

Collaborative Ventures

- Hospital-Physician Collaboration

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Principal Legal Landmines

- Stark Law
- Anti-Kickback Statutes
- Civil Monetary Penalty Law
- False Claims Act
- Reassignment Rules
- Purchased Diagnostic Test/Anti-Mark-Up Rules
- Provider-Based Status Rules
- 340B Drug Pricing
- Tax-Exemption Requirements
- State Law Issues (License, CON, corporate practice, fee-splitting, etc.)
- HIPAA, HITECH Act, Red Flag and privacy/security rules
- Antitrust/Unfair Competition Laws

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Impact of Recent Legal Developments on Collaborative Ventures

- Stark Law
 - Phase III rule (effective December 4, 2007)
 - Additional proposed rules; Incentive Payment and Cost Savings Exception
 - Additional final rules (effective Oct. 1, 2008; Oct. 1, 2009)
- OIG Advisory Opinion 8-10 (August 19, 2008)
- OIG Advisory Opinion 8-16 (October 14, 2008)
- Anti-mark-up rules (Jan. 1, 2009)
- Outpatient Supervision Rule (Jan. 1, 2010)
- HITECH Act (Jan. 6, 2009)
- PPACA (March 23, 2010); HCERA (March 30, 2010)

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Health Reform: Patient Protection and Affordable Care Act ("PPACA")

- Reform begins to change payment/delivery paradigm
 - Reward value instead of volume
 - Value based purchasing, gainsharing, shared savings
 - Coordinating care among and across providers
 - ACOs, medical homes, home based chronic care management, community health teams, health care innovation zones
 - New structures promoting actual and virtual integration
 - Owners/decision-makers vs. vendors

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Health Reform: Patient Protection and Affordable Care Act ("PPACA")

- Impact on Hospital-Physician Relations
 - Moratorium on physician ownership of hospitals, including cancer hospitals (as of 8/1/10)
 - Expanded 340B Program
 - Public disclosure of imaging self-referrals, including MRI, CT, PET
 - Inform that patient can obtain services elsewhere
 - Provide list of alternative suppliers in patient's area of residence
 - Increased funding of cancer research

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Multiple Models for Successful Collaboration

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| <ul style="list-style-type: none"> □ Contracts <ul style="list-style-type: none"> ■ Physician Employment ■ Leased Employee Arrangements ■ Recruitment Agreements ■ Professional Service Agreements ■ Practice Acquisition Agreements ■ Practice Support Agreements ■ Clinical Research Agreements □ Contractual Venture Models <ul style="list-style-type: none"> ■ Block Leases ■ Service-Line Co-Management ■ Gainsharing Arrangements ■ Center of Excellence Model ■ Modified Under Arrangements Model (Hospital Outpatient Facilities) ■ Practice Lease and Management Arrangements □ Non-Clinical Joint Ventures <ul style="list-style-type: none"> ■ Ambulatory center facility development ■ Equipment leasing companies ■ Management companies ■ HIT ventures | <ul style="list-style-type: none"> □ Clinical Joint Ventures <ul style="list-style-type: none"> ■ Cancer Centers ■ ASCs ■ Ambulatory Clinics □ Foundation Model Arrangements □ Hospital-Affiliated Group Practices □ 2nd Generation Practice Management Organizations <ul style="list-style-type: none"> ■ Seeding practice integration □ Physician Enterprise Model □ Physician-Hospital Organizations (PHOs) <ul style="list-style-type: none"> ■ Payor and P4P contracting ■ Risk contracting ■ Clinical Integration □ Captive Insurance Arrangements |
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Trends in Hospital-Physician Collaboration

- Employment
- Practice acquisitions and charitable contributions
- Community oncologists moving on-campus or into hospital-affiliated groups
- Integration and alignment for quality and efficiency improvement and for multi-disciplinary care
- Legal developments narrow somewhat options for collaboration

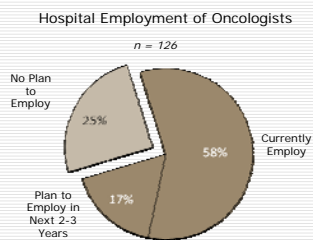
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Physician Employment

- Increase in employment by hospitals
- Shortage of oncologists by 2011
- Change in attitude of younger physicians toward employment
 - 8/9 of 10 graduating residents prefer employment
- Financial distress of community medical oncologists
- Integrate, align and control destiny
- Less legal risk

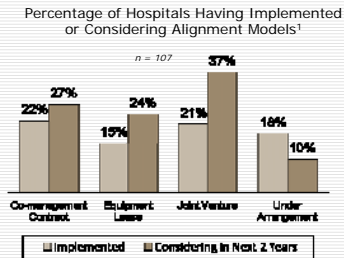
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Hospital Employment of Oncologists



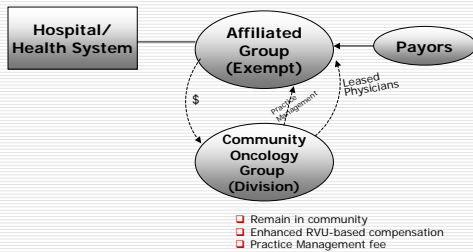
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Continued Interest in Collaborative Arrangements



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Model 1: Leased Physicians: Enhanced Rates



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Impact of Recent Legal Developments on Collaborative Arrangements

- Affects space, equipment and block lease/sharing arrangements
 - Stark prohibition of percentage based space and equipment leases (411.357(a), (b) and (p), effective October 1, 2009)
 - Stark prohibition of per unit service ("per click") arrangements (411.357(a), (b) and (p), effective October 1, 2009)
 - No more FMV exception for space leases (411.357(a) and (p), effective December 4, 2007)
 - Affects "next available room" shared space arrangements
 - Space lease must include period of exclusive use

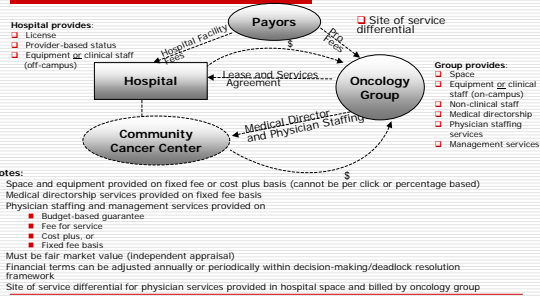
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Impact of Recent Legal Developments on Collaborative Arrangements

- Affects investment in “under arrangements” entities and turn-key management or leasing companies
 - Stark prohibition on ownership interest in entity that performs the DHS (411.351, definition of “entity”, effective October 1, 2009)
 - Exception for ownership interests in rural providers and public companies
 - CMS declines to provide guidance on what it means to “perform” the service (i.e., what combination of providing space, equipment, supplies, non-physician clinicians, administrative staff, executive services)
 - Modified under arrangements ventures permitted

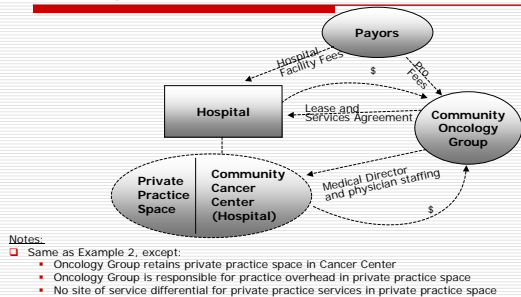
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Model 2: Hospital (Modified) Under Arrangement Model



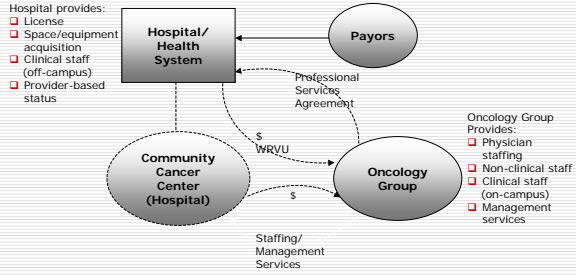
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Model 3: Hybrid (Modified) Under Arrangement Model



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Model 4: Professional Services Agreement



Key PSA Issues

- Qualification for Medicare provider-based status
 - Physical space standards for licensure/accreditation
 - Can't lease mid-levels/techs at off-campus sites
 - Hospital reporting lines
 - CON issues
- Increased patient co-pays
- Payor pushback

Key PSA Issues

- wRVU Valuation
 - Relation to existing physician compensation/margins on drugs, labs, imaging
 - Practice expense component
- Exclusivity
 - Existing relationships
- Expansion
 - Right of first opportunity
- Noncompetes/restrictive covenants
- Term/Termination

Key PSA Issues

- Unwind rights
 - Asset repurchase
 - Lease assignment/real estate repurchase
 - Solicitation of employees
 - Data/records access/transfer
 - Systems issues
- Dispute resolution/arbitration
 - Perform during pendency

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Impact of Recent Legal Developments on Collaborative Arrangements

- New opportunities for quality and efficiency improvement ventures
 - Proposed Stark Law exception for Incentive Payment and Shared Savings Programs (411.357(x))
 - Service Line Co-Management, gainsharing, pay-for-performance, pay-for-quality arrangements
 - OIG Adv. Op. 08-16
 - PPACA
 - CMP Law amendment: Increase access without risk of harm
 - Legal waivers for quality/efficiency improvement demo projects

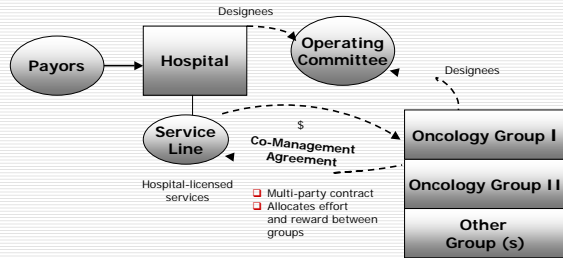
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Model 5: Service Line Co-Management Arrangements

- The purpose of the arrangement is to recognize and appropriately reward participating medical groups/physicians for their efforts in developing, managing, and improving quality and efficiency of the hospital's cardiology service line

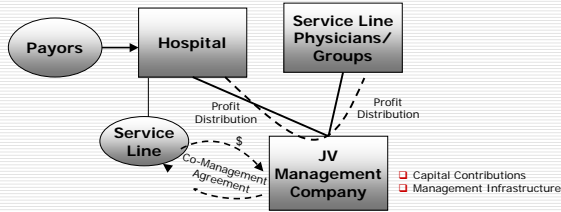
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Model 5A: Service Line Co-Management Direct Contract Model



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Model 5B: Service Line Co-Management Joint Venture Model



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Service Line Co-Management Arrangements

- There are typically two levels of payment to oncologists under the service line contract:
 - Base fee – a fixed annual base fee that is consistent with the fair market value of the time and efforts participating oncologists dedicate to the service line development, management, and oversight process
 - Bonus fee – a series of pre-determined payment amounts contingent on achievement of specified, mutually agreed, objectively measurable, program development, quality improvement and efficiency goals
 - Pays participating oncologists 3-6% of service line revenues
 - Fixed, fair market value fees; independent appraisal advisable

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Sample Medical Oncology Performance Standards

- Increase in percentage of patients with written treatment plans at start of infusion
- Increase in percentage of written treatment plans with indication of:
 - Staging
 - Intention of therapy
 - Approved treatment regimen for tumor site/staging
- Increase in percentage of written treatment summaries at completion of course of treatment

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Sample Medical Oncology Performance Standards

- Increase in patient satisfaction
- Increase in staff satisfaction
- Decrease in infusion site infections
- Substitution of lower cost drugs/items for drugs/items of equivalent efficacy and quality
- Increase in patient accruals for hospital clinical trials

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Regulatory Considerations

- Legal constraints on Service Line Co-Management Agreements
 - No stinting
 - No steering
 - No cherry-picking
 - No gaming
 - No payment for changes in volume/referrals
 - No payment for quicker-sicker discharge
 - Must be FMV; independent appraisal required
- Proposed Stark Law Exception for Incentive Payment and Shared Savings Programs

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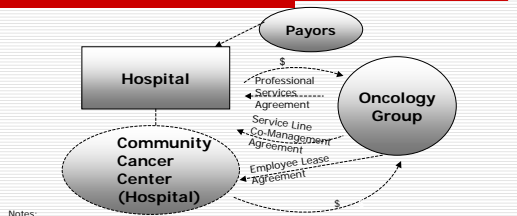
Service Line Co-Management

Other Considerations:

- Commits 3-6% of service line revenues
- Requires active participation and real time and effort by busy physicians
- Durability: need to periodically adjust performance standards and targets?
- No accretion with additional physicians
- No overlap with other agreements
- Cost of independent appraisal (and clinical monitor to validate standards/performance?)
- Some irreducible legal risk

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Model 6: PSA with Service Line Co-Management Agreement



Notes:

- Same as Model 4, plus
- Service Line Co-Management Agreement (3-6% of Service Line revenue, which can be of both cancer Center and Hospital)
 - PSA component –RVU rate equal to aggregate current revenue
 - Co-management component – fixed fair market value fee
 - Incentive component contingent on meeting specified quality and efficiency improvement standards – fixed FMV fee per standard

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Joint Ventures

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Joint Ventures

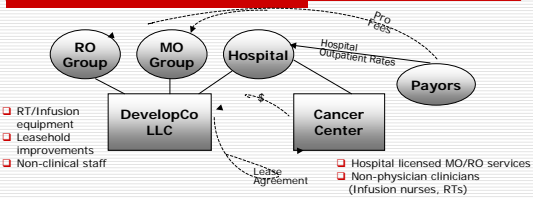
- Existing vs. new services
- Joint ventures that cannibalize existing services rarely "make it up on volume!"*

Hospital		Freestanding	
Net Revenue	\$4.0 M	1/3 More Volume!	\$4.0M
Margin	35%	Net Income	20%
		Ownership	50%
Net Pretax Income	\$1.4M		\$400,000
Taxes	-----		35%
Net Contribution	\$1.4M		\$260,000

* Kaufman Strategic Advisors, LLC

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Model 7: Equity Joint Venture



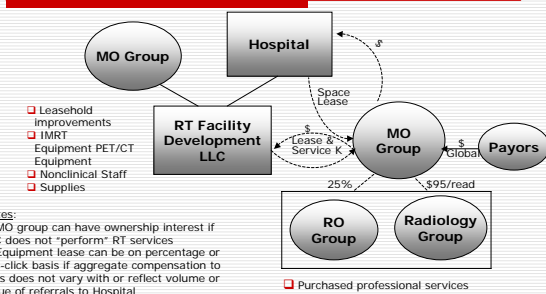
- RT/Infusion equipment
- Leasehold Improvements
- Non-clinical staff
- Hospital licensed MO/RO services
- Non-physician clinicians (Infusion nurses, RTs)

Legal Issues

- New or upgrade vs. existing service
- DevelopCo cannot "perform" the technical component of the RO/MO services
- Lease agreement cannot be percentage-based or per-click for equipment or leasehold improvements
- Lease agreement must be fair market value
- Site of service differential on pro fees if professional services provided in hospital space

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Model 8: RT Facility Joint Venture



Notes:

- MO group can have ownership interest if LLC does not "perform" RT services
- Equipment lease can be on percentage or per-click basis if aggregate compensation to MOs does not vary with or reflect volume or value of referrals to Hospital
- Purchased professional services

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Other JV Compliance Considerations

- ❑ 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
 - The joint venture tracks its sources of referrals, and distributes this information to investors

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Other JV Compliance Considerations

- 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
- 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

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Other JV Compliance Considerations

- ❑ Non-Profit/For-Profit JVs: Preserving Tax Exemption
 - Where substantial charitable assets/activities are contributed by an exempt hospital:
 - ❑ Hospital must have majority control of board
 - ❑ Charitable purposes must take priority over profit opportunities
 - ❑ JV should not be managed by the for-profit investor on a long-term, lock-in basis
 - ❑ Transactions with for-profit investor must be at arm’s-length and FMV
 - ❑ Private use of tax exempt space must meet Rev. Proc. 97-13 durational limits (i.e., generally 2-3 years)

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Permissible Collaborative Ventures

- Employment/Leased Employee Arrangements**
- Joint Venture ASCs** (e.g. Clarian Health System)
- Equipment/Facility Joint Ventures** (e.g., Chesapeake Potomac Regional Medical Center; Center for Cancer and Blood Disorders; Green Bay Oncology)
- Foundation Model Arrangements** (e.g., Palo Alto Medical Foundation)
- “Modified” Under Arrangements Model** (e.g., Hematology Oncology Patient Enterprises; Cancer Care Northwest)
- PSA/Co-Management** (e.g., UPMC/Oncology Hematology Association)

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Permissible Collaborative Ventures

- Physician Lease/Management Arrangements** (e.g., New England Hematology/Oncology Associates)
- Quality and Efficiency Improvement Ventures** (Service Line Co-Management, Gainsharing, P4P, Pay for Quality Arrangements) (e.g., Hematology Oncology Patient Enterprises; Baycare Hospital; Parkview Health System)

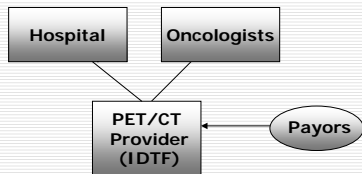
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Key Deal Maker/Breaker Issues

- Governance
- Financial Terms
- Term/Duration
- Termination
- Restrictive Covenants
- Unwind Rights
- Addition of New Physicians
- Buy-In/Buy-Out Rights (if applicable)
- Break-Up Fees?
- Arbitration/Dispute Resolution

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Impermissible Joint Venture



- ❑ May violate Stark Law
- ❑ May violate Anti-Kickback Statute

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Top 5 Reasons to Redouble Your Regulatory Compliance Efforts

5. If it makes sense in any other industry, it is probably illegal in healthcare
4. If you are sure you have it legally right, you have probably overlooked something
3. As soon as you truly have it right, the law can and will change
2. Just because everyone else is doing it doesn't mean you won't get caught
1. I can assure you that you do not want to do time cleaning toilets with Bernie Madoff at San Quentin

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