)
- State law (licensure, anti-self referral, CON, if applicable)
- Securities law (applicable to physician investment)

Reimbursement Analysis

- ❑ What services can be billed by possible health care entities?
Medicare rules:
 - 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
- ❑ Will service be provided and billed by hospital and reimbursed at hospital rates?
- ❑ Will service be provided and billed by free-standing (non-hospital-based) entity?
- ❑ Legal structure may impact reimbursement from Medicare, Medicaid and commercial payors

Reimbursement Analysis (cont.)

❑ 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

- ## ❑ 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

Provider-Based Requirements

- Requirements applicable whether on- or off-campus include:
 - Operated under hospital's license (if permitted by State law)
 - Clinical services of the facility and the hospital are integrated as evidenced by:
 - Professional staff of the facility have clinical privileges at the hospital.
 - Hospital maintains monitoring and oversight of the facility
 - Medical director of the facility reports to Hospital's chief medical officer
 - Hospital medical staff committees are responsible for facility's medical activities, including QA, UR, and coordination and integration of services between the facility and the hospital
 - Integrated medical records
 - Integrated services, with facility patients having full access to all hospital services
 - Financial integration of hospital and facility
 - Facility held out to the public as part of the hospital

Provider-Based Requirements

- Additional requirements applicable if off-campus:
 - Wholly owned and controlled by hospital (i.e., no off-campus provider-based joint ventures)
 - Facility is under the direct supervision of the hospital and meets monitoring, oversight, supervision, and accountability requirements
 - The following administrative functions of the facility are integrated with those of the hospital: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services
 - Facility is located within 35 miles of the hospital (subject to certain exceptions)
 - Management contracts must meet specified requirements

Provider-Based Requirements

- Requirements applicable to off-campus management contracts:
 - Hospital (or another organization that employs the staff of the hospital) must employ the staff of the facility who are directly involved in the delivery of patient care, except for management staff and staff furnishing patient care services paid for under a Part B fee schedule
 - The administrative functions of the facility must be integrated with those of the hospital
 - Hospital must have significant control over the operations of the facility
 - Management contract must be held by the hospital itself and not by a parent organization
- All services at facility cannot be furnished under arrangements

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 substantially all diagnostic imaging services (other than interventional radiology) and all hospital services; freestanding ASC and cardiac cath services are not DHS
- ❑ 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

□ 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

Stark Law Group Practice Exception

- ❑ Imaging 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

Stark Law “In-Office Ancillary” Exception

- ❑ 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

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
 - 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

Anti-kickback Statute Safe Harbors

- ❑ OIG has published safe harbors to protect certain financial relationships between referring parties
- ❑ Joint Venture Models – possible safe harbors include:
 - ASC
 - 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

“Contractual Joint Ventures”

- ❑ 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

Purchased Diagnostics Rule

- ❑ If arrangement is treated as a purchased diagnostics services agreement, then:
 - physician group cannot “mark up” the technical component
 - Physician group purchasing the technical component must perform the interpretation and bill for both components as separate line items to permit identification of the purchased technical component
 - Technical component supplier must be enrolled in Medicare

Purchased Diagnostics Rule

- Lease arrangement can be treated as the practice providing the technical component itself rather than purchasing the service, in which case the purchased diagnostics rules do not apply, if:
 - Lessee is sufficiently at risk
 - Lessee pays fixed compensation
 - Arrangement is not “turnkey” lease
 - 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

Tax-exempt Status Considerations—Joint Venture

- ❑ 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 assure 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
- ❑ Leasing arrangements may generate UBTI

Tax-exempt Status – 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

Private Use Prohibition

- ❑ 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

Other Legal Issues

- Other common legal issues that may be relevant include:
 - State antikickback 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

Overview of Legal Structures

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
- ❑ 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

Service Line Joint Ventures

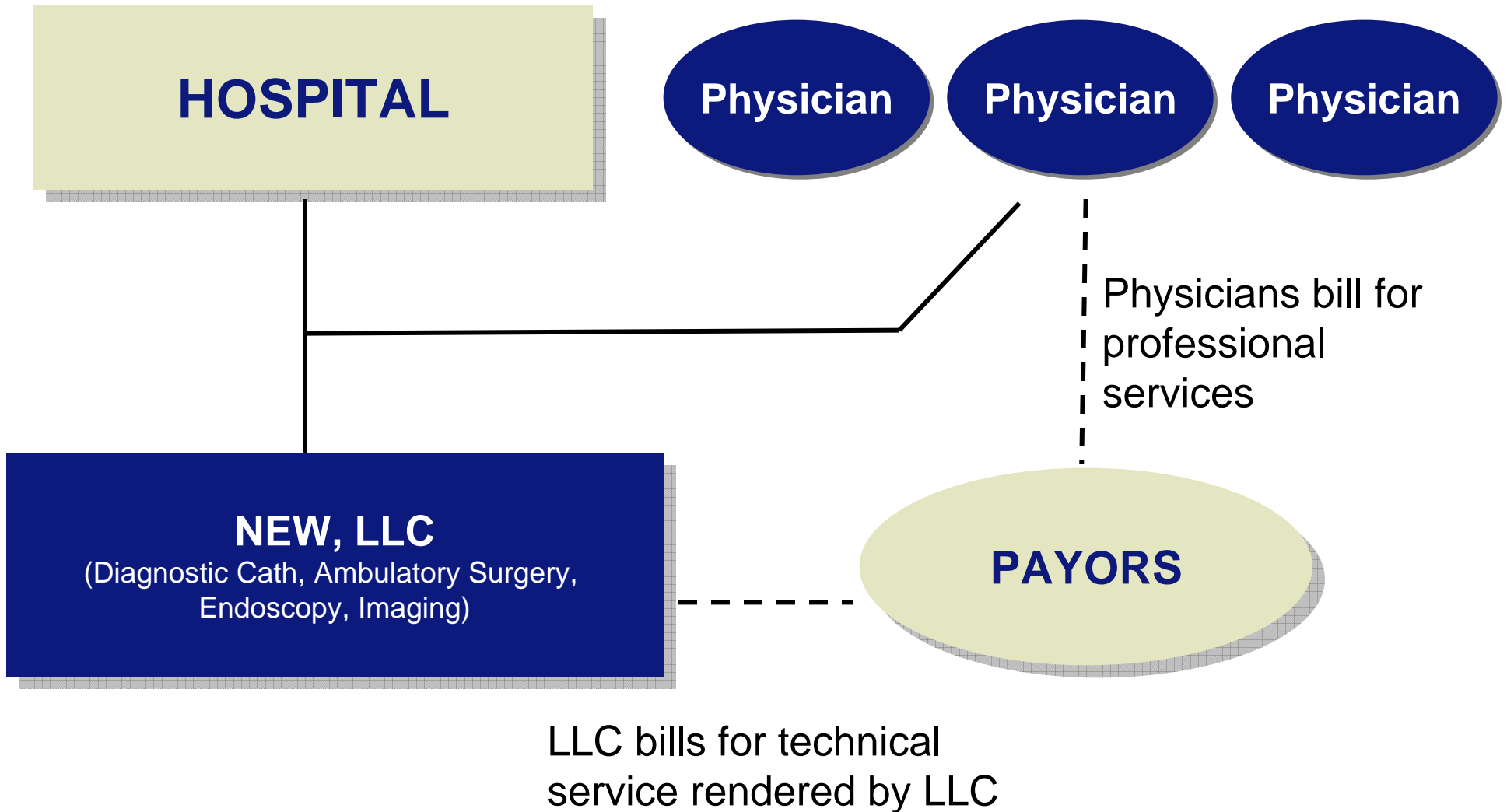
□ Common examples:

- Ambulatory Surgical Centers (hospital and surgeons)
- Endoscopy Centers (hospital and gastroenterologists)
- Imaging Centers (hospital and radiologists)
- Cardiac Cath labs (in states that allow non hospital-based cath labs) (hospital and cardiologists)
- Radiation Therapy Centers (hospital and radiation oncologists)

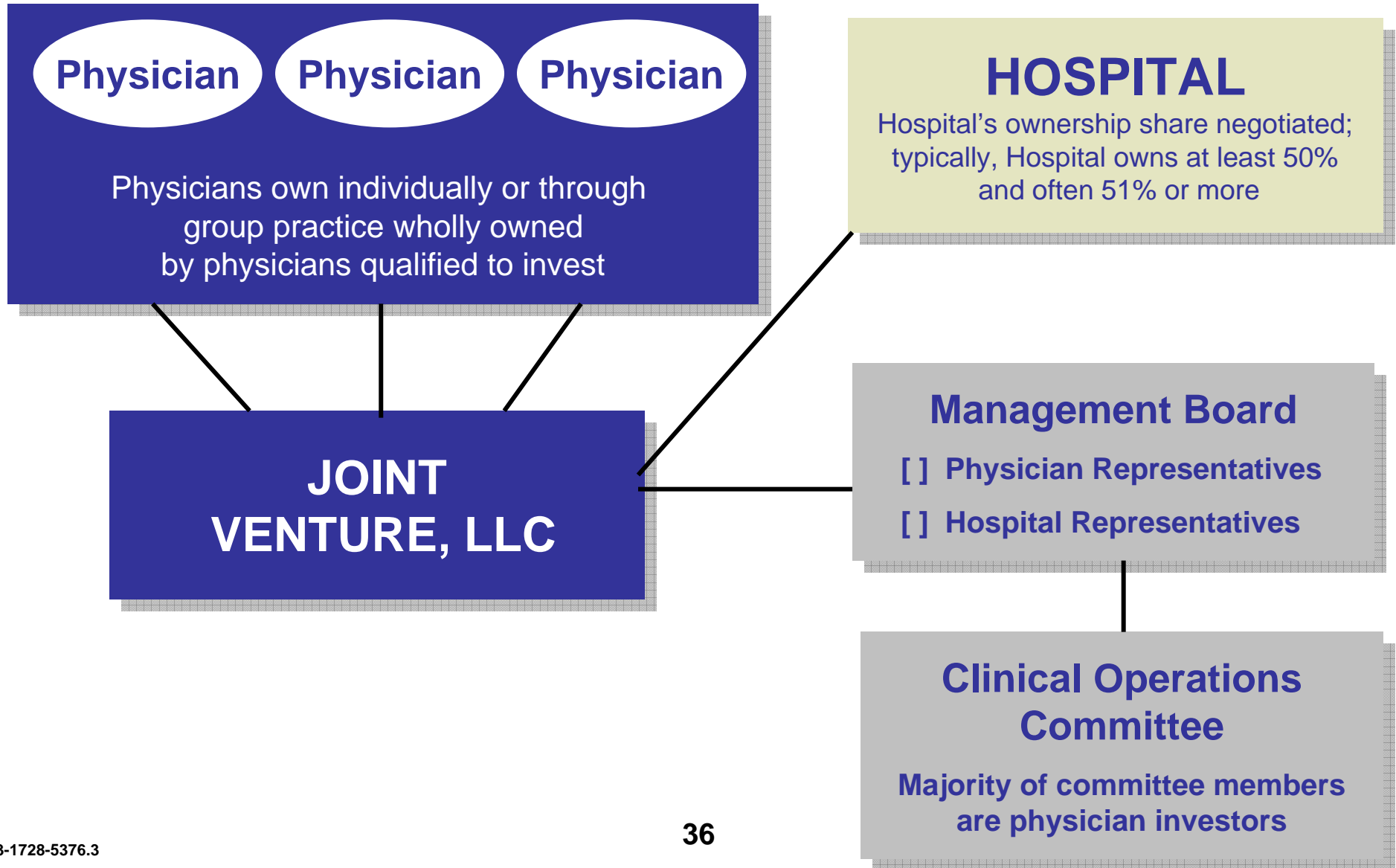
□ Alternatives:

- Joint venture to provide services to hospital “under arrangements”
- Joint venture to lease space, equipment and/or personnel to physicians/physician groups or hospital

Equity Joint Venture



Joint Venture Legal Structure



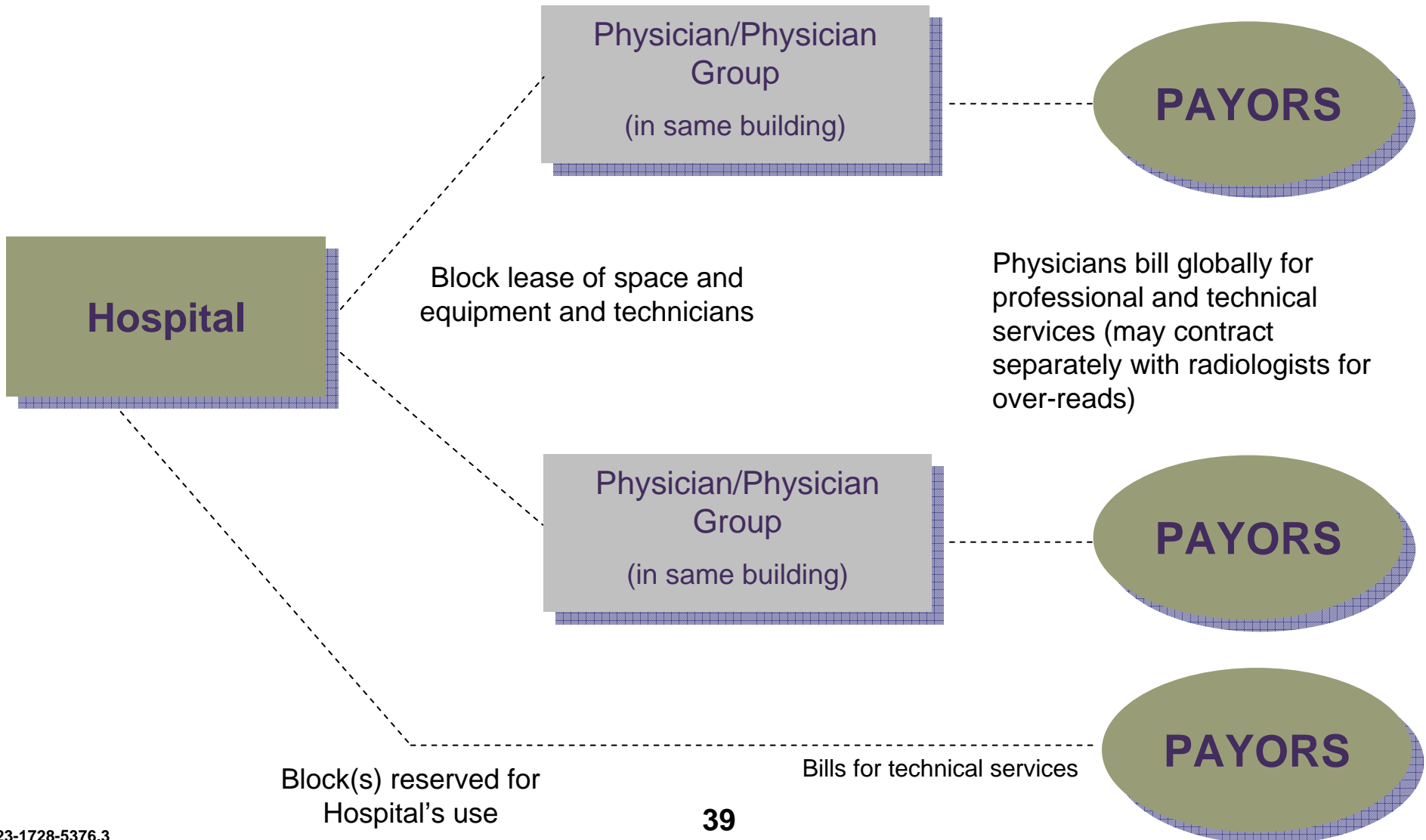
Contractual Models

- ❑ If legal or business considerations prevent a service line joint venture model, a contractual affiliation may be an alternative
- ❑ Possible contractual affiliations include:
 - Leasing
 - Purchased Services Agreement
 - Clinical co-management
- ❑ Contractual affiliation may, but need not, include a joint venture component

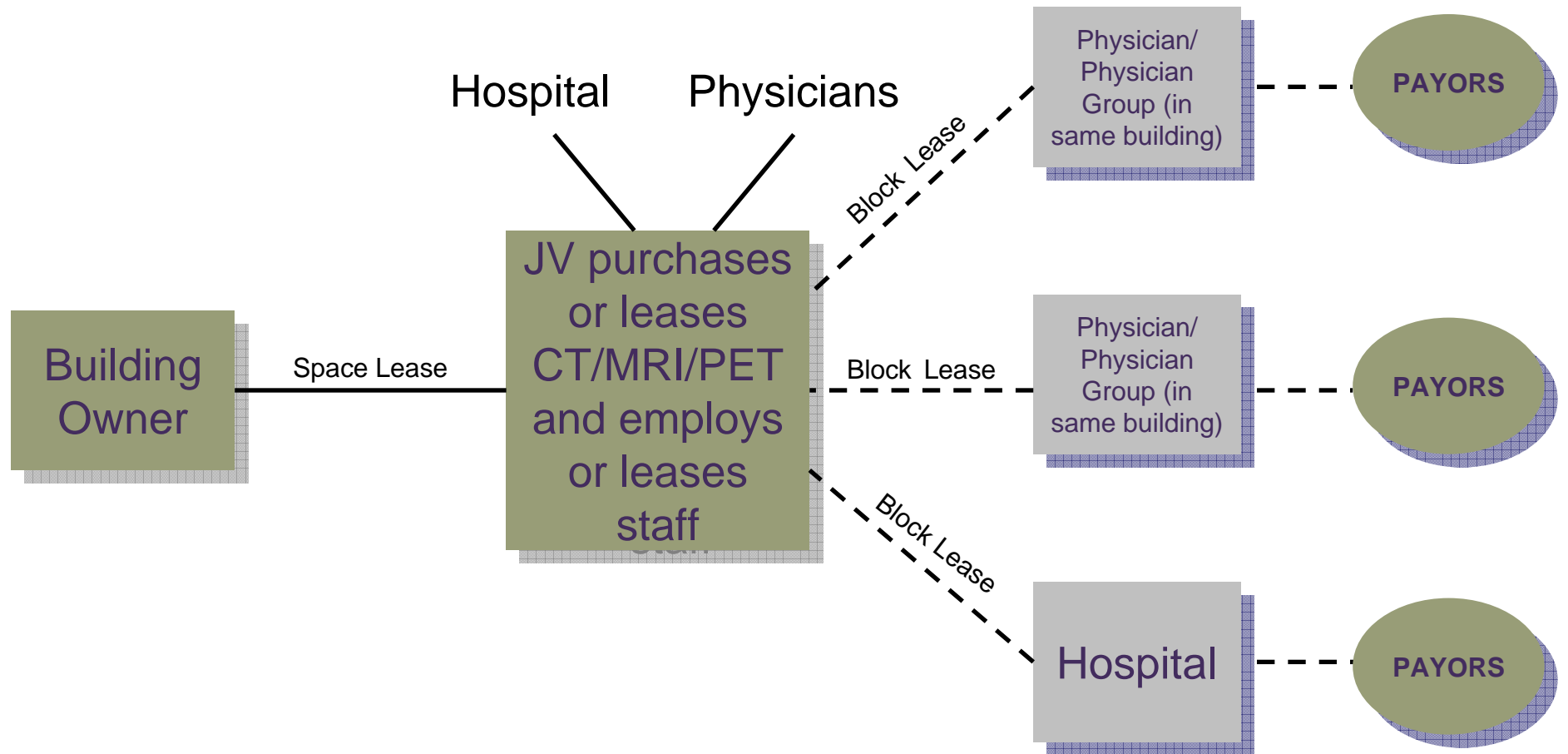
Leasing: Time Share Lease

- ❑ Physician group leases imaging equipment, space and possible technical personnel from hospital or hospital/physician joint venture on a time-share basis
- ❑ Physician group performs tests on its patients during leased block of time as an “in-office ancillary service” under Stark Law
- ❑ Legal issues:
 - Do financial arrangements meet Anti-kickback Statute safe harbor requirements?
 - Are arrangements structured to avoid “contractual joint venture” characterization?
 - Do arrangements qualify for Stark Law exceptions?
 - Can arrangements be demonstrated to be fair market value?
 - Do physician groups meet Stark Law in-office ancillary service requirements (requires office in same building)?
 - Are agreements structured to avoid purchased diagnostic services agreement characterization?

Time Share Lease



Time Share Lease-Joint Venture Model



Purchased Services Agreement

- ❑ Contractual model in which hospital purchases technical component of service from a third party “under arrangements”
- ❑ Service treated and billed as a hospital service; patients registered and treated as hospital patients
- ❑ Third-party service provider may be specialty physician practice or a joint venture that is co-owned by hospital and physicians
- ❑ Hospital purchases the service from the third-party service provider for a fair market value fee
 - Typically a “per service” fee pursuant to a fee schedule
 - Service provider does not bill patients or third-party payors for services
 - Sole compensation is compensation received from hospital

Purchased Services Agreement

- ❑ Can be structured to fit within Stark Law exception
- ❑ Does not fall within Anti-kickback Statute safe harbor and thus involves some Anti-kickback Statute risk
- ❑ Purchased services provider should not obtain staff or management/administrative services from hospital
- ❑ Valuation opinion should be obtained to document that fees for services are fair market value
- ❑ 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”
- ❑ Off-campus provision of services under arrangements by physician/hospital joint ventures may trigger CMS concerns

Example: Cath Lab Venture “Under Arrangements” Structure

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

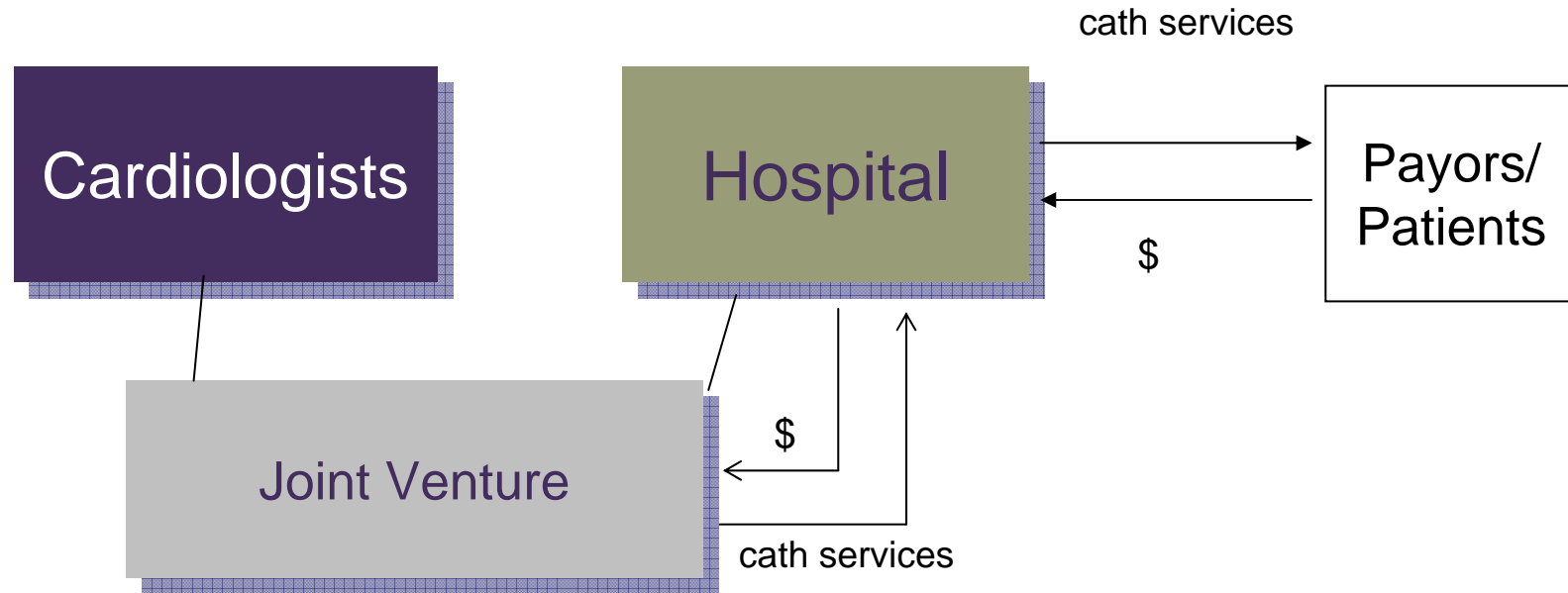
Example: Cath Lab Joint Venture “Under Arrangements” Structure

- ❑ 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 remains the provider of cardiac cath services
 - Hospital contracts with payors
 - Hospital bills payors and collects the technical fee
- ❑ 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

Example: Cath Lab 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
- ❑ Physicians bill professional fees

Example: Cath Lab Joint Venture “Under Arrangements” Model



Joint venture owns/leases equipment and employs techs

Hospital is the provider of cath lab services

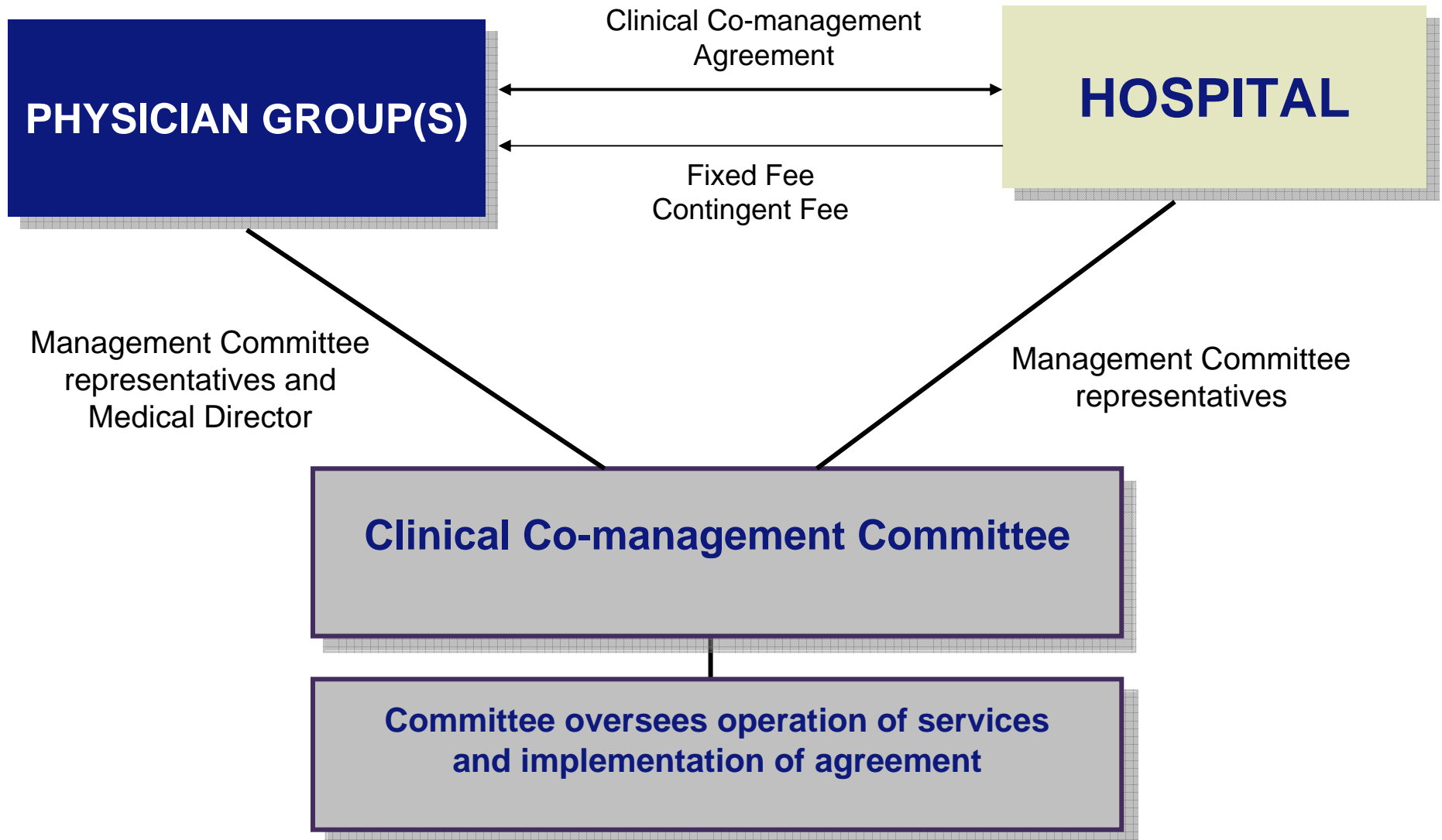
Payors pay Hospital

Hospital purchases cath lab service components from joint venture and pays joint venture on fee schedule basis

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)

Clinical Co-Management



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

Questions and Discussion