PHYSICIAN-HOSPITAL ALIGNMENT STRATEGIES

Models for Successful Collaboration With Physicians
MARCH 2, 2011
Models for Successful Collaboration with Physicians

March 2, 2011
12:00 p.m. CST

Web Participants: For Audio Access Dial 866.814.1917
Conference ID: 1514625
Presentation may be printed via Foley.com/HPA3
Housekeeping

- Today's program will last approximately 3 hours and will include one 10-minute break at 1:40 p.m. Central time.

- We encourage you to ask questions during our interactive Question and Answer session. For those of you participating in our offices, your Foley office host will assist you in asking your question. For those participating via web conference, simply click “Q&A” on the menu bar and type your question. Please indicate to whom your question is directed. If time does not allow for us to answer your question, we will follow up with you to address it.

- To print today’s handout materials, our web participants are encouraged to go to Foley.com/HPA3 to print a PDF.

- Additionally, should web participants require audio assistance please press *0.
Today’s Speakers

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

• Lawrence C. (Larry) Conn, Special Counsel, Foley & Lardner LLP

• Alan H. Einhorn, Of Counsel, Foley & Lardner LLP

• Kent Nicaud, Vice President, Physician Administrative Services, Memorial Hospital at Gulfport
Today’s Speakers

• Chris E. Rossman, Partner, Foley & Lardner LLP

• Matthew Searles, Manager Member, Merritt Healthcare Solutions

• Martin Shenk, Administrator Oncology Services, Memorial Hospital at Gulfport
Service Line Co-Management Arrangements

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Why Do It, and Why Now?

- Economic and regulatory realities are creating/enforcing the need for new payment/delivery approaches
  - Value versus volume
    - Value based purchasing, gainsharing, shared savings
  - Coordination of care among and across providers
  - Structural changes to promote integration
What IS a Service Line Co-Management Arrangement?

- At its core, a contractual relationship

- Between a hospital and physicians, or between a hospital and a joint venture comprised of the hospital and physicians

- Focused on a hospital service line (e.g., ambulatory surgery, orthopedics, cardiology, oncology)

- To provide a broad and deep array of management and clinical oversight services within a collaborative framework
How Does it Work?

- Operations Committee as coordination/collaboration vehicle
- Enumerated services, including medical director services
- Establishment, and measurement of performance pursuant to, mutually agreed performance standards
- Compensation based, in part, on achievement of agreed performance standards
Core Principle and Shared Vision

- The recognition, and appropriate rewarding of, bona fide participation in the development, management, and improvement of quality and efficiency of the hospital’s service line
Service Line Co-Management Direct Contract Model

- Payors
- Hospital
- Service Line
  - Hospital-licensed services
- Operating Committee
  - Designees
  - Co-Management Agreement
    - Two, or multi-party contract
    - Specifically enumerated services
    - Allocates effort and reward between groups
- Group I
- Group II
- Other Group (s)
Service Line Co-Management Joint Venture Model

- Payors
- Hospital
- Service Line
  - Profit Distribution
- Service Line Physicians/Groups
- JV Management Company
  - Capital Contributions
  - Management Infrastructure

Co-Management Agreement
Service Line Co-Management Arrangements

- Typically two levels of payment to physician managers:
  - Base fee – a fixed annual base fee that is consistent with the fair market value of the time and effort participating physicians dedicate to service line development, management, and oversight
  - Bonus fee – a series of pre-determined payment amounts, each of which is contingent on achievement of specified, mutually agreed, objectively measurable, program development, quality improvement and efficiency goals
  - Aggregate payment generally approximates 3-6% of service line revenues
    - Fixed, fair market value; independent appraisal advisable
Regulatory Considerations

- There are legal constraints on Service Line Co-Management Agreements, and participants must consider Stark, CMP, and AKS; e.g.:
  - No stinting
  - No steering
  - No cherry-picking
  - No gaming
  - No payment for changes in volume/referrals
  - No payment for quicker-sicker discharge
  - Must by FMV; independent appraisal required
Stark Law

Stark Law: Incentive payments to physicians, or payments to physicians under an incentive payment or shared savings plan constitute a compensation arrangement, and therefore an exception is needed

- Need direct compensation exception for service line co-management agreement with participating individual physicians, and medical group owners who “stand in the shoes” of their “physician organization”
- Indirect compensation analysis for joint venture model and other physician entities (e.g., faculty practice plans)
  - Outside of Stark if aggregate compensation to referring physician does not vary with or reflect volume or value of DHS referrals
  - Otherwise, need to rely on indirect compensation arrangements exception (411.357(p))
    - Fair market value requirement
Stark Law

What Stark exceptions can be used?
- Personal service arrangement (411.357(d))
- Fair market value (411.357(l))
- Both of these exceptions contain requirement that compensation be FMV and “set in advance” and not vary with volume/value of referrals
  - “Set in advance” permits a specific formula that is set in advance, can be objectively verified and does not vary with volume/value of business generated (e.g., fixed payment for objective quality metrics) – percentage comp can “be set in advance”
Regulatory Considerations

- CMP Statute, Section 1128A(b) of the SS Act, 42 USC 1320a-7a(b): prohibits a hospital (or CAH) from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to a Medicare or Medicaid beneficiary who is under the direct care of the physician
  - CMP of not more than $2,000 for each such individual with respect to whom the payment is made
  - A physician who knowingly accepts payment subject to a CMP of not more than $2,000 for each individual with respect to whom the payment is made
  - Potential for exclusion from Federal and State Healthcare programs (see 1128(b)(7) of the SS Act)
Regulatory Considerations

- Cost savings metrics/incentives implicate Civil Monetary Penalty Law
  - Hospital cannot pay a physician to reduce or limit services to Medicare/Medicaid beneficiaries under the physician’s care
  - Cannot pay for reduction in LOS or overall budget savings
- Can pay for cheaper not fewer items of equivalent quality?
  - Potential to incent verifiable cost-savings from standardizing supplies or reducing administrative expenses as long as quality is not adversely affected and volume/case mix changes are not rewarded
Volume/revenue-based performance measures implicate the Anti-Kickback Statute
- Should not reward increase in utilization, revenue, or profits of service line
- Should not reward change in case mix
- Should not reward change in acuity
- Should obtain independent appraisal of FMV to help negate inference of improper intent

Advisory Opinions indicate that the AKS could be violated if the requisite intent is present, but that OIG would otherwise not seek sanctions
Co-Management contract will not meet Personal Services and Management Contracts safe harbor if “aggregate compensation” is not set in advance
- Maximum and minimum compensation may be set in advance, but aggregate compensation may not be
- OIG’s position is that percentage compensation is not “set in advance”

Joint venture probably will not meet small investment safe harbor 40/40 tests
- More than 40% of interests held by persons in a position to refer

Analyze under AKS “one purpose” test; some irreducible legal risk
OIG Adv. Op. 08-16: Pay-For-Quality

- OIG Adv. Op. 08-16
- Participating physicians are members of Medical Staff for at least one year
- Participating physicians equally capitalize Medical Staff Entity
- Quality targets are measures listed in CMS' Specification Manual for Hospital Quality Measures
- Payments to Medical Staff Entity are capped at 50% of base year P4P dollars (with inflation adjuster)
- Quality targets and payments renegotiated annually
- Monitoring to protect against inappropriate reduction or limitation in patient care services
- Termination of physicians who change referral patterns (e.g., cherry pick patients) to meet targets
- Maintain records of performance
- Patients informed of Program in writing
Key Service Line Co-Management Issues

- Scope of service line under management
  - Service line co-management services
  - No overlap with, e.g., PSA, Employee Lease or other agreements (to be discussed later)
  - Documentation

- Performance standards and targets
  - Validation
  - Achievability
  - Reset
Key Service Line Co-Management
Issues

- Term/durability
  - Rev. Proc. 97-13 (3 years)
- Dilutive effect of adding physicians due to FMV limitation for services rendered
- Independent appraisal of fair market value
- Cost of independent monitor, valuation, security offering (for JV)
- Some irreducible legal risk
Professional Services Arrangements

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Introduction

- Professional Services Agreements
  - COE: Conversion of existing medical group facility; staffing of existing hospital facility or development of new hospital facility
  - Hospital license and payment rates
  - Clinically and financially integrate and align
  - Medical group stop loss: hospital bears risk of reimbursement reductions and nonpayment
  - May involve equipment acquisition
  - Potential economic win-win
Professional Services Agreement

Hospital provides:
- License
- Provider-based status
- Space/equipment
- Mid-levels (off-campus)

Center of Excellence provides:
- Professional Services Agreement

Group Provides:
- Physician staffing
- Non-clinical staff
- Mid-levels (on-campus)
- Management services

Medical Group provides:
- $ WRVU
- $ Staffing/Management Services

Payors provide:
- Professional Services Agreement
Principal PSA Legal Issues

- Stark Law
  - Under arrangements prohibition: cannot have investment interest in entity (including own medical group) that “performs” the DHS service
  - “Stand in the shoes”
  - Personal services, fair market value or indirect comp exception: fair market value requirement/independent appraisal advisable
Principal PSA Legal Issues

- Anti-Kickback Statute
  - Question of intent/problem of mixed motives
  - New ACA standards of liability
  - Personal services and management contracts and/or space or equipment rental safe harbor: fair market value/aggregate compensation set in advance
  - No advisory opinions available on FMV
  - Some irreducible AKS risk
Principal PSA Legal Issues

- Provider Based Status Regulations
  - Hospital license requirements/Physical space standards
  - CON issues
  - Clinically, financially and administratively integrated
  - Hospital reporting lines
  - Hospital must directly employ mid-levels/techs at off-campus sites (other than NPs)
  - Medical group can lease non-clinical staff to Hospital
  - No off-campus joint venture with medical group
Principal PSA Legal Issues

- HIPAA/HITECH Act
- Tax Exemption Considerations
  - No inurement/private benefit
  - No excess benefit transaction
  - Rebuttable presumption of reasonable compensation process
  - Rev. Proc. 97-13 and private use of bond financed space or equipment/duration limitations (3 years/2 year out)
Other Key PSA Issues

- Payor pushback
- Increased patient co-pays
- wRVU valuation
  - Relation to existing physician compensation/margins on imaging, labs, etc.
  - Other continuing expenses
  - New physicians/NPs/PAs
- Exclusivity and existing relationships
Other Key PSA Issues

- **Staffing Issues**
  - Split staff (off-campus)
  - Salary/benefit differentials
  - Union issues

- **Unwind rights**
  - Asset repurchase
  - Lease assignment/real estate repurchase
  - Solicitation of employees
  - Data/records access/transfer
  - Systems issues
Key Deal Maker/Breaker Issues

- Governance
- Financial terms
- Term/duration
- Termination
- Restrictive covenants
- Unwind rights
- Addition of new physicians/providers
- Break-up fees?
- Arbitration/dispute resolution
**PSA with Service Line Co-Management Agreement**

**Notes:**
- Same as PSA arrangement, plus
- Service Line Co-Management Agreement (3-6% of Service Line revenue)
  - PSA component – WRVU rate equal to aggregate current physician comp/benefits
  - Employee Lease – cost plus
  - Co-management component – fixed fair market value fee
  - Incentive component contingent on meeting specified quality and efficiency improvement standards – fixed FMV fee per standard
Martin Shenk, Administrator
The Medical Oncology Group

Kent Nicaud, Vice-President
Physician Administrative Services
Lessons Learned

Developing a winning alignment between a Health System and Medical Oncology Practice

“… and the two shall become one!”
“…and the two shall become one!”
The Parties

The Medical Oncology Group (TMOG)
The Parties

Memorial Hospital at Gulfport (MHG)
The Intent (or Strategy)

To develop a State-of-the-Art Consolidated Cancer Center including:

- CyberKnife®

Benefiting community members in a catchment area of above 400,000
The Intent (or Strategy)

To develop a State-of-the-Art Consolidated Cancer Center including:

- CyberKnife®
- Radiation Oncology

Benefiting community members in a catchment area of above 400,000
The Intent (or Strategy)

To develop a State-of-the-Art Consolidated Cancer Center including:

- CyberKnife®
- Radiation Oncology
- Medical Oncology

Benefiting community members in a catchment area of above 400,000
The Intent (or Strategy)

To develop a State-of-the-Art Consolidated Cancer Center including:

- CyberKnife®
- Radiation Oncology
- Medical Oncology
- Infusion Center

Benefiting community members in a catchment area of above 400,000
The Intent (or Strategy)

To develop a State-of-the-Art Consolidated Cancer Center including:

- CyberKnife®
- Radiation Oncology
- Medical Oncology
- Infusion Center
- Tumor Registry
- Research
- Adjacent ancillary services

Benefiting community members in a catchment area of above 400,000
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<td>2009</td>
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<td>August 29, 2005</td>
<td>Katrina</td>
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<td>Professional Service Agreement (PSA) effective June 2010</td>
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Memorial Hospital 1998
Aerial Photo post Hurricane Katrina September 2005
Memorial Hospital post Hurricane Katrina 2005
Memorial Physician Clinics
Acadian Plaza 2009
Market Drivers for Alignment

TMOG and MHG
- Financial benefits
- No major cancer centers within 60 miles east or west
- Mississippi is a Certificate of Need (CON) state - difficult to develop standalone cancer center

MHG
- Dominant hospital system in market
- Control of referral sources – employs 160+ Physicians
- Cancer Center already including CK, RadOnc, Tumor Registry, ancillary services

TMOG
- Dominant practice in area with good payor mix
- Changes in reimbursement
- Partners nearing retirement age
- Health Law uncertainties
Business Drivers for Alignment

MHG
- 340b drug pricing availability
- Ability to mix poor payors with good to improve overall payor mix
- Ability to serve community regardless of ability to pay

TMOG
- Cancer Center referral system
- Costs of converting to Electronic Medical Record (EMR)
- Eliminates drug inventory and A/R risk
The Deal

• Over a year to negotiate - lots of push pull back and forth
• A level of trust was necessary for the deal to happen
• Five year term, with renewal options for both parties
• Assets sold to hospital but maintained physician corporation as contractor for:
  • medical oncology management services
  • administrative management services
  • employees leased to hospital per provider based regulations
  • practice manages billing and collection functions even though at this point only in an advisory capacity.
Deal Details

• Payment based on a rate per FMV wRVU
• Medical Director Hourly Fee
• TMOG’s Employee’s leased to MHG (provider based regulations)
• Lease Fee for management of employees
• TMOG pays physician’s malpractice, CME, health and disability insurance and other direct physician expenses as part of wRVU value.
• MHG covers all other operating expenses
• Key concept to understand in negotiation
• Must by defendable by valuation specialist
• Important to choose an experienced valuation firm – in oncology if possible.
• Document prior years earnings from all sources
• Payment rate should consider all clinical and administrative services provided.
Financial Drivers

• 340b Drug cost 30-35 per cent below practices old cost.
• Savings of $2.5MM on $7MM annual drug buy
• Physician group collects balance of A/R with no further A/R risk, reduces A/R by $1.5mm
• Physician group no longer purchases $30-$40K of drugs daily. No more A/P of $500-$600K
Psychic Rewards

- Community hospital serves all comers
- Physicians do not have to turn away patients due to negative reimbursement
- Patients get better care
- Win for hospital, win for physicians and big win for community.
How to Focus / Communicate

- Spiritual Alignment
- Mental Focus
- Emotional Connections
- Physical Engagement
Do’s and Don’ts

Do

– Have a transition plan that is time sensitive
– Know your partners
– Review the functionality of any system to be adopted
– Understand the Health System’s accounting and patient registration process and how the clinic’s processes fit
– Get an organization chart with names, numbers and responsibilities for both sides
– Get a clear and up-front understanding of The Joint Commission’s impact on clinic operations
– Make sure available reports, financial and HIM, will meet needs of the clinic
– Have a clear understanding of lines of authority for budgets (income and expense) and hospital processes
– Flexibility
– HEAVY AND CONSTANT COMMUNICATION

Don’t

– Assume ANYTHING
Before
After
Physician Alignment Strategies

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Modified Under Arrangement Structures

- Why “modified?”

- Relevant legal restrictions
  - Stark law
  - Medicare billing rules
Physicians may not refer Medicare-covered designated health services ("DHS") to a hospital or other entity with which physician (or immediate family member) has a financial relationship, unless an exception applies.

- DHS includes all inpatient and outpatient hospital services.

- Hospital (or other entity) may not bill for services resulting from prohibited referral.

- Financial relationship includes both ownership and compensation arrangements.
Stark Law (cont’d)

- Sanctions include civil money penalties, and a requirement to refund timely (now 60 days) amounts collected for services arising out of prohibited referrals.

- PPACA’s “reverse false claim” provision further weights the hammer.

- Physician ownership in an entity that performs DHS is very limited, if the physicians intend to refer.
Stark Law (cont’d)

- Limited exceptions, such as public companies and rural areas, but PPACA’s ban on new physician-owned hospitals applies even to rural hospitals (PPACA § 6001; 42 U.S.C. §1395mm(d)). Radiologists can own and use diagnostic imaging facilities.

- In pure “under arrangements” structure, the under arrangement venture performs the service for admitted/registered hospital patients; hospital bills under PPS/OPPS. Physicians would have ownership in the venture because it doesn’t bill Medicare.
Stark Law (cont’d)

- The good old days:
  CMS: “...we will treat ‘under arrangements’ financial arrangements between hospitals and physician-owned entities as compensation arrangements and not ownership relationships.” (66 Fed. Reg. 942-43 (Jan. 4, 2001).)

- The current, modified days:
  Stark prohibition on ownership interest in entity that performs the DHS (411.351, definition of “entity,” effective October 1, 2009).

- Significance: Previously only the entity submitting the claim was affected; now, both the entity that bills and the one that performs are subject to Stark’s ownership restrictions.
Stark Law (cont’d)

What does it mean to perform DHS?

CMS, in short: Take a guess.

[“Physicians and other suppliers and providers generally know when they have performed a service...” 73 Fed.Reg. 48433, 48726 (8/19/08). “[W]e decline to issue a specific proposal concerning the definition of entity at this time.” (74 Fed.Reg. 61737, 61933 (11/25/09)).]
Stark Law (cont’d)

- CMS, in long:
  - By way of example only, we consider a service to have been “performed” by a physician or physician organization if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or physician organization has contracted with the hospital and the hospital bills for the service instead....
  - We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS. (73 Fed.Reg. 48433, 48726 (8/19/08), emphasis added [!]).
Stark Law (cont’d)

- CMS very quietly added emphasis (italics) to the or’s, in its 2009 rule; did not italicize them in 2008.

- Why? Depends on what or is?

- CMS has requested comments on how to craft a definition; more guidance may be in our future.

- Still effectively an exception for physician-owned ASCs (exception for services reimbursed as part of composite rate; 42 CFR 411.351 – definition of DHS).
Medicare Billing Rules

Under Arrangements.

- CMS’s general requirements for under arrangements.
  
  [F]or services provided under arrangements to be covered, the provider must exercise professional responsibility over the arranged-for services....The provider must accept the patient for treatment in accordance with its admission policies, and maintain a complete and timely clinical record on the patient, which includes diagnoses, medical history, physician's orders, and progress notes relating to all services received, and must maintain liaison with the attending physician regarding the progress of the patient and the need for revised orders. (Medicare Manual 100-01, Chapter 5, §10.3 [emphasis added].)
Medicare Billing Rules (cont’d)

- Services provided under arrangements are considered hospital services, and Medicare pays the hospital for these services (under OPPS, if outpatient).
  - Hospital pays the under arrangements venture directly, and only hospital can bill Medicare or beneficiary (copays and deductibles).
Hospital Outpatient Services Under Arrangement.

■ 42 CFR 410.27.
  - (a) Medicare Part B pays for hospital... services and supplies furnished incident to a physician or nonphysician practitioner service to outpatients...if:
    ■ (1) They are furnished:
      - (i) By or under arrangements made by the participating hospital...;
      - (ii) As an integral, though incidental, part of a physician's or nonphysician practitioner's services; or
      - (iii) In the hospital... or in a department of the hospital..., as defined in § 413.65 of this subchapter....

■ 42 CFR 410.28 addresses diagnostic services; 410.27 covers therapeutic.
Medicare Billing Rules (cont’d)

- Must be provided in the hospital or in a department of the hospital as defined in 42 CFR 413.65 (i.e., provider-based department “PBD”).

- PBD rules (e.g., common ownership and licensing with hospital, financial and administrative control of hospital, held out to public as part of hospital, etc.).

- If under arrangement service is performed in PBD, physician ownership may be tantamount to ownership in hospital itself, in which case Stark prohibition would apply.
Joint venture *may* be possible, but arguably is also tantamount to physician ownership in hospital. Additional wrinkles as to joint ventures:

- Must be on hospital campus.
- May be licensure questions.
Navigating Stark and Billing Rules: Modified Under Arrangement

- What’s left?
- Physician ownership in an ASC may work.
  - ASC exception under Stark makes physician ownership feasible.
  - But, can ASC be a PBD?
  - 42 CFR 413.65: provider-based determinations are not made for ASCs (ASCs are paid per “payment group” so CMS presumably did not want an ASC to convert reimbursement to OPPS by becoming provider-based).
  - Does this mean that that ASCs need not be PBDs to meet under arrangement location requirements?
  - Or does it mean ASCs can never furnish services under arrangement to hospital outpatients?
Modified Under Arrangement (cont’d)

- Does location requirement of 42 CFR 410.27 (i.e., in hospital or PBD) really mean what it appears to say?
  - Some CMS Regional Offices have said, in informal guidance, that it doesn’t (at least not for radiation therapy services such as cyberknife, gamma knife).
  - CMS Central says, in informal guidance, that it does.

- The legal/billing landscape is very unclear.

- Properly structured modified under arrangement venture is a solution that clearly works under both Stark and billing rules.
Modified Under Arrangement Ventures.

- Physician venture supplies elements of service, short of actually performing it.

- Hospital provides:
  - License.
  - Provider-based status.
  - Equipment or clinical staff other than physicians & PA’s (if off campus).
Physicians provide (some or all, subject to any future definition of “perform”):

- Space.
- Equipment or clinical staff (if on-campus).
- Non-clinical staff.
- Medical directorship.
- Physician (and PA) staffing services/PSA.
- Management services.
- Space and equipment provided on fixed fee or cost plus basis (cannot be per click or percentage based).
- Medical directorship services provided on fixed fee basis (e.g., flat monthly or per hour rate).
Modified Under Arrangement (cont’d)

- Management services (and physician staffing, if no corporate practice of medicine issue under state law) furnished on:
  - Budget-based guarantee;
  - Fee for service;
  - Cost plus; or
  - Fixed fee basis.
Modified Under Arrangement – Physician’s Role

- Physician venture cannot provide *entire* service, because of both Stark and PBD rules.
- Physician venture items and services must be fair market value (independent appraisal strongly advised).
- Financial terms can be adjusted annually (adjustments cannot take referrals into account).
- Site of service differential for physician services provided in hospital space and billed by group.
Modified Under Arrangement – Physician’s Role (cont’d)

- Possible overlay of Co-Management possible to put as much economic value as possible into the venture, short of performing the service.

- **Caution:** Future Stark definition of what it means to *perform* the service could further limit items and support the physician venture can supply.
Joint Ventures – Viable Tactic to Enhance Physician/Hospital Affiliation

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Joint Ventures

Pros:

– Allow physicians and hospitals to work toward same goals:
  – Quality, control cost, patient satisfaction
  – Financial return
  – Efficiencies
– Physicians may become more used to functioning as a group
– Physicians obtain better understanding of hospital’s issues
Joint Ventures

- **Challenges:**
  - Effectively managing a potentially new line of business
  - Physicians as management
  - Financial losses may result
  - Changes in payment policies
  - Termination/withdrawal issues
  - Will physicians function together as a unified group?
Services Where Joint Venture May Make Sense

- ASC
- CyberKnife
- Diagnostic
- Whole hospital (PPACA limitations)
- Leases
- Management
- Ownership of assets
Legal issues

- Anti-Kickback Statute
- Stark Law
- State licensure, other state laws
- Accreditation
- Medicare payment
- Medicaid participation?
- Tax-exempt status, private use?
Legal Issues

- Zoning
- State property and other taxes
- Blue Sky law if there is sufficient number of investors
- Key structural issue: Will physicians invest through a single entity (e.g., LLC), or individually and/or their group practices?
**Joint Ventures - Anti-Kickback Statute**

- Whoever knowingly and willfully solicits or receives any remuneration directly or indirectly, overtly or covertly, in cash or in kind—
  - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
Anti-Kickback Statute

- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
Anti-Kickback Statute

- Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
The same penalty applies to anyone who knowingly and willfully offers or pays any remuneration directly or indirectly, overtly or covertly, in cash or in kind to any person to induce the same actions.
ASC Safe Harbor (under AKS)

- **Ambulatory surgical centers.**—
- “Remuneration” does not include
  - any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor,
  - as long as the investment entity is a Medicare certified ASC
  - whose operating and recovery room space is dedicated exclusively to the ASC
  - patients referred to the investment entity by an investor are fully informed of the investor’s investment interest
  - and all of the applicable standards are met within one of the following four categories—
Safe Harbor

(1) Single-Specialty ASCs.—If all investors
- are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients;
- group practices composed exclusively of such physicians;
- or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—
(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.
(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

- (v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

- (vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.
(2) Multi-Specialty ASCs.—
   - Same as Single-specialty ASCs, except
   - (i) Physicians or group members practice in more than one specialty.
(ii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.
(3) Hospital/Physician ASCs.—If at least one investor is a hospital, and all of the remaining investors are
- physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section;
- group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or
- investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—
Physician/Hospital ASC Safe Harbor

– (i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

– (ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

– (iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.
(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.
Physician/Hospital ASC Safe Harbor

- (vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.
- (vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).
- (viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.
ASC Safe Harbors

- For purposes of paragraph (r), *procedures* means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and *group practice* means a group practice that meets all of the standards of paragraph (p) of this section.

- *Surgical group practice* means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.
Stark Law Applies only to Designated Health Services

- Clinical laboratory services. Physical therapy services.
- Occupational therapy services.
- Radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
DHS

- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices.
- Home health services and supplies.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.
- Outpatient speech-language pathology services.
Joint Ventures

- Various legal structures have proven to be workable
- Up front financial viability study is critical
- Contemporaneous documentation of fair market value and commercial reasonableness is important: appraisal?
- Hospital board or board committee approval
Service Line Co-Management Agreements and Hospital/Physician JVs for Ambulatory Surgery

Matt Searles – Merritt Healthcare
Presentation Goals

- Provide an overview of the two most common collaborative models between physicians and hospitals relating to ambulatory surgical centers (ASCs).
  - Motivations for pursuing each model.
  - Financial implications
  - Benefits/drawbacks
  - Important “lessons learned”
- Review Case Studies for Each Model
Drivers of the Collaborative Model

- **Key Drivers in the Current Marketplace:**

  - ACO development continues to drive need for increased quality of care at the lowest possible cost. Integration of delivery system (hospitals/surgeons/ASCs) can improve outcomes and create economies of scale.
    - ASC environment conducive to efficiency and cost savings.
    - Financial alignment of Hospital and Surgeons with the goal of improved outcomes and ancillary income streams.

  - Recapture of lost cases from Hospital ORs

  - Prevent potential loss of cases from hospital ORs.
    - Need for a model that benefits all parties.
General Advantages of ASCs to Hospitals and Physicians

- **Hospital Benefits, Collaborative ASC Models can:**
  - *Recapture outpatient surgical procedures* currently performed in physician offices and other surgical facilities.
  - *Strengthen market share*, in light of competition from existing and future outpatient surgery centers, as well as other local acute care Hospitals.
  - Offer an opportunity to *earn or maintain income* through participation in ambulatory surgical center joint venture.
    - Moving procedures to a low cost free-standing environment will increase bottom line.
  - Enable the Hospital to rebalance procedure mix and *refocus resources in existing OR suites to optimize facility utilization* and *maximize profitability*. 
General Advantages of ASCs to Hospitals and Physicians

- **Hospital Benefits, Collaborative ASC Models can;**
  
  - **Pre-empt the future migration of procedures** to physician offices or to other surgical facilities.
  
  - Require minimal resources of the Hospital, allowing the Hospital to focus on delivery of other services. Provides the Hospital with a *sustainable competitive advantage* vis-à-vis other facilities.
  
  - **Enhance ability to attract physicians** to Hospital staff, thereby increasing inpatient admissions and revenue.
  
  - **Integration of delivery system in anticipation of impact of ACOs on healthcare marketplace.**
General Advantages of ASCs to Hospitals and Physicians

- **Physician Benefits, Collaborative ASC Models can;**
  - Deliver *quality care, ease of access, and efficiency of treatment* to patients at the facility.
  - Provide patients positive experience in an ASC that creates *value for the Physicians’ reputation* in the community.
  - Offer a *safe, efficient environment* for the performance of outpatient procedures.
  - Create an *economic opportunity* for physicians by providing supplemental income during this time of declining professional fees.
  - *Enable flexibility in scheduling & efficiency* which affords physicians the opportunity to focus on the growth of their practices.
Model One
Service Line Co-Management Agreement ("SLCMA")

Overview of Structure

- **Surgeons**
  - Professional Fee
  - Surgeons Provide Management Services
  - FMV Base And Performance Fees

- **Payers**
  - Hospital or "Provider Based" rates

- **Hospital Owned Outpatient Surgery Unit**
Model One - SLCMA
Pro/Cons

PROS

CONS

100% Hospital Ownership = Hospital Rates
Provides Revenue to Physicians
Incentive to MDs to Improve Operations and Quality
Physician Have Input Into Management
Low Risk to Physicians
Recruiting Tool
Potentially Allows Expansion of Inpatient ORs

Hospital Bears Capital Risk of Development
Operational Challenges
No Physician Ownership
Term of Agreement is Under 3 Years
Service Line Co-Management Agreement
“Win-Win” Case Study

- **Background - Hospital Enters into Service Line Co-Management Agreement with Surgeons.**
  - Surgeons plan to develop physician owned ASC. Migration of cases to the ASC would have had a deleterious impact on Hospital where cases are currently being performed.
  - Parties agree to explore alternative development options. Both free standing hospital/physician JV considered as well as SLCMA.
  - Hospital and physicians agree to co-develop new hospital owned ASC. Hospital assumes capital risk. Physicians enter into Service Line Co-Management Agreement.
  - New Hospital owned, co-management facility developed in a new Medical Office Building on campus owned jointly by the surgeons and the Hospital.
Service Line Co-Management Agreement
“Win-Win” Case Study

Hospital Interests
- Prevent Migration of Cases away from Hospital ORs
- 100% Hospital Ownership
- Development of New Outpatient Facility
- Marketing Tool for Recruitment of Additional Surgeons to the Market
- Improved outcomes and efficiency

Physician Interests
- Development of a New, Specialized ASC, improved efficiency and outcomes.
- Significant Input into Operations, Ability to Influence Management Decisions
- Receipt of Income from Co-Management Services
- No Financial Risk Related to Development
- Alignment with Hospital, No Longer Competitors
Service Line Co-Management Agreement
“Win-Win” Case Study

**What Went Right?**

- Hospital and Physicians *partner* in the development. Collaboration with input from all.

- Circumstances favored development of a hospital owned ASC. Goals of all Parties are met.

- Physicians engage in development and management because they are given significant input into operations in return for a meaningful income stream. Physicians income from co-management agreement tied to quality & efficiency measures.

- Agreements properly structured relative to regulatory and operational concerns.

- Facility carefully planned. Guidance from outside resources obtained when needed.

- Co-ownership of medical office building further aligns interest.
Service Line Co-Management Agreement
“Work in Progress” Case Study

- **Background – Hospital Enters into SLCMA with Surgeons.**
  - Background and circumstances nearly identical to “Win-Win” Case Study.
    - Loss of cases would have been catastrophic for hospital.
    - Includes MOB with physician ownership.

- **What Is Going Wrong?**
  - Planning and pre-development was collaborative and included input from key surgeons and relevant experts.
  - Actual development encountering “silo” mentality. From ASC design to staff planning the facility is developing well below its potential due to a lack of collaboration and development experience.
  - Likely outcome is that surgeons are not pleased with operations which could lead to threat of the loss of cases once again.
  - Facility will be challenged to improve quality measures from what is experienced now.
Model Two
Hospital Physician Joint Venture

Overview of Structure

Surgeons

Payers

Professional Fee

ASC Rate

Hospital/Affiliate

Ambulatory Surgery Center

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Model Two – Hospital/Physician JV Pro/Cons

CONS

- Hospital & Physician Ownership
- Access to Revenue Stream
- Recruiting Tool
- Potentially Allows Expansion of Inpatient ORs
- Improved efficiency
- Lower Cost of Care to Delivery System

PROS

- Capital Risk of Development
- Potential Loss of Cases from Hospital ORs
- ASC Rates Lower than Hospital Rates for Same Cases
- Difficult for Hospital to Maintain Comparable Income Stream
  (compared to hospital owned facility)
Hospital Physician JV
“Win-Win” Case Study

- **Background - Hospital Purchase of an Interest in Existing Endoscopy Center.**
  - Hospital purchases interest in physician owned GI Center.
  - Cases at this GI Center originally migrated from this Hospital’s Endo Suite. GI Center performed roughly 8,000 cases and the Hospital’s existing endo suite still performed approximately 6,000 cases. Hospital had did not capitalize on initial opportunity to co-develop facility or to enter into SLCMA with the physicians.
  - Hospital’s ORs were nearing capacity. While remaining GI cases were profitable the Hospital had a need for more OR space for other types of cases.
  - Economies of scale created by the Transaction were significant not only in terms of profit to the ASC but also return of ancillary pathology business to the Hospital.
    - Hospital’s opportunity to lower “effective” multiple.
    - Highly accretive to the physicians.
Hospital Physician JV
“Win-Win” Case Study

Hospital Interests

- Re-align interests of Hospital and GI Physicians. Establish Center of Excellence
- Reconfigure Hospital Endo Center to Accommodate More Profitable Cases
- Realize Significant Returns from Investment and Recapture of Ancillary Businesses.
- Option for Hospital to Purchase 100% and Move to SLCMA Model

Physician Interests

- Growth of Facility
- Realize Return on Investment
- Alignment with Hospital, No Longer Competitors
- Highly Accretive because of Addition of New Cases.
- Added Community-based Partner with Local & State Influence
Hospital Physician JV
“Win-Win” Case Study

- **What Went Right?**
  - Addition of Hospital cases provides enormous economies of scale which lower the cost of care. By migrating cases the Hospital’s effective multiple is lowered and the Transaction is highly accretive to the Physicians.
  - Hospital presence is complimentary, adding mainly to contracting leverage and quality assurance.
  - “Backfilling” of vacated Hospital facility space with more profitable cases.
  - Creation of “Center of Excellence” improves quality of care to community.
  - Physicians allow Hospital ROFR for purchase of entire facility and creation of SLCMA for surgeons.

- **What Could Have Been Done Better (hindsight is 20/20)?**
  - Partnering earlier or co-developing.
  - After 10 years of competition between the 2 GI suites, 1 mile apart, both were at 50% capacity. Now the newly expanded JV facility will be at nearly full capacity and benefitting Hospital, Physicians, patients and the healthcare system in general.
Hospital Physician JV
“Work in Progress” Case Study

- **Background - Hospital Develops ASC with Staff Surgeons**
  - Hospital develops ASC as a 50/50 joint venture with surgeons.
  - Facility is developed and managed by individuals with no prior experience with free standing centers.
  - Financial & operational performance of facility was well below any industry benchmarks.
    - Hospital loses significant income stream from cases and physicians are not earning any ancillary income.
    - Quality and operational measures below industry standards, expectations.
Hospital Physician JV
“Work in Progress” Case Study

- *What Went Wrong, Lessons Learned*
  - General lack of willingness to recognize and correct underlying issues with structure of staff expenses and physician's behavior.
  - Operating agreement did not allow for fluid decision making – “stalemate” Board.
  - Members set realistic benchmarks early on but did not have the expertise to positively improve operations.
    - Over staffed, poor turnover, physician offices controlled scheduling, etc.
    - Low contracted rates, no supply carve-outs.
  - After 4 years of operation the facility is now seeking to correct underlying issues.
    - Operating agreement modified to allow for fluid decision making.
    - Benchmarking study performed, problem areas identified and steps taken to improve operations and outcomes.
Conclusion

- **Collaborative Models for Ambulatory Surgery Centers can Provide Opportunity for Physicians and Hospitals to Align Interests, Improve Outcomes and Lower Cost.**

- **Individual Circumstances will Often Dictate Which Model to Pursue.**

- **Collaboration is Key, Each Party to the Transaction Brings Specific Talents and Expertise.**

- **Facility Must Benchmark Itself to “Best Practices”**.

- **Outside Expertise Should be Obtained Wherever Needed (legal, development, operations). The Cost of a Struggling Operation is too High & Unsustainable.**
Questions?
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Michael L. Blau is a partner with Foley & Lardner LLP. He is the chair of the Health Care Venture Practice and a member of the Health Care and the Emerging Technologies Industry Teams. Mr. Blau's practice focuses on advising clients on corporate and regulatory matters, including mergers, acquisitions and affiliations; financing transactions; contracting; and forming provider groups, networks, alliances, and joint ventures.

For three years in a row, Mr. Blau was recognized as one of the top 10 health attorneys in the country in his specialty by Nightingale's Healthcare News. Mr. Blau enjoys a #1 ranking in healthcare by Chambers USA and an AV (top) rating by Martindale-Hubbell. He has again been selected by his peers for inclusion in The Best Lawyers in America® 2011 in the field of health care. He is perennially named by Boston Magazine to the list of Massachusetts Super Lawyers®, and has been recognized as one of the Top 100 Massachusetts Super Lawyers. In 2008, Mr. Blau also received an RX for Excellence Award by Massachusetts Medical Law Reports for Leadership in Quality.

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Lawrence C. Conn is special counsel to Foley & Lardner LLP. A member of the firm's Health Care Industry Team, he represents hospitals, physicians, clinical laboratories, pharmacies, and therapy and DME suppliers in a wide range of legal areas and issues. Mr. Conn has extensive experience in health care compliance issues including the federal Stark and anti-kickback statutes, as well as Medicare billing and reimbursement matters. He has represented numerous hospitals in connection with governmental investigations and self-disclosures related to these issues.

In addition to his compliance practice, Mr. Conn has extensive experience in health care transactional matters, including structuring hospital-physician arrangements such as joint ventures and physician practice acquisitions. His practice also includes managed care, licensing and health care reform.
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Alan H. Einhorn is of counsel with Foley & Lardner LLP, where he is a member of the Health Care Industry and Health Information Technology Teams. Prior to joining Foley, Mr. Einhorn was a partner with Nixon Peabody LLP, where he established a strong practice in health care law. Mr. Einhorn represents provider networks, hospitals, clinics, practice groups and individuals in entity formation, mergers, corporate reorganization, joint ventures, health planning, medical staff development, physician/hospital integration strategies and disciplinary matters, and licensure. He also regularly advises clients on strategic, corporate compliance and tax exemption–related issues as well as regulatory issues.

Mr. Einhorn has authored numerous articles on health care topics and has spoken at health care conferences and seminars sponsored by such groups as the National Conference of State Legislatures, the American Hospital Association, the New England Health Care Assembly, the Massachusetts Hospital Association, and the Massachusetts Department of Public Health.

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Mr. Kent Nicaud received a double BA in Philosophy and sociology along with an Accounting degree from Tulane University in New Orleans. He then attended Tulane University’s MBA program. He has over 24 years of healthcare management experience from both the private sector and non-profit arena. Kent was an owner of Crescent City Rehabilitation for over 10 years and the sole owner of Gulf Coast Rehabilitation for 8 years. Both entities had consulting contracts with hospitals located in Louisiana, Mississippi and Alabama. Kent currently serves as the Vice-President for Physician Administrative Services for Memorial Hospital at Gulfport in Gulfport, Mississippi. In his current position, he manages a budget in excess of $175,000,000 and over 800 employees. Kent lives in Pass Christian Mississippi with his wife, Jenny and two children - Jourdan and Field.
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Merritt has a wide range of experience, having worked on facilities ranging from freestanding, single specialty ambulatory surgery centers to multi-specialty hospital outpatient departments. Since its inception Merritt has developed, managed or consulted for dozens of outpatient facilities, including both physician owned and hospital/physician joint ventures.
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Drawing on his 25 years experience in the distribution industry, Marty focuses on the diligent application of the core principles of asset management by implementing inventory control and revenue cycle management disciplines to minimize waste and inefficiency and maximize bottom line profitability. He is also the founder and CEO of Vista Group Management Consulting.

Mr. Shenk holds a BA in management and is a Certified Medical Practice Executive with the Medical Group Management Association.