Business Models For Cancer Center Success

Michael L. Blau, Esq.
Partner, Foley & Lardner LLP

“It is difficult to make predictions, especially about the future.”

-- Yogi Berra
Business Models

- Hospital-Physician
- Hospital-Hospital
- Physician-Physician
- Developers/Financiers

Hospital-Physician Business Models
Why Collaborate?

- Avoid destructive competition
- Branding/patient draw
- Coordinate patient-centric care
- Broader continuum of care
- Align for quality and efficiency
- Shared resources, risks and rewards
- Position for growth and competitive advantage
- Solidify relationships

Key Physician Partners
(By Tumor Site)

<table>
<thead>
<tr>
<th>Key Technologies</th>
<th>Key Physician Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BREAST</strong></td>
<td></td>
</tr>
<tr>
<td>PDM</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td>Breast MRI</td>
<td>Radiation oncologist</td>
</tr>
<tr>
<td>Breast tomosynthesis</td>
<td>Breast surgeon</td>
</tr>
<tr>
<td></td>
<td>Radiologist</td>
</tr>
<tr>
<td></td>
<td>PCP/Pgynecologist</td>
</tr>
<tr>
<td><strong>PROSTATE</strong></td>
<td></td>
</tr>
<tr>
<td>PET/CT</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td>Robotic surgery</td>
<td>Radiation oncologist</td>
</tr>
<tr>
<td>IGRT</td>
<td>Radiologist</td>
</tr>
<tr>
<td></td>
<td>Urologist</td>
</tr>
<tr>
<td><strong>LUNG</strong></td>
<td></td>
</tr>
<tr>
<td>PET/CT</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td>Lung CT</td>
<td>Radiation oncologist</td>
</tr>
<tr>
<td>SRS</td>
<td>Thoracic surgeon</td>
</tr>
<tr>
<td>IGRT</td>
<td>Radiologist</td>
</tr>
<tr>
<td></td>
<td>PCP</td>
</tr>
</tbody>
</table>
Looming Physician Shortage

Shortage of 2550 – 4080 oncologists by 2020

“One Can’t Run a Hospital With Doctors, One Can’t Run a Cancer Program Without Them”

-- Anonymous Hospital CEO
<table>
<thead>
<tr>
<th>Competition v. Collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Typical Hospital Strategies</td>
</tr>
<tr>
<td>– 3D</td>
</tr>
<tr>
<td>– Divide and Conquer</td>
</tr>
<tr>
<td>– Rope-a-Dope</td>
</tr>
<tr>
<td>– Extraordinary Rendition</td>
</tr>
<tr>
<td>– Build It and They Will Come</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Competition v. Collaboration (cont’d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Typical Hospital Strategies (cont’d)</td>
</tr>
<tr>
<td>– Scorched Earth</td>
</tr>
<tr>
<td>• Economic Credentialing/Decredentialing</td>
</tr>
<tr>
<td>• Contracts/Leverage</td>
</tr>
<tr>
<td>• Refuse Transfer Agreements</td>
</tr>
<tr>
<td>• Zoning Amendments</td>
</tr>
<tr>
<td>• Opposition To Governmental Approvals</td>
</tr>
<tr>
<td>• Legislation</td>
</tr>
<tr>
<td>• PR Offensive</td>
</tr>
<tr>
<td>• Litigation</td>
</tr>
</tbody>
</table>
Competition v. Collaboration (cont’d)

• Typical Hospital Strategies
  – Increase in direct physician employment and practice acquisitions
    • Response to looming physician shortage and national competition
    • Change in attitude of younger physicians toward employment
    • Existing small groups and solo practitioners without viable succession plans
    • Local competition and desire for control
    • Capture specialty referrals and ancillaries
    • Responsibility to community

Competition v. Collaboration

• Typical Hospital Strategies
  – Collaboration
    • Defensive
      – Free-standing cancer centers
      – 50% of high-end imaging in free-standing settings (30% margin)
      – 40% of outpatient surgery in non-hospital settings (20% margin)
      – Emergence of physician-owned cancer centers and hospitals
    • Offensive
      – Market capture and growth
      – Win-Win ventures
Multiple Models for Successful Collaboration

- Contracts
  - Physician Employment
  - Recruitment Agreements
  - Professional Service Agreements
  - Practice Acquisition Agreements
  - Practice Support Agreements
  - Clinical Research Agreements

- Contractual Venture Models
  - Gainsharing Arrangements
  - Block Leasing
  - Service-Line Co-Management
  - Institute Model
  - Center of Excellence Model
  - Under Arrangements Model (Hospital Outpatient Facilities)

- Non-Clinical Joint Ventures
  - Cancer center facility development
  - Equipment leasing companies
  - Management companies
  - HIT ventures

- Clinical Joint Ventures
  - Whole cancer hospitals
  - Specialty surgical hospitals
  - Oncology ASCs
  - Oncology Clinics

- Physician-Hospital Organizations (PHOs)
  - Payor and P4P contracting
  - Medicare/Medicaid risk contracting
  - Clinical Integration

- Foundation Model Arrangements
- Hospital-Affiliated Group Practices
- 2nd Generation Practice Management Organizations
  - Seeding practice integration

- Participating Bond Transactions
- Captive Insurance Arrangements

Integration Continuum
Quality Improvement Through Service Line Co-Management

The Problem of Variability

Check List for Landing a 747 in a Strong Cross Wind*
  *(Had It Been Written by a Physician)
  
  - Use only the settings of the plane’s instruments that were available when you were trained
  - Follow your instincts, not the autopilot
  - Every airline and pilot can use different landing sequences
  - Be really, really careful as you get close to the ground
Quality Shortfall: Getting it Right 50% of the Time


Medical Errors Are a Leading Cause of Death

Medical Errors Compared to Other Common Causes of Death

Number of Deaths per Year

HIV 14,000
Breast Cancer 41,000
Motor Vehicles 47,000

Medical Errors 44,000-98,000

Sources: National Vital Statistics Report, Institute of Medicine
Costs of Poor Quality

- Cost of Litigation: 2%
- Cost of Defensive Medicine: 8%
- Remaining Cost of Poor Quality Healthcare: 20%
- Healthcare Costs Not Associated with Poor Quality: 70%


Ventures To Improve Quality

- Predicates to quality improvement
  - Data transparency
  - IT infrastructure for clinical data capture and evaluation
  - Development of evidence-based (and accepted) clinical protocols/standards
  - Development of quality metrics/outcomes measures
  - Incentives to comply with quality standards
  - Processes to monitor compliance with quality standards
  - Effective processes to deal with noncompliance
## Service Line Co-Management Model

- Service Line Management or Co-Management Arrangements
- Institute Model
- Center of Excellence Model
- Pay for Quality Arrangements

---

## Service Line Co-Management Arrangements

- The purpose of the arrangement is to recognize and appropriately reward participating medical groups/physicians for their efforts in managing and improving quality [and efficiency] of a hospital service line (e.g., oncology)
Service Line Co-Management Arrangements (cont’d)

- The arrangement is contractual in nature
- There are typically two levels of payment under the contract:
  - Base fee: a fixed annual base fee that is consistent with the fair market value of the time the medical groups/physicians dedicate to the service line management, development, implementation and oversight processes
  - Bonus fee: a series of pre-determined payment amounts associated with achievement of specified, mutually agreed, objectively measurable, quality improvement [and efficiency] goals

Service Line Co-Management Arrangements (cont’d)

- Bonus fee may include:
  - Quality of service incentives
  - Operational efficiency incentives
  - [Budgetary objective incentives]
  - New program development incentives

- Fair market appraisal of fees for health regulatory reasons
Service Line Co-Management Direct Contract Model

- Payors
- Payors
- Hospital
- Operating Committee
- Payors
- Payors
- Hospital licensed

Payors
- Facility
- Equipment
- Staff
- Payors
- Payors
- Hospital licensed

Service Line
- Hospital licensed
- Payors
- Payors

Designees
- Designees
- Designees
- Designees
- Designees

Oncology Group I
- RT Group II
- Other Specialty Group(s)

- Quality improvement processes
- Clinical protocols
- Clinical oversight/ enforcement
- Budget process
- Quality initiatives
- Strategic/business plans
- Other?

Sample Surgical Oncology Performance Metrics

<table>
<thead>
<tr>
<th>Incentive</th>
<th>Priority</th>
<th>Allocation</th>
<th>Payment Limit ($)</th>
<th>Current Performance</th>
<th>Performance Target</th>
<th>Upper Limit</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational Efficiencies Incentive Compensation (OEIC)</td>
<td>Supply Cost per Case (based on lower costs of equivalent quality)</td>
<td>1</td>
<td>13.2%</td>
<td>$120,000</td>
<td>13.2%</td>
<td>$5,870</td>
<td>% of Budget</td>
<td>95.0%</td>
</tr>
<tr>
<td>Turn Around Time (c)</td>
<td>On-Time Starts (1st Case of Day)</td>
<td>2</td>
<td>8.2%</td>
<td>$75,000</td>
<td>8.2%</td>
<td>$2,760</td>
<td># Hours</td>
<td>&lt;=1.00</td>
</tr>
<tr>
<td>Room Utilization</td>
<td></td>
<td>1</td>
<td>13.2%</td>
<td>$120,000</td>
<td>13.2%</td>
<td>78%</td>
<td># Hours</td>
<td>&gt; = 95%</td>
</tr>
<tr>
<td>Quality of Service Incentive Compensation (QSIC)</td>
<td>Infection Rate: Antibiotics Within 30 Minutes Prior to Incision</td>
<td>1</td>
<td>13.2%</td>
<td>$120,000</td>
<td>13.2%</td>
<td>89%</td>
<td>% Compliance</td>
<td>&gt; = 95%</td>
</tr>
<tr>
<td>Infection Rate: Insulin Drip for Patients with Blood Sugar Level &gt;150</td>
<td>Return to OR for Post-Op Bleeding</td>
<td>2</td>
<td>8.2%</td>
<td>$75,000</td>
<td>8.2%</td>
<td>0%</td>
<td>% Compliance</td>
<td>&gt; = 95%</td>
</tr>
<tr>
<td>Mortality Rate</td>
<td></td>
<td>1</td>
<td>13.2%</td>
<td>$120,000</td>
<td>13.2%</td>
<td>2.9%</td>
<td>% Rate of Return to OR</td>
<td>&gt; = 2.7%</td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td></td>
<td>3</td>
<td>7.1%</td>
<td>$65,000</td>
<td>7.1%</td>
<td>Peer Group Percentile</td>
<td>&gt; = 80</td>
<td>&gt; = 85</td>
</tr>
<tr>
<td>Peer / Employee Evaluations</td>
<td></td>
<td>3</td>
<td>7.1%</td>
<td>$65,000</td>
<td>7.1%</td>
<td>360° Feedback Scores</td>
<td>Survey Development / Administration</td>
<td>TBD</td>
</tr>
<tr>
<td>Total Incentives</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$910,000</td>
<td></td>
</tr>
</tbody>
</table>

Quality of Service Threshold

Mortality Rate (e) | Quality Threshold would be required to be met in order for any of the above incentives to be paid out. | 2.98% | Gross Mortality % and/or O/E Rate (TBD) (e) | 2.98% |

| Note: | (a) Based on maximum total incentives payout of $910,000 (Subject to Fair Market Value and Legal Approval) |
| (b) O/E = Observed % - Expected % |
| (c) Turn Around Time Defined as time of incision closure to time of next incision |
| (d) % of Return to OR Defined as time of incision closure to time of next incision |
| (e) O/E mortality rate is currently not measured |
| (f) Assumes Quality of Service Threshold will change from gross mortality % to an O/E rate once available |

For Illustrative Purposes Only

Prepared by PricewaterhouseCoopers
Regulatory Considerations

• Cost savings metrics/incentives implicate Civil Monetary Penalty Law
  – Hospital cannot pay a physician to induce reduction or limitation of services to Medicare/Medicaid beneficiaries under the physicians care

• Bottom-line: Cheaper not fewer
  – Can incent verifiable cost-savings to reduce administrative or medically unnecessary costs as long as quality is not adversely affected and volume/case mix changes are not rewarded
  – Independently assess in relation to baseline volume and case mix

Regulatory Considerations (cont’d)

• Volume/revenue based metrics/incentives implicate the Anti-Kickback Statute and Stark law
  – Cannot reward increase in utilization or revenue
**Why Service Line Co-Management?**

- Relatively quick to execute and implement
- Mechanism for using physician competencies to manage service line
- Provides income to physicians outside of normal reimbursement
- Aligns hospital and physicians around service line quality and efficiency
- Maintains hospital reimbursement level for service line
- If form joint venture management company, low capital investment, minimal investment risk, potential financial returns
- Win-Win for hospital, physicians, and community

---

**Why Service Line Co-Management? (cont’d)**

- Cons:
  - Commits 3-5% of service line revenues
  - Requires active participation and real time and effort by busy physicians
  - May not provide adequate long term benefits
    - Adjust performance standards and targets annually
  - Some irreducible legal risk
Joint Ventures

Physician-Hospital Economic Alignment Strategies

Obstacles

- Power
- Money
  - 50¢ dollars
  - Ancillary competition
  - Start-up financing
  - Bank loans/encumbrances
  - Personal guarantees
  - Expense sharing
  - Cross-subsidies
  - Benefit plans
  - Payor participation
  - Charity care
  - Transaction costs
- Scope of Venture
- Scope of noncompetes/exclusivities
- Operational integration
  - Hospital competencies
  - Space
  - Personnel/relatives
    - Office managers
    - Salary/benefit differentials
    - Collective bargaining agreements
  - Equipment/systems
  - Contractual commitments
- Term/Termination
- Buy-in/Buy-out issues
- Deadlock/Dispute resolution
- Duration of commitment/exit
- Legal
- Trust

Competition v. Collaboration

- Existing vs. new services
- Joint ventures that cannibalize existing services rarely "make it up on volume!"

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>Freestanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$4.0 M</td>
<td>$4.0 M</td>
</tr>
<tr>
<td>Margin</td>
<td>35%</td>
<td>20%</td>
</tr>
<tr>
<td>Net Income</td>
<td></td>
<td>$800,000</td>
</tr>
<tr>
<td>Ownership</td>
<td></td>
<td>50%</td>
</tr>
<tr>
<td>Net Pretax Income</td>
<td>$1.4M</td>
<td>$400,000</td>
</tr>
<tr>
<td>Taxes</td>
<td>--------</td>
<td>35%</td>
</tr>
<tr>
<td>Net Contribution</td>
<td>$1.4M</td>
<td>$260,000</td>
</tr>
</tbody>
</table>

Kaufman Strategic Advisors, LLC
Preliminary Considerations

• Win-Win
• Mutual Trust/Build Trust
• Planning/Steering Committee Process
• Consultants to Venture
• Transparency and Confidentiality
  – Confidentiality/Commitment Agreement
• Preliminary Due Diligence
• Agreement on Assumptions/Projections
  – Availability and Accuracy of Data
  – Hospital Data vs. Physician Data

Principal Compliance Considerations

• Stark Law
• Anti-Kickback Statutes
• Civil Monetary Penalty Law
• Reassignment Rules
• Purchased Diagnostic Test/Anti-Mark-Up Rules
• Provider-Based Status Rules
• Tax-Exemption Requirements
Principal Compliance Considerations (cont’d)

- Stark Law – Prohibits physician (or immediate family member) from referring to the hospital or other DHS entity (e.g., IDTF) from which the physician receives anything of value unless a specific exception applies
  - DHS includes all inpatient, outpatient, radiation therapy, imaging (including PET, CT, MRI, and nuclear medicine studies), prescription drugs, lab, prosthetic devices, and physical, occupational, and speech therapy services (among others)
  - Up to $15,000 CMP
  - Up to $100,000 for circumvention schemes
  - Refunds and denials
  - Exclusion

Principal Compliance Considerations (cont’d)

- Stark Law – Pertinent Exceptions
  - RT consultations
  - ASC services reimbursed on a composite rate basis
  - Implants in ASCs
  - Image guided procedures involving insertion of a needle, catheter, tube or probe
  - Imaging performed as an integral part of a non-radiological medical procedure (e.g., brachytherapy)
  - Post-procedure imaging to check placement of implant
  - Preventative screening tests, including mammography, PSA screens, cervical screens and PAP smears
Principal Compliance Considerations (cont’d)

- In-office ancillary services (group practice) exception
- Whole hospital exception-exclusively or primarily for surgical procedures
- Personal services, management contracts, space rental, equipment rental and fair market value exceptions
- Indirect compensation arrangements exceptions
  • Physicians to “stand in the shoes” of physician organization (Phase III)
- Employment: new problem of subsidizing hospital-affiliated groups?
- Rural Providers

Principal Compliance Considerations (cont’d)

- Stark Law – Proposed Rules
  - Under arrangements: applies to interest in an entity that “performs” the service as well as the entity that “bills” the service
  - Per click fees: physician lessor cannot lease equipment or space on a per click basis to a DHS entity to which the physician refers
  - Percentage arrangements: prohibited for space and equipment leases
  - Parent stands in shoes of sub for purposes of evaluating compensation arrangements
Principal Compliance Considerations (cont’d)

• Anti-Kickback Statute – Are distributions from joint venture or service fees disguised kickbacks for referrals?
  – Criminal statute and penalties
    • $25,000 and or up to 5 years in prison
    • $50,000 CMP
    • Exclusion
  – Scienter: any purpose test and the problem of mixed motives
    • Capitalize new enterprise and benefit community vs. inducement for referrals
  – Safe harbors
    • Investment in small entity
    • ASCs
    • Personal services, management contracts, space rentals, and equipment rentals
    • Employment

Principal Compliance Considerations (cont’d)

• Anti-Kickback Statute – OIG Special Fraud Alert on Joint Venture Arrangements (Dec. 19, 1994):
  Suspect features include:
  – Investors are chosen because they are in a position to make referrals
  – Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals
  – Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an “acceptable” level of referrals
Principal Compliance Considerations (cont’d)

– The joint venture tracks its sources of referrals, and distributes this information to investors
– Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire
– Investment interests may be nontransferable
– One of the parties may already be engaged in the particular line of business, and the joint venture is a “shell”
– Investment returns are disproportionately high relative to typical investment in a new business enterprise

Principal Compliance Considerations (cont’d)

• Other suspect features:
  – Physician investors invest only a nominal amount ($500-$1,500)
  – Physician investors borrow money for the investment from the joint venture (or from co-venturers) and repay out of joint venture distributions
  – Extraordinary investment returns of more than 50-100% per year
### JVs with EOs: Governance and Control

#### Urban Myth: Hospital must have majority control of governing board

- St. David’s Case; Redlands Surgical Services: Rev. Rul. 98-15
- Involve ceding control of all of the assets of an exempt organization to a for-profit joint venture that is not controlled by the exempt organization
  - Involved contribution of substantial charitable activities and more than incidental benefit

#### JVs with EOs: Governance and Control (cont’d)

- Contribution by a hospital to a joint venture may not involve substantial assets of the hospital (e.g., ASC or PET/CT venture)

  - Where substantial charitable assets/activities are contributed by an exempt hospital (e.g., Proton Beam venture):
    - Nonprofit must have majority control of board
    - Charitable purposes must take priority over profit opportunities
    - JV should not be managed by the for-profit investor
    - Arm’s-length FMV transactions with for-profit investor
JVs with EOs: Governance and Control (cont’d)

- Where insubstantial charitable assets/activities are contributed by an exempt hospital:
  - Can be a 50/50 venture (or hospital can have a minority position) with reserved powers
  - But see Rev. Rul. 2004-51: Nonprofit may need to control JV activities relating to its tax exempt purposes (e.g., scope of clinical services, QA, credentialing)

Impermissible Joint Venture

- May Violate Stark Law
- May violate Anti-Kickback Statute
# Top 10 Reasons to Redouble Your Regulatory Compliance Efforts

10. If it makes sense in any other industry, it is probably illegal in healthcare
9. If you are sure you have it legally right, you have probably overlooked something
8. As soon as you truly have it right, the law can and will change
7. A clear conscience about compliance may only be a sign of bad memory
6. In healthcare, today’s loophole may be tomorrow’s noose

---

## Top 10 Reasons to Redouble Your Regulatory Compliance Efforts (cont’d)

5. Just because everyone else is doing it doesn’t mean you won’t get caught
4. Regardless of the season, whistleblower suits are always in fashion
3. If you came to the conclusion you are in compliance, remember that a conclusion is just the place that you stopped thinking
2. In healthcare, one man’s “creative” business may be the OIG’s bulls-eye
1. I can assure you that you do not want to do time cleaning toilets with Scooter Libby at San Quentin
Appendix

Select Hospital-Physician Models
- Block Lease Arrangements (e.g., Chesapeake Potomac Regional Medical Center)
- Joint Venture ASCs (e.g., Clarian Health System)
- Equipment Joint Ventures (e.g., Fox Chase Virtua Health Center)
- Under Arrangements Model (e.g., Christiana Health System)
- Whole Cancer Center Ventures (e.g. National Surgical Hospitals; United Surgical Partners)
- Participating Board Transactions

Select Hospital-Hospital Models
- Satellite Clinic within a Hospital (e.g. Mass General/Emerson Hospital)
- Hospital Under Arrangements JV (e.g., Dana Farber Partners Cancer Care)
- Whole Cancer Center JV (e.g., The Regional Cancer Center – St. Vincents/Harnot Hospitals (Erie, PA); West Michigan Cancer Center-Borgess Medical Center/Bronson Methodist Hospital (Kalamazoo, MI))

Block Lease Arrangements
- Infusion Services
- Laboratory Services
- Imaging Services (e.g., PET, CT, MRI, Ultrasound)
- Equipment Ventures (Lin Acc, IMRT, IMGT, Cyberknife, Gammaknife)
- ASCs
- Cancer Care Facilities
Block Lease Arrangements (cont’d)

Medicare Reimbursement - Physician/Clinic Rates
- Stark Law - In-office ancillary services exception; same (shared) building prong
  - Same post office address (not interior space or parking lots; no mobile vehicles, vans or trailers)
  - Open at least 8 hours/week with physician on-site at least 6 hour/week
  - Some non-DHS services
  - Indirect compensation exception for hospital lease (prior to 12/4/07)
  - After 12/07, space, equipment rental and personal services exceptions for lease
    - FVM annual fixed fee
    - No AKS violation
  - Physician services exception (purchased interps) requires reading on-site to bill for pro fee
- Anti-Kickback statute
  - Personal Service and Management Contract, Space and Equipment Rental Safe Harbors?
  - Payments should not be per procedure (purchased diagnostic test (no mark-up), “swaps”, and “marketing the spread risks”)
- Proposed reassignment rule changes would prohibit reassignment except by full-time employees
- Proposed purchased PC/TC rule would prohibit mark-up if lessor “performs” the service
- State licensure and CON requirements
  - Separate licensure, accreditation and Medicare certification requirements for block lease of hospital-based facilities
Select Clinical Joint Venture Models

- ASC Ventures
- Equipment Ventures (e.g., LinAcc, IMRT/IGRT, Cyberknife, Gammaknife)
- Imaging Ventures (e.g., PET, CT, MRI)

Joint Venture ASC

Issues
- Medicare certification – separate legal entity
- ASC reimbursement vs. hospital OPPS
- No Stark law issue for ASC composite rate services
- Other exceptions needed for co-located DHSs
- Antikickback ASC safe harbor?
- 1/3 tests
- Absence of suspect features
- Hospital affiliated physicians
- State licensure and CON requirements
Equipment Joint Ventures

- Hospital reimbursement rates
- Stark Law
  - JV is not a DHS entity
    - MedPac recommendation that JV be treated as DHS entity if its revenue is primarily generated from management of DHS services
  - Equipment rental safe harbor – FMV set in advance
- Anti-kickback Statute
  - Small entity investment safe harbor (40/40 tests)
  - Absence of suspect features
  - Equipment rental safe harbor – aggregate fair market rental set in advance
- State licensure and CON requirements

Hospital Under Arrangements Model

- Cancer Centers
- Radiation Therapy Services
- Infusion Centers
- Ambulatory Surgery Centers
- Other Hospital Outpatient Services
Hospital Under Arrangements Model

Medicare Reimbursement
- Licensed and held out to public as hospital service
- Hospital/outpatient rates
- "On-campus" – within 250 yards of main campus buildings
- Hospital provides some clinical service (not all services in facility provided under arrangements)
- Common JCAHO accreditation
- Clinically, financially and administratively integrated with hospital

Stark Law
- Hospital services are DHSs
- Indirect compensation exception - FMV per procedure
- No violation of AKS
- Proposed Stark rule would prohibit ownership of entity that “performs” DHS service
- MedPac recommendation on management JVs

Anti-kickback Statute
- Small entity safe harbor
- Purchased service contract not safe harbored unless fixed annual FMV fees (space, equipment, personal service safe harbor)
- No intent to induce referrals; intent to establish new business enterprise for convenience of patients
- OIG Special Advisory Bulletin on contractual JVs

State license and CON requirements
- Hospital or satellite clinic license
- CON threshold for substantial change in service; substantial capital expenditure; major equipment
Is This Coming Soon Near You?

Physician Owned Oncology Hospital
Whole Hospital Ventures

Stark Law whole hospital exception
- Hospital vs. subdivision must be primarily engaged in inpatient services
- Moratorium on referrals to specialty hospitals (through 6/8/05) for hospitals primarily providing cardiac, orthopedic or surgical services is over
- Freeze of provider enrollment for new specialty hospitals is over
- Rural hospital exception
- Pete Stark proposal to eliminate whole hospital exception in S-CHIP bill

Anti-kickback Statute
- Small entity safe harbor (40/40 rules)

CMP Law
- Special Advisory Bulletin on GainSharing - specialty hospital ventures may induce investor physicians to limit or withhold Medicare services to produce profit

State hospital license and CON requirements

Participating Bond Transactions
Participating Bond Transactions

- Tax Efficient, Potentially Lower Cost Alternative to Equity Joint Ventures
- Uses: – Finance New Hospital Facilities, Refinance Existing Facilities, Specialty Hospitals, ASCs, Other Stark Compliant Physician Investments, Practice Acquisitions and Other Purchase Transactions
- Features
  - Thin Layer of Subordinated Tax Exempt Debt Issued to Participating Physicians (e.g., $2 Million of $8 Million ASC project)
  - Return on Investment Tied to Cash Flow From Operations in Excess of Specified Amount
  - High Interest Rate (Tax-exempt) Set By Underwriter on Market Basis
  - Accrual Bonds vs. Contingent Interest Bonds
  - 15-25 Year Balloon
  - 60% of Bonds Sold to Nonphysicians

PBT Cost Savings

<table>
<thead>
<tr>
<th>$8 Million ASC Project</th>
<th>Equity JV</th>
<th>PBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Sales tax</td>
<td>8.25% x $1,111,687</td>
<td>-0-</td>
</tr>
<tr>
<td>- Income taxes</td>
<td>35% x $1,822,525</td>
<td>-0-</td>
</tr>
<tr>
<td>- Property taxes</td>
<td>2.7% x $1,423,201</td>
<td>-0-</td>
</tr>
<tr>
<td>Total</td>
<td>$685,524</td>
<td>-0-</td>
</tr>
<tr>
<td>- Physician ROI</td>
<td>$230,000</td>
<td>$230,000</td>
</tr>
</tbody>
</table>

Transaction costs
Participating Bond Transactions
Typical Structure

- **Issues**
  - Stark Law
    - Whole hospital exception for hospital financings/refinancings
    - Specialty hospital moratorium and provider enrollment freeze are over
    - Pete Stark proposal to eliminate whole hospital exception
    - ASC exception (composite rate services)
  - Anti-kickback Statute
    - Small investment interest safe harbor (40/40 rules)
    - ASC safe harbor – qualified surgeons and hospital (1/3 rules)
  - IRS – reasonable compensation and incidental benefit limits

Key Joint Venture Issues

- Scope of venture
- Governance
- Capital contributions/distributions
- Dilution
- Noncompetition
- Term/Termination
- Buy-in/Buy-out
- Succession planning
Hospital-Hospital Business Models

Advantages of Hospital Collaboration

- Shared market growth opportunity
- Branding/patient draw
- Patient convenience
- Access to (super) specialists
- Access to clinical trials
- Access to broader treatment options
- Shared resources/systems
- Shared risks and rewards
- Avoid destructive competition
Integration Continuum: Hospital - Hospital

Service Line Management Contract
Branding

Satellite Clinic within a Hospital
Staffing or Specialists Rotation Contract

Joint Venture Hospital within a Hospital
Joint Venture (Under Arrangements)

Integration Continuum: Hospital - Hospital

Satellite Clinic Within A Hospital

AMC

Community Hospital
AMC Clinical Affiliation

AMC Cancer Clinic

Clinic Service
$ Space Lease

Payors

Hospital Services
$ AMC license/CON

71 72
Hospital Under Arrangements Joint Venture

- AMC
- Community Hospital
- Cancer Care NewCo
- Payors

Under Arrangements Contract

- Leasehold improvements
- Equipment
- Systems
- Staffing
- Services

Community Hospital (Cancer Program)

Community hospital license/CON

Whole Hospital Joint Venture

- AMC
- Community Hospital
- Cancer Hospital NewCo
- Payors

- Free-standing or within hospital
- NewCo license and CON
- Range of service requirements
- Separateness requirements
# Key Hospital-Hospital Collaboration Issues

- Scope of affiliation
- Name use rights
- Governance/decision-making
- Capitalization and financial relationship
  - Anti-Kickback Statute constraints
  - Bond restrictions
  - Obligated group issues
- Term/Termination
- Buy-in/Buy-out rights
- Restrictive covenants
- Dispute resolution
- Tax-exemption considerations

---

## The Future
Hybrid Integrated Model

Back to the Future?

- Consolidation and Integration – Vertical or Virtual
  - Clinical, economic and business interdependence
  - Technology and IT imperatives
  - Quality/risk management imperatives
  - P4P
  - Consumer driven health care/pricing
  - Market clout with payors and vendors
Contact

Michael L. Blau
Partner
Foley & Lardner LLP
111 Huntington Avenue, 26th Flr.
Boston, MA 02199
Tel: 617.342.4040
mblau@foley.com