HOSPITAL-PHYSICIAN

ALIGNMENT STRATEGIES

NOVEMBER 18, 2008

TABLE OF CONTENTS

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Physician/Hospital Alignment Strategies

November 18, 2008

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Introduction

- Recent Florida Developments Affecting Hospital-Physician Relations - Richard Johns
- Background on Strategies for Physician Alignment - Michael Blau
- Recent Federal Developments Affecting Hospital-Physician Relations - Gary Koch
- Business Models for Successful Physician Alignment - Michael Blau

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Florida Law Update

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Background on Strategies for Physician Alignment

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Medical Staff Snapshot

- Culture of independent private practice
  - Mostly small groups and solo practitioners
  - Some large group presence
- Aging physician complement
  - Average age of physicians is > 50 in many specialties
- Lack of viable succession plans
  - Most solo and small group practitioners have no viable succession plan
  - Large groups are better able to sustain their practices
  - At risk for loss of practices or redirection of practices

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Physician Role

- Principal relationship is staff privileges
  - Some employed hospital-based physicians
  - Salaried Chairs
  - Medical Director stipends and coverage agreements
- Traditional medical staff: focus on peer review patient safety
  - Interests not aligned even around clinical and quality issues
  - Not suited to joint strategic/business planning
  - Rife with conflicts of interest

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"One Can't Run a Hospital
With Doctors,
One Can't Run a Hospital
Without Them"

Anonymous Hospital CEO

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Hospital Snapshot: Competition v. Collaboration

- Typical Hospital Strategies
  - Collaboration
    - Defensive
      - 50% of high-end imaging in free-standing setting (30% margin)
      - 40% of outpatient surgery in non-hospital settings (20% margin)
      - Emergence of physician-owned hospitals
    - Offensive
      - Market capture and growth
      - Win-Win ventures

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Hospital Snapshot: Competition v. Collaboration

- 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%		20%
		Net Income	$800,000
		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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Common Duty?

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Both Hospital and Private Practitioners Have Obligation To Replenish and Renew Physician Manpower and Assure Access to Needed Healthcare Services for the Benefit of the Community

No MDs: No Mission

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Physician Engagement and Alignment Team

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Physician Engagement and Alignment Team

- New paradigm
- Process for selection, engagement and development of physician strategic plan
- Identify physicians who can transcend other considerations and act in the best interest of the community

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Charge To Team

- Build trust and mutual respect
- Develop goals for hospital-physician relations in support of community mission
- Develop strategies and tactics to achieve hospital-physician goals (short, medium and long term)
- Recommend to Board and medical staff organizational and administrative structures to support strategies and tactics

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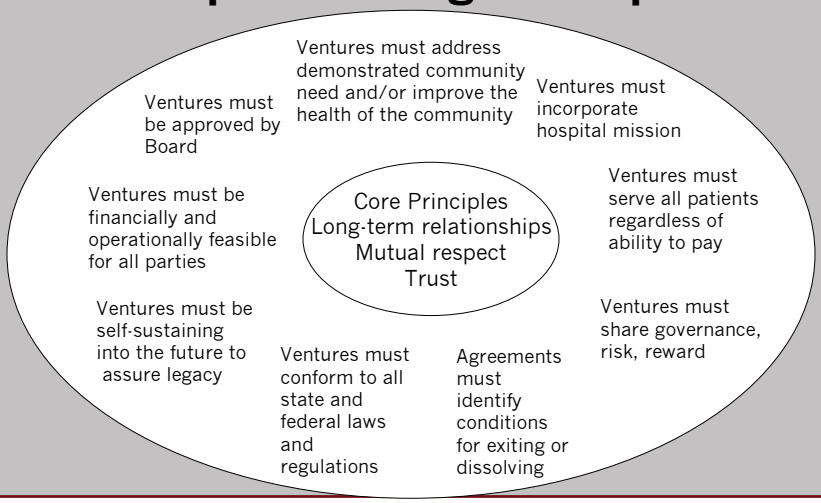
Sample Guiding Principles



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Sample Strategic Goals

- Strategic engagement and best use of intellectual capital
- Physician alignment and integration: economics, quality and efficiency
- Common interoperable IT platform and clinical integration
- Improve bargaining power for physicians and hospital
- Primary care access and growth strategy
- Specialty centers of excellence
- Recruitment, retention and succession planning for aging practices
- Market capture and growth

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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**

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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
- State Law Issues (License, CON, corporate practice, fee-splitting, etc.)

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Multiple Models for Successful Collaboration

- **Contracts**
  - Physician Employment
  - Recruitment Agreements
  - Professional Service Agreements
  - Practice Acquisition Agreements
  - Practice Support Agreements
  - Clinical Research Agreements
  - AS&T Contracts
- **Contractual Venture Models**
  - Service-Line Co-Management
  - Gainsharing Arrangements
  - Pay for Quality/Pay for Performance
  - Block Leasing
  - Foundation Model
  - Centers of Excellence Models
  - Modified Under Arrangements Model
- **Non-Clinical Joint Ventures**
  - Facility development companies
  - Space leasing companies
  - Equipment leasing companies
  - Management companies
  - HIT ventures
  - Medical office building ventures
- **Clinical Joint Ventures**
  - Whole Hospitals
  - Hospital-Within-a-Hospital
  - Specialty Surgical Hospitals
  - ASCs
  - Ambulatory Facilities
- **Physician-Hospital Organizations (PHOs)**
  - Participation agreements
  - Payor and P4P contracting
  - Risk contracting
  - Clinical Integration
- **RHIO and EHR**
- **Hospital-Affiliated Group Practices**
- **2nd Generation Practice Management Organizations**
  - Joint venture MSOs
  - Seeding practice integration
- **Participating Bond Transactions**
- **Captive Insurance Arrangements**

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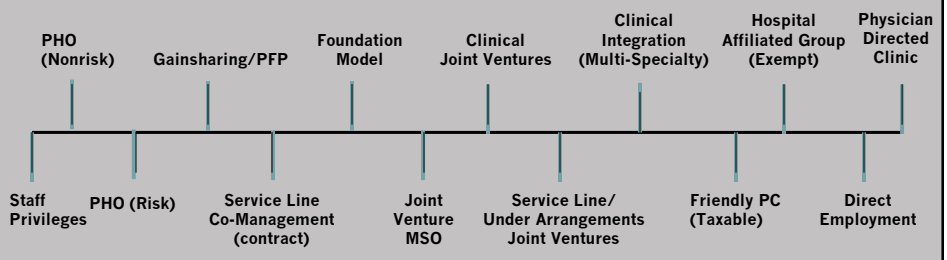
Integration Continuum

Hospital - Physician



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Hospital-Physician Strategies Organization

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Impact of Recent Federal Law Developments On Hospital-Physician Relations

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Principal Recent Legal Development

- Stark Law
  - Phase III rule, 72 Fed. Reg. 51012 (September 5, 2007; effective December 4, 2007)
  - Additional proposed rules Incentive Payment and Cost Savings Exception (73 Fed. Reg. 130, July 7, 2008)
  - Additional final rules (73 Fed. Reg. 161, August 19, 2008)
- OIG Advisory Opinion 8-10 (August 19, 2008)
- OIG Advisory Opinion 8-16 (October 14, 2008)
- Anti-mark-up rules, 414.50 and 424.80 (72 Fed. Reg. 66401, 66406, November 27, 2007; 73 Fed. Reg. 38606, July 7, 2008)
- IDTF rules, 410.33(g)(15) (72 Fed. Reg. 66398, November 27, 2007; 73 Fed. Reg. 38603-4, July 7, 2008)
- Final 2009 Physician Fee Schedule and regulations (to be published on November 19, 2008)

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Impact on Hospital-Physician Relations

- 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 of 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)
    - Space lease must include period of exclusive use
    - Affects "next available room" shared space arrangements

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Impact on Hospital-Physician Relations

- No mark-up of professional or technical component if the service is performed or supervised by a supplier who does not "share a practice" with the ordering/billing physician (414.50 and 424.80, effective January 1, 2009)
  - Supplier "shares a practice" if: (1) the supplier is an owner, employee or independent contractor of the billing physician or group and furnishes at least 75% of his professional services through the billing physician or group, or (2) supplier's services are performed in the same building as the billing physician or group in space in which the billing physician regularly furnishes patient care, or in which the billing group provides substantially the full range of services of the ordering physician
  - Billing physician or group must conduct and supervise the technical component service (i.e., billing group must provide the tech)

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Impact on Hospital-Physician Relations

- IDTF rule prohibits physicians from block leasing space, equipment or operations from a fixed site IDTF (e.g., PET/CT, MRI)
  - Deferred until January 1, 2009 only for existing shared space arrangements where IDTF is the space lessor
- Fixed site and mobile IDTFs (e.g., Mobile MRI, CT, U/S) and other entities that lease equipment and provide the tech must enroll as IDTFs and bill directly for the services they provide, effective January 1, 2009

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Impact on Hospital-Physician Relations

- Affects investments in "under arrangements" entities and turn-key management or leasing companies
  - Stark prohibition on ownership interest or entity that performs the DHS (411.351, definition of "entity", effective October 1, 2009)
    - Exception for lithotripsy and dialysis
    - 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)

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Impact on Hospital-Physician Relations

- Affects turn-key management contracts and contractual joint ventures
  - OIG Adv. Op. 8-10
  - Block Lease of IDTF equipment by MO/RO group to urologists, together with turn-key support services on a fixed, FMV basis, constitutes impermissible contractual joint venture that may violate anti-kickback statute
  - Providing opportunity for urologists to profit may be improper remuneration that is not safe harbored

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Impact on Hospital-Physician Relations

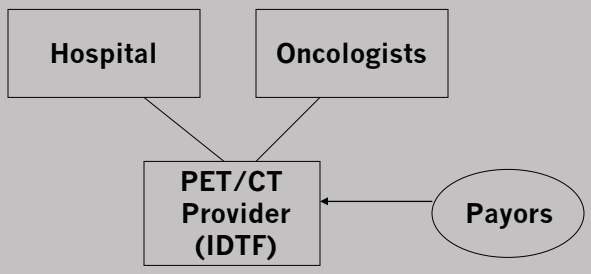
- Marginally broadens scope of physician recruitment/retention exceptions
- May affect Service Line Co-Management, Gainsharing and PFP arrangements
  - Proposed Stark Law exception for Incentive Payment and Shared Savings Programs (411.357(x))

Models For Future Success

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

-- Yogi Berra

Impermissible Joint Venture



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

Top 5 Reasons to Redouble Your Regulatory Compliance Efforts

5. If it makes sense in any other industry, 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 Scooter Libby at San Quentin

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Permissible Hospital-Physician Ventures

- Employment
- Quality and Efficiency Improvement Models
- Seeding Primary Care Consolidation/Alignment
- Block Lease Arrangements
- Equipment Joint Ventures
- Joint Venture ASCs
- Foundation Model Arrangements
- Modified Under Arrangements Model
- Whole Hospital (and Physician Owned Hospital-Within-A Hospital) Models

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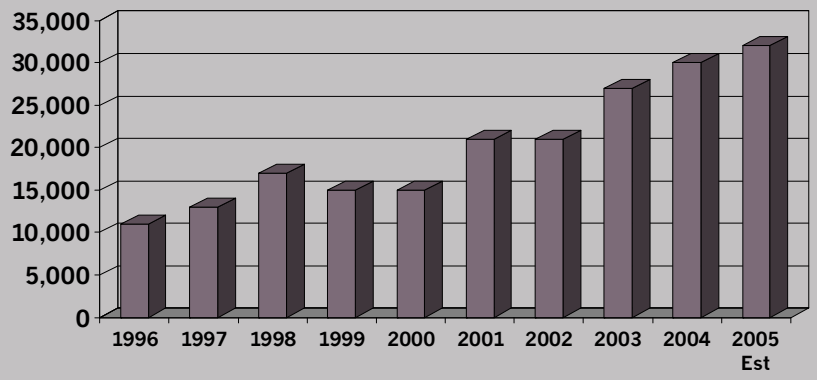
Employment

Direct Physician Employment

(Physicians in Groups of 5 or More Employed by Health Systems)



Source: Verispan LLC, Aventis Managed Care Digest Series®

Physician Employment Considerations

- Do you have infrastructure to manage physicians?
- Do you have relevant competencies?
- Are you willing to outsource to address weaknesses?
- Do you have competent committed physician leadership?
- Can you create a market-based compensation system that aligns incentives?
- Is there a governance structure that empowers the physicians and creates an environment of trust and alliance?
- Can you create an integrated environment in which ancillary revenue is appropriately captured or deployed?
- Can you negotiate better rates with the payers?

Physician Employment Considerations

- Avoiding mistakes of the past
  - Financial losses vs. prudent investments
  - No effective incentives
    - Productivity and quality incentives
    - Select ancillaries?
  - No effective medico-administrative leadership
    - CMO
    - Physician role in governance
  - Hospital info system and management
    - Practice info system and management
  - No consideration of secondary benefits (e.g., return on investment)

Physician Employment Considerations: Legal

- Employment by hospital or medical group
  - Stark Law and Anti-Kickback Statute employment exceptions – remuneration consistent with fair market value and not based on value or volume of referrals
  - Flexible Stark Law compensation rules
    - Fair market value safe harbor eliminated
    - Cannot receive allocation of technical component of DHSs ordered by employee
    - Can be paid professional component of DHSs personally performed by employee
    - Employee cannot be paid profit share
  - Reasonable compensation limits for tax-exempt organizations
    - No part of net earnings can inure to employed physicians

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Employment Arrangements

- Rebuttable presumption of reasonable compensation under Intermediate Sanctions rules
  - Board/Board committee obtains appropriate comparability data
  - Members of Board/Committee who participate have no personal interest in the arrangement
  - Board/Committee approves the arrangement in advance without participation by any person with conflict of interest
  - Board/Committee documents basis for its decision, including terms and approval date, members present, comparability data relied on and recusal of members with conflicts
  - Documentation prepared within 60 days of decision
  - Board reviews/approves documentation as being reasonable, accurate and complete

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Quality and Efficiency Improvement Ventures

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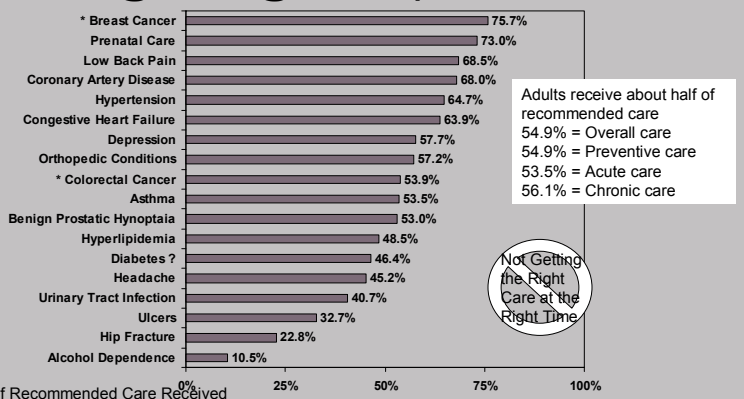
Quality Shortfall: Getting it Right 50% of the Time



Percentage of Recommended Care Received

Glynn EA, et al., "The Quality of Health Care Delivered to Adults in the United States," Journal of Medicine, Vol. 348, No. 26, June 26, 2003, pp. 2635-2645

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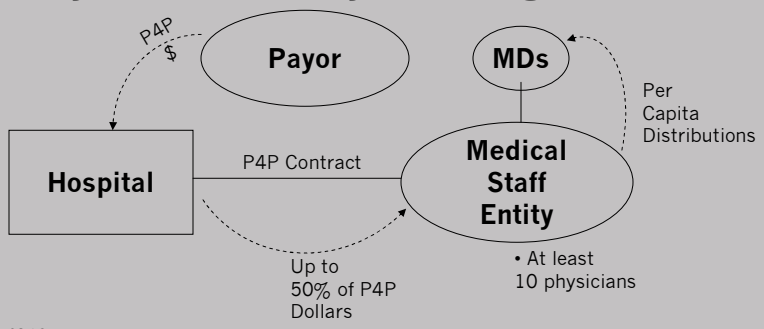
Pay-For-Quality Arrangement



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 measurers 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

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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 a hospital service line (e.g., orthopedics, cardiovascular, general surgery)

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Service Line Co-Management Arrangements

- 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 and efforts participating physicians 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

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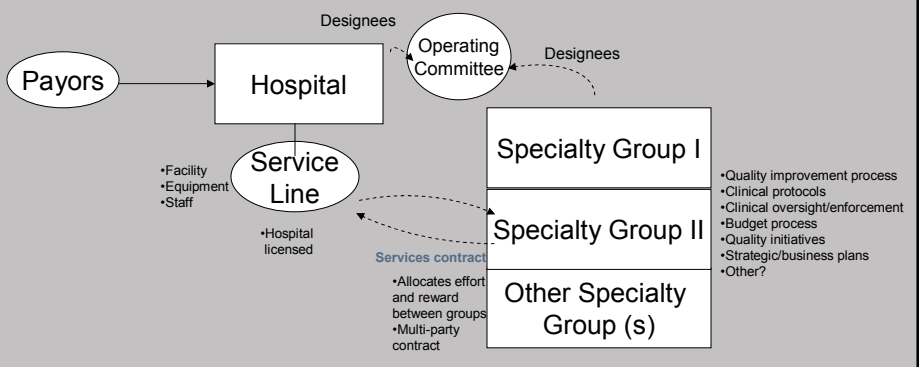
Service Line Co-Management Direct Contract Model



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Sample Surgical Performance Metrics

Incentive	Priority	Allocation	Upper Payment Limit (a)	Current Performance	Performance Target		
					Measurement	Year 1	Year 2
Operational Efficiencies Incentive Compensation (OEIC)							
Standardization of supplies of equivalent quality	1	13.2%	$ 120,000	40%	Order Preferred Items	95.0%	95.0%
Turn Around Time (c)	2	8.2%	$ 75,000	2.56	# Hours	</=1.00	</=1.00
On-Time Starts (1st Case of Day)	2	8.2%	$ 75,000	20%	Improvement On Target	>/= 95%	>/= 95%
Room Utilization	1	13.2%	$ 120,000	76%	# Hours	>/= 85%	>/= 85%
Quality of Service Incentive Compensation (QSIC)							
Infection Rate: Antibiotics Within 30 Minutes Prior to Incision	1	13.2%	$ 120,000	89%	% Compliance	>/=95%	>/=98%
Infection Rate: Insulin Drip for Patients with Blood Sugar Level > 150	2	8.2%	$ 75,000	0%	% Compliance	>/=50%	>/=75%
Return to OR for Post-Op Bleeding	2	8.2%	$ 75,000	2.9%	% Rate of Return to OR	</=2.7%	</=2.5%
Mortality Rate	1	13.2%	$ 120,000	(d)	O/E Rate (b)	</=1.00	</=0.95
Patient Satisfaction	3	7.1%	$ 65,000		Peer Group Percentile	>/=80	>/=85
Peer / Employee Evaluations	3	7.1%	$ 65,000		360° Feedback Scores	Survey Development / Administration	TBD
Total Incentives			**$ 910,000**				
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%	Conversion to O/E Rate

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

For Illustrative Purposes Only

* Prepared by PricewaterhouseCoopers

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Regulatory Considerations

- Cost savings metrics/incentives implicate Civil Monetary Penalty Law[1]
  - 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 for overall budget savings
- 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?
  - Independently assess in relation to baseline cost, volume and case mix and other safeguards?

[1] See OIG Special Advisory Bulletin on Gainsharing (July 8, 1999) and Clarification Letter (Aug. 19, 1999); See also OIG Adv. Ops. 01-1, 05-01-5, 06-22, 07-21, 07-22

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Regulatory Considerations

- Volume/revenue based performance measures implicate the Anti-Kickback Statute and Stark law
  - No AKS safe harbor protection
    - Maximum and minimum, but not "aggregate", compensation is set in advance
  - Cannot reward increase in utilization, revenue, profits (or change in acuity)

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Proposed Incentive Payment and Shared Savings Exception

- Challenge of aligning hospital and physician incentives to improve quality and efficiency
- Proposed Stark Law exception for Incentive Payment and Shared Savings programs
  - Aimed at permitting appropriate quality improvement and cost savings programs while guarding against:
    - Stinting
    - Steering
    - Cherry-picking
    - Gaming
    - Paying for referrals/volume increase
    - Quicker-sicker discharges
  - 16 detailed standards
  - Positive development, but limited utility

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Stark Law Considerations

- Preamble to proposed exception addresses regulatory compliance with:
  - Stark Law (42 USC § 1395nn)
  - Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a)
  - Anti-Kickback Statute (42 U.S.C. § 1320a-7b)

Stark Law Considerations

- Key Constraints of Proposed Exception on Service Line Co-Management Agreements
  - Quality measures must be listed on CMS' Specification Manual for National Hospital Quality Measures – too limited?
  - Applies to "cost savings resulting from reduction in waste or changes in physician or clinical practices"
    - Efficiency gains (e.g., turn-around times, on-time starts) that reduce unit cost, but not overall costs?
  - Performance measures to be judged against Hospital's baseline historic and clinical data – Hospital may not have baseline information for some key measures
  - Targets developed by comparing to national/regional performance norms – may not be available benchmarks
  - At least 5 physicians must participate in each performance measure – service line may have less than 5 physicians

Stark Law Considerations

- Independent medical review prior to commencement and annually thereafter
- No payment to any physician for using an item if the physician has a financial relationship with the selling manufacturer, distributor or GPO
- Physicians must have access to same selection of items as before commencement of program – implications for standardization initiatives
- Term of no less than 1 nor more than 3 years – implications for attractiveness, durability and continuous quality improvement
- Re-basing – cannot pay for "maintenance" of quality/efficiency gains
- Remuneration set in advance and cannot change during term – no opportunity to set new performance standards and reappraise during multi-year agreement

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Stark Law Considerations

- How useful is the proposed exception?
  - Other potentially available exceptions provide greater flexibility
    - Fair Market Value Compensation
    - Personal Services
    - Indirect Compensation
  - Does not propose that more specific new exception "trump" more general existing exceptions
  - Greater assurance of AKS/CMP compliance?

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Regulatory Considerations

- Other Direct/Indirect Compensation Exception Common Elements
  - In writing, signed by parties
  - Specified "services"
  - Legitimate business purpose
  - Set in advance (except Indirect)
  - Fair market value – independent appraisal
  - Does not vary with volume or value of referrals
    - Permits set in advance, objectively measured performance standards that do not vary with volume/value or business generated
  - Duration
  - Compliance with AKS and other laws

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Service Line Co-Management

- Other Potential 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
    - Periodically adjust performance standards and targets?
  - Cost of independent appraisal and clinical monitor
  - Some irreducible legal risk

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Seeding Primary Care Consolidation and Alignment

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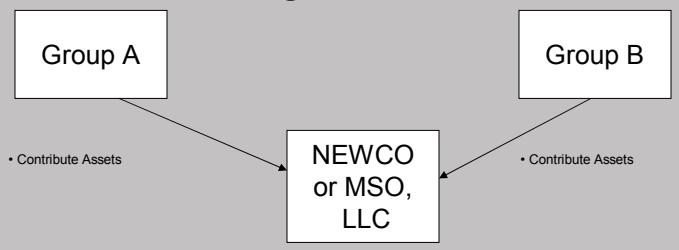
PCP Consolidation: Asset Contribution



- No assumption of liabilities
- Recontracting
- Tax-Free contributions
- No deemed distribution of goodwill?
- Carry-over basis in assets

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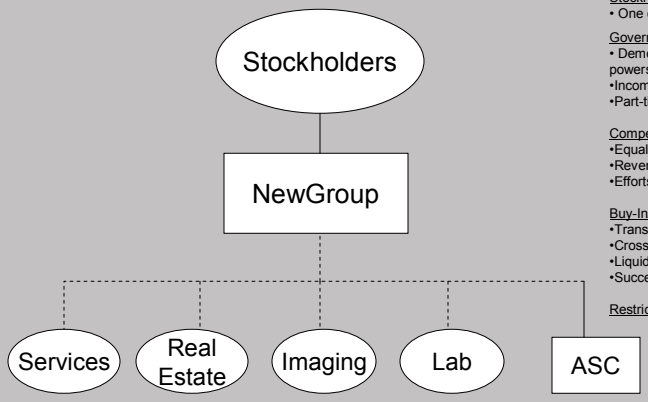
Fully Integrated Group



Stockholders
• One class?

Governance
• Democratic vs. founders reserve powers
•Income partners
•Part-timers

Compensation
•Equal or productivity
•Revenue/expense allocation
•Efforts/RVUs

Buy-In/Buy-Out
•Transfer events
•Cross purchase vs. redemption
•Liquidation value vs. goodwill
•Succession planning

Restrictive Covenants

- Stark Law – In-office ancillary services and employment exceptions
  - DHS technical revenue cannot be allocated based on referrals
- Anti-Kickback Statute – Group practice and employment safe harbors

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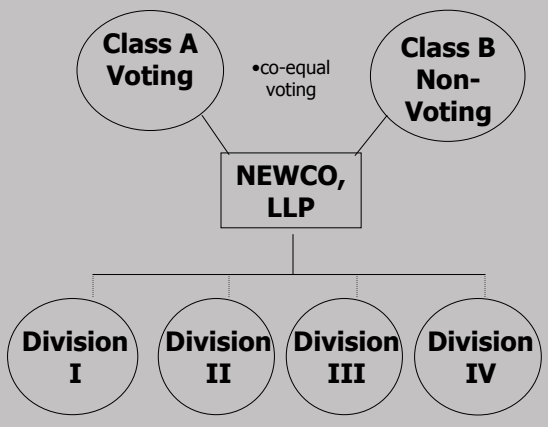
Group Practice Without Walls



Members
- Each Member receives 1 Class A Unit; Class B Units based on relative value of contributed practice

Member Actions
- Supermajority voting

Board
- Representative of constituent interests
- Central authority

Board Voting
- Routine - majority
- Major Actions - supermajority

Divisions
- Profit center accounting
- Delegated authority for day-to-day operations
- Cross-indemnity for divisional deficits?
- Departing physicians responsible for guaranteeing pro rata share of divisional long term debt?

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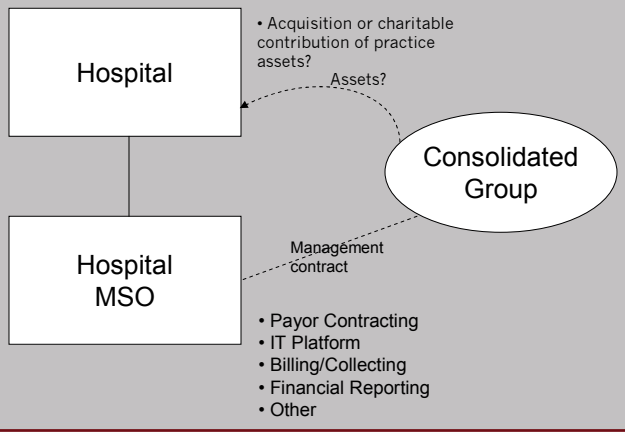
MSO Support for Consolidated Group



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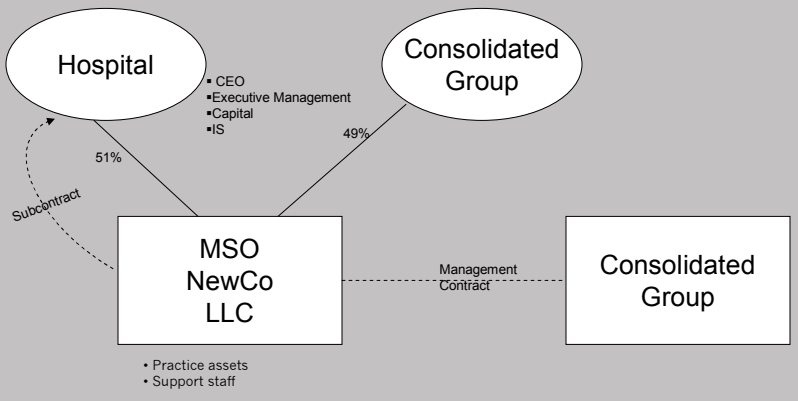
Equity Model MSO



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Block Leases and Equipment Joint Ventures

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Block Lease Arrangements

- Laboratory Services
- Imaging Services (e.g., PET, CT, MRI, Ultrasound)
- Equipment Ventures
- ASCs
- Infusion Services
- Ambulatory Care Facilities

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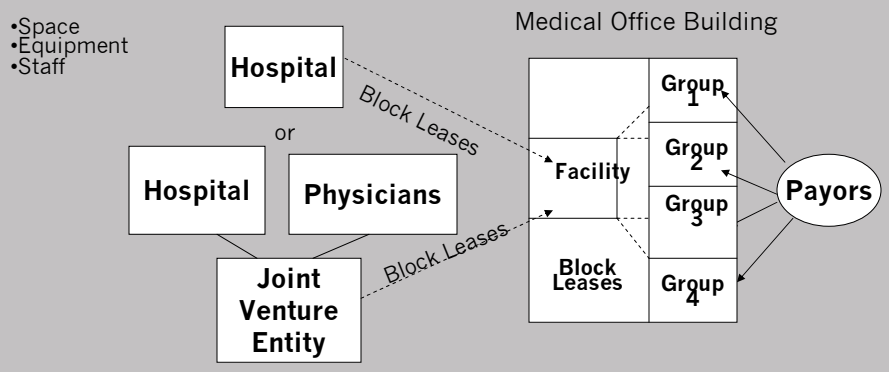
Block Lease Arrangements



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Block Lease Arrangements

- 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
  - Space, equipment rental and personal services exceptions for lease
    - FMV annual fixed fee – no percentage or per-click 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?
  - Impermissible contractual joint venture if Lessor is a supplier that can itself "perform" the service. See OIG Adv. Op. 08-10

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Block Lease Arrangements

- Purchased PC/TC rule would prohibit mark-up if performed or supervised by a physician who does not "share a practice" with the billing physician or group
- State licensure and CON requirements
  - Separate licensure, accreditation and Medicare certification requirements for block lease of hospital-based facilities

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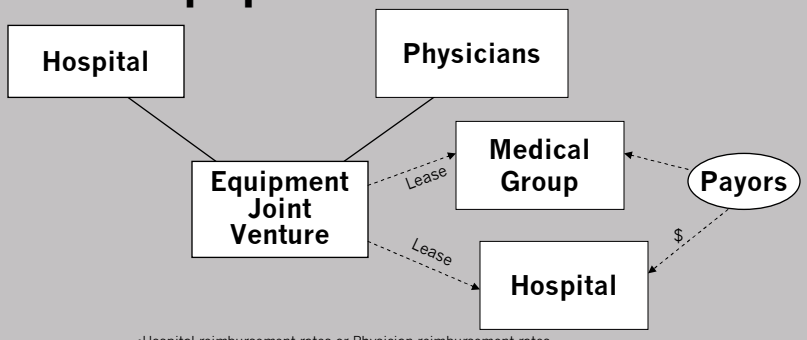
Equipment Joint Ventures



- Hospital reimbursement rates or Physician reimbursement rates
- Stark Law
  - JV is not a DHS entity
  - After Oct. 1, 2009, JV treated as DHS entity if it "performs" the service
  - Equipment rental exception – FMV set in advance
  - Same building or centralized building (exclusive, full-time use) standard
- 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

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ASC Joint Ventures

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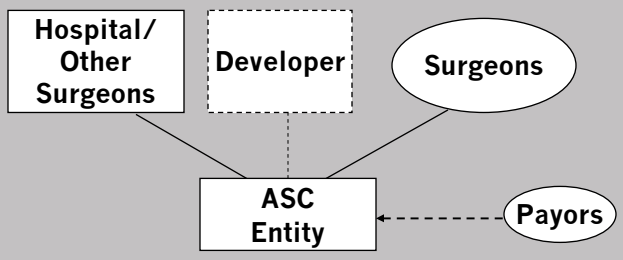
Joint Venture ASC



Issues

- Medicare certification – separate legal entity
  - ASC reimbursement phasing to 65% of hospital OPPS
- No Stark law issue for ASC composite rate services
  - Other exceptions needed for co-located DHSs
- Antikickback ASC Safeharbor?
  - Only surgeons and hospitals are qualified owners
  - 1/3 tests
  - Absence of suspect features
  - Hospital affiliated physicians
- State licensure and CON requirements

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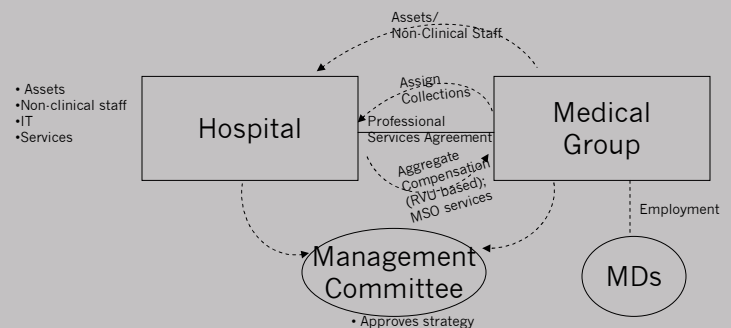
Foundation Model

Foundation Model



- Assets
- Non-clinical staff
- IT
- Services

- Medical Group staffs Hospital outpatient facilities and community-based sites
- Non-compete

- Approves strategy
- Approves budgets
- Establishes compensation principles
- Performance standards/Bonuses

Issues

Stark Law
- Stand in shoes
- FMV exception-compensation methodology set in advance
- Can't pay for space/equipment on percentage or per unit of service basis

Antikickback Statute
- Not safe harbored – "aggregate" compensation not set in advance
- Structure to avoid contractual joint venture

State Law
- Licensure – outpatient sites may be licensable as clinics in some states (e.g., NY, MA)
- CON – CON may apply in some states (e.g., NY)
- Corporate practice of medicine restrictions (e.g., Illinois)
- Fee splitting, antisolicitation, patient brokering laws

Modified Under Arrangements Ventures

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Modified Under Arrangements Model

- Cardiovascular Centers
- Cancer Centers
- Radiation Therapy Services
- Bone & Joint Centers
- Ambulatory Surgery Centers
- Other Hospital Outpatient Services

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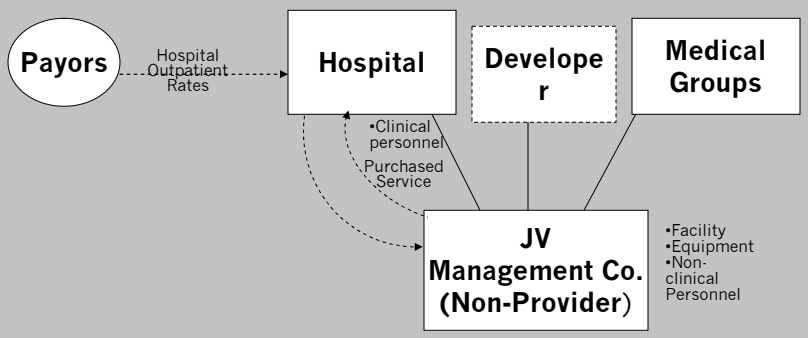
Modified Under Arrangements Model



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Modified Under Arrangements Model

Medicare Reimbursement – Hospital outpatient rates
- Licensed and held out to public as hospital service
- "On-campus" -- within 250 yards of main campus buildings or off-campus and meet provider-based status rules
- 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
- JV cannot "perform" the DHS service
- Indirect compensation exception - FMV fixed fee (no percentage or per click payment)
- No violation of AKS

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

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Whole Hospital Ventures

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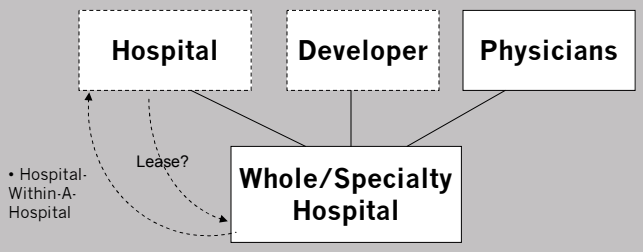
Whole Hospital Ventures



Stark Law whole hospital exception

- Hospital vs. subdivision, must be primarily engaged in inpatient services
- Moratorium is over for specialty hospitals primarily providing cardiac, orthopedic or surgical services
- 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)
- Special Advisory Bulletin on GainSharing - specialty hospital ventures may induce investor physicians to limit or withhold Medicare services to produce profit in violation of CMP law
- State hospital license and CON requirements

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Charting Future Course

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Charting Future Course

- Do nothing is not a viable option
- Do something
- What to do?

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Charting Future Course

- Time to re-evaluate traditional medical staff model?
- Board responsibility and role?
- Medical Staff responsibility and role?
- Can the parties collaborate in community interest?
- Can the key parties build mutual trust and respect?
- Non-alienating approach

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Charting Future Course

- Sustain focus on physician manpower and relations
- Process for defining physician strategies, tactics and goals
- Assure that structures selected are self-sustaining, durable and capable of producing a legacy
- Position for long-term success

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Michael L. Blau is a partner with Foley & Lardner. He is the chair of the Health Care Venture Practice and a member of the Emerging Technologies and Private Equity and Venture Capital Practices and the Health Care Industry Team.

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.

Prior to joining Foley, Mr. Blau was partner-in-charge of the Health Law Department in the Boston office of McDermott Will & Emery LLP.

For the third year in a row, in 2007, Mr. Blau was recognized as one of the top 10 health attorneys in the country in his specialty by *Nightingale's Healthcare News*. In 2007, Mr. Blau once again received a #1 ranking in healthcare by *Chambers USA* and was again named a *Massachusetts Super Lawyer.* This year he was also named by *Boston Magazine* as one of the *Top 100 Massachusetts Super Lawyers*. He is also listed in the current edition of *The Best Lawyers in America*®.

A frequent lecturer and writer on health law topics, Mr. Blau co-authored a book entitled *Complying with Stark Physician Self-Referral Rules* (Atlantic Information Services) and a McDermott Will & Emery white paper entitled *Encouraging a Responsible Approach to Consumer-Driven Health Care*. He also co-authored *Developing and Managing Physician Networks* (Thompson Publishing). His articles have appeared in numerous health law publications.

Mr. Blau formerly served as executive editor of the ABA publication *The Tax Lawyer*, chaired the editorial advisory board of *The PPM Profitability Update* (Fulcrum Information Services), served as a contributing legal editor for *Physician's News Digest* and *E-Healthcare*

Connections, and has been a member of the editorial board of the *Boston Bar Journal, The Managed Care Payment Advisor* (Aspen Publishing), *Surgical Malpractice Prevention Reporter* (American Health Consultants) and *Journal of Healthcare Safety, Compliance & Infection Control* (Prime National Publishing Corporation).

Mr. Blau received his J.D. (*cum laude*) from Georgetown University Law Center in 1979. He received his A.B. (*magna cum laude*) from Harvard College in 1976.

Mr. Blau is a member of the American Health Lawyer's Association, and the health law committees of the American Bar Association, Massachusetts Bar Association and Boston Bar Association.

Mr. Blau is the past chair of the Health Law Section of the Boston Bar Association (BBA), currently serves on its steering committee and is co-chair of its Social Action Committee. He is editor-in-chief of the BBA's *Parent's How-to-Guide to Children's Mental Health Services In Massachusetts*. He is a member of the Curriculum Advisory Committee of Massachusetts Continuing Legal Education, Inc., and annually chairs health law programs for MCLE and the BBA. He is also a frequent speaker at seminars sponsored by health care trade associations.

Mr. Blau currently serves as chairman of the board of Project HEALTH, a national charity that works to break the link between poverty and poor health for inner city children and families.

Mr. Blau is also a partner in Angel Healthcare Investors, LLC, a seed-level health care venture capital company.

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Richard W. Johns is a partner with Foley & Lardner LLP. Mr. Johns is a member of the Health Care Industry Team, as well as the Business Counseling & Technology Practice. His clients include publicly traded, multi-national, privately held and nonprofit organizations. His health care clients include a spectrum of health care providers with an emphasis in hospitals and physicians. Mr. Johns regularly advises clients regarding regulatory and compliance issues, information technology issues, as well as various state licensing and regulatory requirements. Mr. Johns represents clients in transactional matters, mergers and acquisitions, compliance and regulatory counseling, and state and federal investigations.

Mr. Johns was among 114 attorneys nationwide who made The BTI Consulting Group's coveted Client Service All Star Team for 2005. This honor is bestowed upon individual attorneys who deliver outstanding client service according to corporate counsel interviewed at Fortune 1000 companies. This is the second consecutive year he has received the honor and is among only 14 attorneys nationwide receiving the honor two or more times. Mr. Johns has been named as one of Florida's Legal Elite™ by *Florida Trend* magazine. He has also been selected by his peers for inclusion in the 2008 and 2009 editions of *The Best Lawyers in America®.*

Mr. Johns has lectured on corporate, regulatory and health care issues before many professional and trade organizations, and has frequently written on these topics. Mr. Johns' most recent article is entitled "Successor Liability in Healthcare Mergers and Acquisitions" and appeared in the *Journal of Healthcare Compliance*.

Mr. Johns graduated from the University of Southern California School of Law in 1982. He attended the University of Maryland and Harvard University, and earned his undergraduate degree in social science from

Pacific Union College (B.S., 1979).

Mr. Johns is a member of compliance and health care trade organizations. He is admitted to practice law in California, Colorado, the District of Columbia, Florida and Maryland.

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Prior to beginning his career in law, Dr. Koch completed an internal medicine residency at Pacific Medical Center in San Francisco, California. He is a diplomate of the American Board of Internal Medicine, a fellow of the American College of Legal Medicine, and a member of the American Health Lawyers Association and the Florida Academy of Healthcare Attorneys.

Dr. Koch is a graduate of the University of California, Los Angeles, School of Law (J.D., 1989), where he was elected to the Order of the Coif, Thomas Jefferson University (M.D., 1982) and Pennsylvania State University (B.S., 1980). He was admitted to the California Bar in 1989 and The Florida Bar in 1995. He is also admitted to practice before the United States District Court, Central District of California and the Middle District of Florida.