Strategies for Successful Hospital/Physician Alignment

February 26, 2009 • The Westin Los Angeles Airport
A Medical Necessity: Strategies For Successful Hospital/Physician Alignment

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1. OIG Issues Green Light to Hospital “Pay for Quality” Arrangement, Compliance Today
2. Hospital-Physician Alignment Models in California, California Health Law News
A Medical Necessity: Strategies for Successful Hospital/Physician Alignment

Summit Agenda
As of January 28, 2009

8:00 – 9:00  Registration and Networking

9:00 – 9:15  Introduction, Welcome, and Overview of Current Hospital/Physician Alignment Challenges and Opportunities
- Market Drivers
- Strategic Considerations

Presenter:
Charles B. Oppenheim, Partner, Foley & Lardner LLP

9:15 – 10:45  It's All About Physicians: Attracting and Retaining the Best
Panelists, including a hospital CEO/physician, a health care attorney, and management consultants, will discuss subjects ranging from the broad perspective of integration strategy to the nuts-and-bolts of fair-market value analysis. This panel will present case studies in both primary care and physician subspecialties and service lines to illustrate how health care leaders are creating successful physician relationships across the spectrum of professional service arrangements, including call stipends, income guarantees, compensation plans, and co-management programs.

Panelists:
Lawrence R. McEvoy II, MD, Chief Executive Officer, Memorial Health System, Colorado Springs
Mark T. Schieble, Partner, Foley & Lardner LLP
Daniel P. Stech, MBA, CMPE, Executive Director, The Pinnacle Group
David V. White, MBA, Executive Director, The Pinnacle Group

11:45 – 11:00  Morning Break

11:00 – 12:30  Integrated Delivery Case Studies: What Works/What Doesn't
Integrated delivery systems have come a long way from the integration frenzy of the 1990s. This panel includes leaders of health care organizations that have multi-year track records with successful models in use in California: 1206(l) medical foundations, 1206(d) clinics, and “friendly PC.” Learn from these experienced leaders about what has worked, what recent developments have enhanced performance, and the future directions of these tested models.

Panelists:
William L. Abalona, Partner, Foley & Lardner LLP
Larry Harrison, MBA, MHS, Chief Executive, Scripps Clinic
Laura Jacobs, Senior Vice President, The Camden Group
Linda Procci, Ph.D., Vice President, Service Line Operations, Cedars-Sinai Medical Center
12:30 – 1:30  Networking Lunch

1:30 – 2:30  The Quality Imperative — Real-Life Solutions and Innovative Approaches to Improve Quality and Compliance
Quality of patient care is a top priority for health care providers and industry leaders. This session will focus on the government’s effort to improve quality of care through payment reform, data mining, and the False Claims Act. The panel also will discuss compliance and quality assessments and the recent OIG Advisory Opinion that allows hospitals to use pay-for-performance (P4P) programs as incentives for physicians to improve quality of care.

Panelists:
Janice A. Anderson, Partner, Foley & Lardner LLP
Judy Ringholz, RN, JD, CHC, Manager, Huron Consulting Group
Cheryl L. Wagonhurst, Partner, Foley & Lardner LLP

2:30 – 2:45  Afternoon Break

2:45 – 3:45  What’s Ahead: The Future of Hospital/Physician Alignment (Panel)
This panel will explore the future of hospital/physician alignment strategies and models. Topics include electronic medical records, patient electronic portals, and the impact of the retail medical clinic trend. These future alignment strategies will be discussed in the context of the current economic climate and the new administration’s ambitious health care reform agenda.

Moderator:
Charles B. Oppenheim, Partner, Foley & Lardner LLP

Panelists:
Laura Jacobs, Senior Vice President, The Camden Group
Judy Ringholz, RN, JD, CHC, Manager, Huron Consulting Group
Daniel P. Stech, Executive Director, Pinnacle Products and Innovation, The Pinnacle Group
It’s All About Physicians: Attracting and Retaining the Best

Lawrence R. McEvoy, II, MD
Memorial Health System

Mark T. Schieble, JD
Foley and Lardner, LLP

Daniel P. Stech, MBA, CMPE
Pinnacle Group

David V. White, MBA
Pinnacle Group
Themes

- **Vision and Strategy - McEvoy**
  - An Integrated System Approach

- **Aligning Incentives - Stech**
  - Dealing with Physician Compensation

- **Fair Market Value “Matters” - White**
  - Approach and Considerations + Case Study

- **The Legal Perspective - Schieble**
  - Working within the Limits
Three things docs seek...

- **Meaningful work**
- **Connection to those they work with**
- **Clear positive and negative feedback**
Highest quality healthcare where patients heal and people thrive
Three questions docs have to answer...

- Does an organization exist—is it possible?

- If it exists....is it worth my effort?

- If my usual effort doesn’t work, how do I make it work?
“A TRUSTED Team of Colleagues”

T. = Team player (make others better)
R. = Responsive and respectful
U. = Understanding (listen & learn w/o judgment)
S. = Safe (easy to approach; I invite other opinions)
T. = Talent (skill, knowledge, judgment, proficiency)
E. = Execution (get things done; get results)
D. = Dedication and devotion (work ethic)
Vision and Strategy

- Suppliers
- Facility
- Physician
- Health Plan
- Foundation
- Retail
- Corporate Partnerships
- Payers
- Diversified

Highest quality care
Key Strategies by Priority Ranking

1. Transform the Patient Experience (FLOW)
2. Leverage Physician & Clinical Capital to Build a Quality Enterprise
3. Build Robust Financial Strength
4. Become the Best Place to Work
5. Grow a Lean Culture
6. Develop the Business Intelligence Platform that Drives Strategy, Operations, Quality, and Care at the Bedside
7. Develop an Integrated Health Delivery Network
8. Develop a Learning Organization Focused on Creativity, Adaptability, Discipline, and Innovation
9. Focus on Cradle to Grave Health Management
Aligning Incentives
Aligning Incentives

- Connecting Pay with Strategy
- Elements of Effective Compensation Plans
- Plan Structures
- Design Process
Connecting Pay with Strategy

- **Fundamental**
  - Financial viability
  - Relationship stability

- **Clear and Shared Expectations**
  - Income
  - Performance and Management
  - Opportunity

- **Objective-driven Compensation Plans**
  - Well-defined and devised

- **Reflect Contributions**
  - Productivity, leadership, etc.

- **Effectively Managed**
  - On time with accurate data
Elements

1. Directly linked to goals and objectives
2. Encourage/reward hard work and production
3. Balance individual and team responsibility
4. Clarify performance expectations
5. Aligned with reimbursement environment
6. Simple, understood and explainable
7. Clearly defined and consistently applied
8. Open and transparent
9. Fiscally responsible
10. Legally compliant

- Johnson and Walker-Keegan
Dimensions of Compensation

- **Equal Share**
  - Quality / Mission
    - Diligence
    - Efficiency
    - Events
    - Mission
    - PQRI
  - Productivity / Profitability
    - Speed
    - Output
    - Encounters
    - Profit
    - FFS

- **Team**
  - Long Term
    - Growth
    - Care Coordination
    - Cost Sharing

- **Individual**
  - Short Term
    - Benchmarks
    - Specialty
    - Cost Accounting

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Objectives

- Recruitment / Retention
  - Benchmarks and market comparable data

- Productivity
  - Charges, collections, WRVUs

- Profitability
  - Minimizing losses

- Organizational Improvement / Advancement
  - Patient Satisfaction
  - Quality
  - Citizenship / Leadership

- Access / Coverage
  - Creating service lines, 24/7 expectations, etc.
Structures

- **Models – Integrated Practices**
  - Base plus Incentive(s)
    - Relate to Objectives
  - Revenue – Expense
    - Modified for other objectives

- **New Physicians**
  - Guarantee plus discretionary bonus
  - Relocation, sign-on
  - Know your market
  - Mentoring and feedback
## Key Challenges
- Very poor productivity (< 25th percentile) – no accountability
- Straight salary history and physician mind-set
- Poor payer mix, and mission to “care for everyone”
- Moderate recruiting difficulties
- Inefficient infrastructure (facilities, staffing, etc.)
- Physicians had no data on performance
- Desire to earn more money – recognize other service (teaching)

## Objectives
- Competitive incomes for recruitment and retention
- Promote productivity
- Shield providers from poor payer mix
- Ease transition to new compensation / productivity expectations
- Compliance
Structures...Primary Care...cont.

| Philosophy                                      | - Allow physicians to earn market competitive incomes despite payer disadvantages  
|                                                | - Walk before they run  
|                                                | - Require market competitive productivity  |
| Formula                                         | - Establish benchmark compensation and productivity expectations (base line)  
|                                                | - Create 3-Phase transition to Base Plus Incentive Compensation Arrangement (P1 - 90% of benchmark, P2 – 85%, P3 – 80%)  
|                                                | - Incentive Threshold based on 50% of 25th Ptile WRVUs (national)  
|                                                | - Threshold initially set low to make incentive tangible – threshold raised to 60% of benchmark in P3  
|                                                | - $8/WRVU incentive in P1 to $22/WRVU in P3  |
| Outcomes                                        | - Immediate increase in productivity  
|                                                | - Addressing operational limitations (staffing, etc.)  |
| Cautions                                        | - “Cut in Pay”  
|                                                | - Gaming the WRVU system – need for education and audit control  
|                                                | - Accurate data and quarterly bonuses  |
## Structures...ED

<table>
<thead>
<tr>
<th>Key Challenges</th>
<th>Objectives</th>
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<tbody>
<tr>
<td>- High patient demand environment</td>
<td>- Competitive incomes for recruitment and retention</td>
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<tr>
<td>- Moderate physician productivity</td>
<td>- Promote productivity / efficiency</td>
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<tr>
<td>- Crummy patient satisfaction</td>
<td>- Ensure coverage of second campus with lower volume</td>
</tr>
<tr>
<td>- Some quality concerns – physician personality problems</td>
<td>- Address patient satisfaction</td>
</tr>
<tr>
<td>- Loosely administered compensation incentives – total compensation capped near 75th Ptile</td>
<td>- Assure high quality of care</td>
</tr>
<tr>
<td>- Some physician turnover</td>
<td>- Compliance</td>
</tr>
<tr>
<td>- High performers dissatisfied with cap on compensation</td>
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<tr>
<td>- Hourly employee mentality</td>
<td></td>
</tr>
</tbody>
</table>
| Philosophy                                      | - Allow high performers to earn high performer incomes  
|                                               | - Quality and patient satisfaction are paramount  
|                                               | - Align productivity and compensation |
| Formula                                        | - Establish benchmark compensation and productivity expectations -  
|                                               | Base Compensation set above Median (regional)  
|                                               | - Establish Quality and Patient Satisfaction Measures  
|                                               |   - Individuals required to meet quality standards to be eligible for productivity or patient satisfaction incentives  
|                                               |   - Fixed $ for Patient Satisfaction based on group and individual scores ($4,000 / quarter)  
|                                               | - Productivity Incentive Threshold based on Median Ptile WRVUs (national measured per hour) + $ differential for second campus work  
|                                               | - Total compensation must be within FMV (audit trigger) |
| Outcomes                                       | - Majority of physicians above 75th Ptile productivity  
|                                               | - Group patient satisfaction scores at 98th Ptile (PG) |
| Cautions                                       | - Coding, being too quick to order tests and consults (cost and quality concerns)  
|                                               | - Need for strong physician leader |
# Structures...Specialists

| Key Challenges | Attractive incomes for recruitment and retention, including incentives  
| - Competition for physicians in limited supply  
| - Demand of physicians to earn above average incomes  
| - Need for productivity to support income and expenses  
| - Poor payer mix and mission to “care for everyone”  
| - Some physicians carry administrative duties in addition to full clinical schedule – some with disproportionate call |  
| Objectives | Stable / improved access to key specialty services  
| Promote financial viability  
| Recognize non-patient care contributions  
| Consistency across specialties  
| Compliance |
### Structures...Specialists...cont.

| Philosophy       | - Offer competitive salary guarantees with incentives for contributions above employment / practice costs  
|                  | - Reflect private practice arrangements |
| Formula          | - Establish benchmark base compensation – varies by specialty  
|                  | - Identify Professional Collections per WRVU (benchmark or actual)  
|                  | - Determine Employment Costs (Salary, Benefits and Taxes)  
|                  | - Determine Practice Cost (billing, malpractice, facilities, support, IT, etc.)  
|                  | - Calculate WRVU Cost Equivalent (Total Costs / Collections per WRVU)  
|                  | - Identify Compensation per WRVU (benchmark or actual)  
|                  | - Bonus physician based on % of Compensation per WRVU above Cost Equivalent  
|                  | - Reduce Base Compensation if physician fails to meet Cost Equivalent  
|                  | - Stipends / hourly compensation for additive administrative services |
| Outcomes         | - Higher physician satisfaction / retention  
|                  | - Competitive levels of productivity |
| Cautions         | - Clear expectations about performance  
|                  | - Effective cost management |
Design Process

- **Plan**
  - Educate and inform
- **Gather Data**
  - Evaluate Performance
- **Assess Environment**
  - Internal and external
- **Agree on Objectives**
  - Management and physicians
- **Develop and Finalize Models**
  - Know the market
Implementation

- **Document**
  - Performance, objectives and methods

- **Ensure Compliance**
  - Medicare and IRS

- **Educate and Inform**
  - Physicians and managers

- **Data and Management Systems**
  - Regular reporting and timely administration

- **Transition Plans**
  - Ease the pain

- **Monitor and re-evaluate**
  - Assess against objectives and strategy
Aligning Incentives
# Fair Market Value “Matters”

## PAIN ASSESSMENT SCALES

<table>
<thead>
<tr>
<th>Descriptions</th>
<th>0</th>
<th>2-3</th>
<th>4-5</th>
<th>6-7</th>
<th>8-9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Face</strong></td>
<td><img src="image" alt="No pain" /></td>
<td><img src="image" alt="Mild pain" /></td>
<td><img src="image" alt="Moderate pain" /></td>
<td><img src="image" alt="Disabling pain" /></td>
<td><img src="image" alt="Severe pain" /></td>
<td><img src="image" alt="Unbearable pain" /></td>
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<tr>
<td><strong>Words</strong></td>
<td>no pain feel &quot;ok&quot; does not hurt</td>
<td>mild pain hurts a little annoying nagging</td>
<td>moderate pain discomforting getting worse nauseating/numbing</td>
<td>distressing very strong miserable agonizing</td>
<td>intense horrible viciouss/rushing awful/dreadful</td>
<td>unbearable excruciating worst possible pain</td>
</tr>
<tr>
<td><strong>SPANISH</strong></td>
<td>no dolor me siento bien no me duele</td>
<td>poco dolor duele poco molestia incomfortable</td>
<td>dolor moderado incomforable empeorando</td>
<td>perturbador muy fuerte miserable agonizante</td>
<td>intenso horrible vicioso muy doloroso</td>
<td>insoportable demolidor el mpo fuerte dolor posible</td>
</tr>
<tr>
<td><strong>PORTUGUESE</strong></td>
<td>não tenho dor sinto-me &quot;ok&quot; não magoa</td>
<td>dor brands mago um pouco de maneira incomoda enervante</td>
<td>dor moderada descomfor a ficar peor enojativa/dormente</td>
<td>que aflige muito forte deprimente/teoror atra</td>
<td>intensa horrorvl m/territoror tentivel/machador</td>
<td>insoportavel excrutinante peor dor possível</td>
</tr>
<tr>
<td><strong>RUSSIAN</strong></td>
<td>НЕТ БОЕЙ чувствует себя хорошо</td>
<td>ЛЁГКАЯ БОЛЬ болит немного носит собой боль</td>
<td>СРЕДНЯЯ БОЛЬ усиливается, боль терзает боль</td>
<td>МУЖИТЕЛЬНАЯ ОЧЕНЬ СИЛЬНАЯ ТЕРЗАЮЩАЯ БОЛЬ</td>
<td>СТРАШНАЯ УЖАСНАЯ СОКРУШАЮЩАЯ БОЛЬ</td>
<td>НЕВЫНОСИМАЯ, КОТОРУЮ НЕЛЬЗЯ ТРЕНЕТЬ БОЛЬ</td>
</tr>
<tr>
<td><strong>VIETNAMESE</strong></td>
<td>không đau/nhức chót nho tuy thay binh thong không thay dau/nhục</td>
<td>dau/nhục nhẹ dau/nhục chóng nho tuy thay dau/nhục</td>
<td>dau/nhục vừa khó chịu dau/nhục nặng tăng lên buen nặng</td>
<td>dau/nhục đứng dau/nhục nhiều dau/nhục đau đớn</td>
<td>dau/nhục nhiều đau/nhục kéo dài dau/nhục ghe gán</td>
<td>Met chiu nó dau/nhục đứng dau/nhức</td>
</tr>
<tr>
<td><strong>HAITIAN</strong></td>
<td>pa gin doule mwen byen li pa fem mal</td>
<td>doule tou pitis ranm mal pitis li pib pou machan li anite'm</td>
<td>doule moder doule pib grav li moun moun li f Sites</td>
<td>man douts doule pib grav li moun moun moun</td>
<td>li pi fô li teb li teb li kanfè</td>
<td>mpa capab ankò li strès doule pib</td>
</tr>
<tr>
<td><strong>CHINESE</strong></td>
<td>不痛 感觉“可以”</td>
<td>轻微痛痛 轻微 不舒服</td>
<td>中度疼痛 疼痛加重 痛苦/麻木</td>
<td>重度疼痛 痛苦的, 扭折</td>
<td>极度疼痛 不能忍受的剧痛</td>
<td>绝对的剧痛 不能忍受的剧痛</td>
</tr>
</tbody>
</table>
Fair Market Value “Matters”

- Key Questions
- Factors of Influence
- Managing the Process
- Case Study – Anesthesia Arrangement
FMV Examples/ Trends

- Acquisition
- Medical Directorship
- Hospital-based Physician Subsidy Arrangement
- Call/ Availability
- Employment
- Other
  - Co-Management
  - Joint Venture
  - Purchased Services

We Can Improve on the Past
Key Questions to Answer

1. Is this a physician arrangement that merits compensation?

2. What are the factors or characteristics that influence compensation?

3. What level of compensation is reasonable?

4. Is the level of compensation commensurate with expectations of the arrangement?
Focused Discussion – Factors of Influence

- What are the factors or characteristics that influence compensation in the arrangement?
  - Expectations
  - Market Forces
Expectations

- **Objectives of the Arrangement**
  - Relationship to organizational strategy
  - Developing / improving a service line
  - Maintaining accreditation
  - Responding to community need

- **Activities Required**
  - Time commitment
  - Job description
  - Staffing requirements

- **Physician Experience / Qualifications**
  - Often a secondary consideration
Market Forces

1. **Physician Specialty / Compensation by Specialty**
   - Survey data
   - Market comparables

2. **Competitive Environment**
   - Insights from other organizations
   - Trends

3. **Personal and Economic Burden**
   - Opportunity costs

4. **Physician Supply / Recruitment Conditions**

5. **Payer Mix**

6. **Region and other Geographic Determinants**
Connecting the Dots

How do the market factors and expectations relate to the Fair Market Value range?

- Available studies and references (Published)
- Market comparable examples: validation (Market)
- Reasonable judgments based on the factors
  - Is the 90th Percentile ever an appropriate benchmark?
    - Extraordinary, compelling circumstances
    - Reliable evidence
    - Know the risk
Managing the Process

“What process?”

or

“We have agreed to what?”
Process - Elements

- Education – knowledge and training
- Reliable Data (Published or Market)
- Who’s on the Team?
- Analytical Tools
- Corporate Standards – methods and payment terms
- Transparency
- Documentation
- Oversight/ Feedback
Process - Benefits

- **Compliance**
  - Consistency
  - Transparency
  - Responsiveness
  - Internal audit

- **Cost Management**
  - Minimizes special deals and range creep
  - Reduces need for outside reviews

- **Timeliness**
  - Reduces uncertainty
  - Speeds negotiation and decision-making
  - Decreases contracting frustration
Case Study – Anesthesia Support

■ Challenge

- 300-bed Hospital, 10 physicians/ 15 CRNA’s
- Difficult payor market, competitive recruitment
- Differing Needs
- Why FMV required?
- Process – attorney client privilege
# The Staffing Matrix

<table>
<thead>
<tr>
<th></th>
<th>Start</th>
<th>End</th>
<th>#hours</th>
<th># Days</th>
<th># Rooms</th>
<th>Anea Req</th>
<th>CRNA Req</th>
<th>Anea Hrs</th>
<th>CRNA Hrs</th>
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<td>7.5</td>
<td>1.0</td>
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<td><strong>CRNA</strong></td>
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<td><strong>Hours Per Week</strong></td>
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<td><strong>Hours Per Year</strong></td>
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Data Request

- Copy of the current contract and proposed new contract (if available).
- Physician Compensation: 2007 and 2008 (please isolate general anesthesia and pain medicine physicians if applicable).
- CRNA Compensation: 2007 and 2008 (if applicable).
- Physician Productivity Data by physician (Cases, ASA Units, RVUs, Collection and Charges): 2007 and 2008 (please isolate general anesthesia and pain medicine physicians if applicable).
- Description of all anesthetizing locations and hours of capacity plus typical utilization of locations.
- Description of call requirements for ED and OB.
- Medical Director job description.
- Description of staffing schedules, time-off, typical shifts, call rotations.
Process

- Set Up with the Team and Data Review
- Interviews (management and physicians) – expectations, history, goals.
- Analysis
- Findings
Findings

### Findings

***Please note the following figures are for illustrative purposes only. They are not representative of actual data and should not be used for FMV purposes.***

<table>
<thead>
<tr>
<th>Analysis Factors</th>
<th>Staffed Hours-Based Approach</th>
<th>Productivity-Based Approach&lt;sup&gt;1&lt;/sup&gt;</th>
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<tr>
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<td>Anesthesiologists</td>
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<td>Coverage Hrs. ·or· Units</td>
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<td>40,000 hrs.</td>
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<td>Per FTE Provider Benchmark&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>Benchmark FTEs</td>
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<td>FMV Compensation&lt;sup&gt;3&lt;/sup&gt;</td>
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<td>$200k · $250k</td>
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<td>FMV Compensation</td>
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<tr>
<td>Total FMV Compensation</td>
<td>$8.8m - $11.0m</td>
<td>$5.6m - $7.0m</td>
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</tbody>
</table>

1) ASA units, WRVUs, TRVUS, etc.
2) Ex., median survey figure, etc.
3) Figure includes salary, benefits and expenses; and is a blend of published and market data sources

50/50 Blend of Approaches

$7.2m - $9.0m
Legal Perspective

“Working within the Limits”

- California Corporate Practice
- Exempt Organization Law – Private Inurement
- Private Business Use of Bond-Financed Property
- Physician Self-Referral and Anti-Kickback Laws
Case Study One

The Situation:

- **ABC Hospital**
  - Serving disadvantaged population
  - Big demand for highly specialized services
  - Dedicated staff – but available reimbursement insufficient to provide reasonable compensation
  - Hospital has resources and willing to provide physician subsidy
Case Study One -- continued

The Goal:

- How to structure a hospital subsidy in light of legal concerns
Case Study One -- continued...

The Solution:

■ Hospital sponsors organization of affiliated PC that employs physicians for fixed compensation determined to be reasonable in amount

■ Hospital subsidizes affiliated PC through periodic grants equal to excess of aggregate physician compensation expense over reimbursement received
Case Study One -- continued

Legal Analysis:

- Paying for physician services – hospital’s mission is to serve a disadvantaged population
  - Affiliated PC is closed economic system
    - Compensation – so long as reasonable in amount in light of services rendered.
    - Prohibition against payments of dividends or sales of stock, through both provisions in organizational documents and grant agreement
  - Possibility of obtaining 501(c)(3) status
Case Study Two

The Situation:

- **1206(I) Foundation model clinic**
  - An economic sinking ship
  - Physician compensation and productivity

The Goal:

- Place clinic on a secure financial footing

The Solution:

- Compensate physicians under an incentive structure that assures compensation not exceed excess of revenues over expense – essentially, basing physician compensation on a share of net profits
Legal Analysis:

- **Historically, private inurement prohibits dividend like distributions – i.e., a sharing of net profits**
  - IRS has softened the historic prohibition, recognizing that profitability can be a legitimate factor to consider in awarding incentive compensation, so long as various factors satisfied:

  - Revenues taken into consideration reflect **personal productivity** of person being compensated and expense savings taken into account reflect **cost savings efforts** of person being compensated
    - E.g., optic shop
    - E.g., cardiac cath lab
Incentive formula must not be inconsistent with furtherance of exempt purposes – e.g., an overzealous focus on the bottom line clearly can adversely affect quality patient care, treatment of indigent patients

- Thresholds for defined minimums – accreditation, minimum patient satisfaction, outcome measures, with achievement of higher levels adding to compensation payable

- Cap to assure not excessive in amount

- **Additional limitations for tax-exempt bond financed property**

  - Incentive compensation can be based on revenues or expense, **but not both**

  - Have physicians assume responsibility for controllable costs
    - E.g., cardiac cath lab
Thank You

Questions and Comments
Integrated Delivery Case Studies: What Works and What Doesn’t

William L. Abalona, Partner
Foley & Lardner LLP

Larry Harrison, MBA, MHS, Chief Executive
Scripps Clinic

Laura Jacobs, Senior Vice President
The Camden Group

Linda Procci, Ph.D., Vice President, Service Line Operations,
Cedars-Sinai Medical Center
HOSPITAL-PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

OVERVIEW

- What is an “affiliated medical group”?  
- How is an affiliated medical group distinguished from licensed and unlicensed clinics?  
- What is the purpose of affiliation?  
- What are the key legal issues regarding affiliated medical groups?  
- Variations on the structure of affiliated medical groups.
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- WHAT IS AN AFFILIATED MEDICAL GROUP?
  - There is no formal definition
  - Can be any relationship between a hospital and a medical group which promotes “alignment”
  - A question of degree
    - A contract for services
    - An exclusive contract for services
    - A group that is partially managed by a hospital (or hospital affiliate)
    - A group that is “fully” managed by a hospital or affiliate
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- A group with a structural relationship with a hospital or affiliate
- A group receiving financial support from a hospital or affiliate
- A group that is financially integrated with a hospital or affiliate
AFFILIATED MEDICAL GROUPS DISTINGUISHED FROM LICENSED AND UNLICENSED CLINICS

- “‘Clinic’ means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours...” Health & Safety Code Section 12000

- “Except as provided in Section 1206, no person, firm, partnership, association, corporation, or public agency shall operate, establish, manage, conduct or maintain a clinic in this state without first obtaining a license...” Health & Safety Code Section 1205
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- Types of licensed clinics:
  - Community clinic
  - Free clinic
  - Surgical clinic
  - Chronic dialysis clinic
  - Rehabilitation clinic
  - Alternative birth center
  - Psychology clinic
Types of clinics exempt from licensure:

- “...owed or leased and used as a clinic or office by one or more (physicians) ...”
- Clinics operated by the federal government
- Clinics operated by an Indian tribe on tribal land
- Hospital outpatient departments
- Licensed health facilities
- Freestanding clinical or pathology labs that are licensed
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- Clinics operated by an institution of learning that teaches a healing art that is approved by the state board or commission that regulates that healing art
- Clinics operated by community or free clinics separate from the licensed clinic and open for limited services no more than 20 hours per week
- Group practices primarily serving health plan members (Kaiser)
- Student health centers
- Nonprofit speech and hearing centers
“Foundations” which are tax exempt, conduct medical research and health education, and have 40 or more physicians who are independent contractors representing not less than 10 board certified specialties, not less than two-thirds of whom practice on a full time basis at the clinic.
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- In vivo diagnostic services by MRI or radiology (not cardiac cath)
- A community mental health center
- A clinic meeting specific requirements designed for a particular operator
WHAT IS THE PURPOSE OF AFFILIATION?

- Some examples:
  - Stability
  - Market driven (3rd party payor relationships)
  - Coverage

- Transfer of capital
  - Electronic medical records
  - Establish a clinic
  - Recruit physicians
  - Subsidize physician compensation
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

KEY LEGAL ISSUES

- Antitrust
  - Vertical price fixing
  - “Tying” arrangements
- Stark, AKS, Section 650
  - What is the nature of payment between hospital and medical group?
  - Can it be safe harbored?
- Tax
  - If the hospital is tax exempt, will there be inurement or private benefit?
Medical Practice Act
- “Administrative” corporate practice
- “Financial” corporate practice
- “Medical” corporate practice

Moscone-Knox Professional Corporations Act
- Restrictions on ownership and control
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

VARIATIONS ON THE STRUCTURE OF AFFILIATED MEDICAL GROUPS

“How friendly can we make a PC?”

Variation 1: MSA only
- No structural relationship between hospital and medical group
- Capital through FMV loans
- PSA safe harbored

Variation 2: MSA, plus:
- Hospital is exclusive contractor of medical group
- Hospital guarantees the budget of medical group
HOSPITAL – PHYSICIAN ALIGNMENT
AFFILIATED MEDICAL GROUP MODEL

- Change of ownership gives hospital the right to terminate exclusive contract
- No structural relationship between hospital and medical group.

Variation 3: MSA, plus:
- Exclusive contract with hospital
- Hospital guarantees budget
- Medical group shareholder is nominee of hospital

Variation 4: Same as Variation 3, except medical group is organized as a PC with dedication clauses in its articles to establish 501(c)(3) status
- Shareholder is a nominee of charitable trust assets
The Quality Imperative: Real-Life Solutions and Innovative Approaches to Improve Quality and Compliance

Janice Anderson, Partner, Foley & Lardner LLP
Shannon Dwyer, Sr. VP and General Counsel, St. Joseph Health System
Judy Ringholz, Healthcare Consultant, Huron Consulting Group
Cheryl Wagonhurst, Partner, Foley & Lardner LLP
The Quality Revolution

- Since the 1999 Institute of Medicine (IOM) report, *To Err is Human*, there has been an increased national focus on quality
- Quality of care is the top priority for health care entities in 2009
CMS’ Strategic Direction

- Incentivizing quality care through payment reform
- Driving quality of care through public reporting
- Enforcing quality of care through the False Claims Act
Update on Payment Reform
“I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem.”

Sen. Chuck Grassley,
Budget Hearing with Michael Leavitt
February 7, 2007
Building Blocks for Value Based Purchasing

- Pay for Reporting
- Pay for Performance
- Measure Resource Use
- Pay for Value (efficient resource use and quality)
- Align financial incentives
- Transparency and public reporting
- EHR, PHR and interoperability between payment and quality data

Hospitals, HHAs, SNFs, physicians and ESRD facilities are CMS priorities
The Hospital Quality Initiative

- The Hospital Quality Initiative was created in 2003 to improve quality of care through public reporting.
- Hospitals are required to report on quality measures to receive their full annual payment update (RHQDAPU and HOP-QDRP).
- 2% reduction in payment update for failing to report.
- Stimulus bill—penalty for failure to report increases to 25% starting in 2016.
Medicare Value Based Purchase Plan ("VBP")

- The Deficit Reduction Act mandated CMS to develop a “Value Based Purchasing Plan” for hospitals, and CMS issued its final report to Congress on Hospital VBP November 21, 2007
- The VBP will build on the RHQDAPU program
- Premier Demonstration Project supports VBP
Hospital Acquired Conditions

No Payment for Poor Quality

- Effective October 1, 2008, hospitals will not be paid for certain “hospital acquired conditions” unless Present on Admission

- CMS intends to extend policy to “Healthcare Associated Conditions” occurring in outpatient departments, physician offices and other settings
On January 15, 2009, CMS issued 3 NCDs to establish uniform national policies that will prevent Medicare from paying for certain serious, preventable errors in medical care

- Wrong surgical or other invasive procedures performed on a patient
- Surgical or other invasive procedures performed on the wrong body part
- Surgical or other invasive procedures performed on the wrong patient
OIG Adverse Event Reports

- Three New Reports issued by OIG in December, 2008 regarding research into “Adverse Events" in hospitals
  - Overview of key issues
  - State reporting systems
  - Case study of incidence among Medicare beneficiaries in two selected counties

- Reports required by Tax Relief and Health Care Act of 2006
OIG Adverse Event Reports

- Significant findings from OIG Adverse Event Reports
  - County Report suggests adverse event incidence rate much higher than previously thought
  - Overall positive view of policy to deny payment of adverse events as a means to prevent them
  - **Current structures not conducive to implementation of recommended practices**
Physician Quality Reporting Initiative

- PQRI is a voluntary program to provide financial incentives to “eligible professionals” who successfully report quality data to CMS.
- “eligible professionals” are physicians, mid-level practitioners, occupational therapists, speech-language therapists, and audiologists.
- Reporting only applies to measures applicable to the services rendered to Medicare beneficiaries.
- Reporting non-compliance also encouraged.
- E-prescribing incentive and PQRI each provide 2% bonus to eligible professionals in 2009.
Incentive payments for eligible professionals and hospitals

Incentivize adoption and meaningful use of EHR Technology
  - Use of electronic prescribing
  - To improve quality of care
  - For quality reporting

Penalties for failure to adopt and use EHR begin 2016 and can erode full update by 2018

$700 million in funding for “comparative effectiveness” research
Physician and Hospital Resource Use (PHRU) Work Group will develop efficiency measures and tools.

MIPPA requires CMS to implement program to provide confidential reports to physicians on resource use.


- P4P and sharing of cost savings.
- Year 2 – physicians earned $16.7 million in incentive payments.
Alignment of Financial Incentives

- Goal: Breakdown “silos” of Part A and Part B
- Acute Care Episode Demonstration Project – testing payments for “episodes of care” and allocate between physicians and hospitals
- Accountable Care Organizations (ACO) – collaboratives of physicians, hospitals and other providers that will be clinically and financially accountable for healthcare delivery. Could allow for competitive bidding, shared savings and P4P
- Gainsharing – Stark exception, 2 demonstration projects, and OIG approval
- OIG approves “pay for quality” model
Public Reporting
Public Reporting

Hospital Compare

- Consumer-oriented website to allow viewing of hospital performance on quality measures
- Contains process of care and outcome measures
- HCAHPS measures added in Spring, 2008
- Volume and price data added in Spring, 2008
- HOPQDRP data to be added by 2010
Hospital Compare

Graph 1 of 4

Percent of Heart Failure Patients Given ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction (LVSD)

The rates displayed in this graph are from data reported for discharges April 2006 through March 2007.

Average for all reporting hospitals in the United States: 83%

Average for all reporting hospitals in the State of Florida - Southern: 83%

Hospital A: 81%

Hospital B: 62%

Top Hospitals represents the top 10% of hospitals nationwide. Top hospitals achieved a 100% rate or better.
Hospital Compare: HCAHPS

Would patients recommend the hospital to friends and family?

These results are from patients who had overnight hospital stays from October 2006 through June 2007. The survey asked patients whether they would recommend the hospital to their friends and family.

Bars below tell the percent of patients who reported YES, they would definitely recommend the hospital.

Average For All Reporting Hospitals In The United States: 67%
Average For All Reporting Hospitals In Louisiana: 72%
HOSPITAL A: 75%
HOSPITAL B: 62%
## Hospital Compare: Payments

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<thead>
<tr>
<th>Hospital Information</th>
<th>Accredited</th>
<th>Provides Emergency Services</th>
<th>Hospital Quality Information</th>
<th>Pneumonia and Pleurisy in Adults With Complications or Preexisting Conditions (DRG 089)</th>
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<td>Hospital Process of Care Measures</td>
<td>Hospital Outcome of Care Measures</td>
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<td>Name, Address, Telephone, Type of Hospital and Distance</td>
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</table>

### Medicare Payment Range for Hospitals in the United States for this Diagnosis Related Group
- $5,241 - $6,415
- Total Number of Medicare Patients Treated in the United States for this Diagnosis Related Group: 470,498

### Medicare Payment Range for Hospitals in Louisiana for this Diagnosis Related Group
- $4,955 - $5,639
- Total Number of Medicare Patients Treated in Louisiana for this Diagnosis Related Group: 7,953

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Accredited</th>
<th>Provides Emergency Services</th>
<th>Hospital Process of Care Measures</th>
<th>Hospital Outcome of Care Measures</th>
<th>Survey of Patients’ Hospital Experiences&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Average Medicare Payment to Hospital</th>
<th>Number of Medicare Patients Treated&lt;sup&gt;b&lt;/sup&gt;</th>
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<td>HOSPITAL C</td>
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<td>$8,264</td>
<td>16 Medicare Patients</td>
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</table>

<sup>a</sup> Survey data not available for HOSPITAL A and HOSPITAL B.

<sup>b</sup> Number of Medicare Patients Treated includes patients from all states, not just Louisiana.
Expansion of Public Reporting

- Physician and Other Health Care Professionals Directory – posted 2007 PQRI participants
- CMS intends that 2009 PQRI will be reported publicly on “Physician and Other Health Care Professional Compare” website in 2010
- Successful e-prescribers to be included
Enforcement
Enforcement of Quality of Care

- The government uses a variety of legal theories under the FCA to attack quality failures, but all follow the same principle: **the government will not pay for medically unnecessary or substandard care**

- Physicians, executives, and board members face **real risks** for poor quality of care
Enforcing Quality of Care Through the False Claims Act

Six themes present in cases:
- Unnecessary treatment/procedures
- Kickbacks
- Big admitters receiving special treatment
- Fraudulent documentation
- Poorly structured, or failure to follow, internal process
- Underlying regulatory violations
## Enforcing Quality of Care Through the False Claims Act

<table>
<thead>
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<th>Traditional Theories</th>
<th>Quality of Care Theories</th>
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<tbody>
<tr>
<td>• Claims for services not rendered</td>
<td>• Express False Certification</td>
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<tr>
<td>• Unbundling</td>
<td>• Implied False Certification</td>
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<tr>
<td>• Claims for services not covered</td>
<td>• Worthless services</td>
</tr>
<tr>
<td>• Duplicate payments</td>
<td>• Criminal statutes</td>
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</table>
Use of Data Mining in Enforcement Actions

Data Mining

 Defined:

 Data mining is a technology that facilitates the ability to sort through masses of information through database exploration, extract specific information in accordance with defined criteria, and then identify patterns of interest to its user.

 Goals

 - Correct inappropriate behavior
 - Identify overpayments
 - Deny payment
“We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same.”

James G. Sheehan
Medicaid Inspector General, New York
February 6, 2007
OIG 2009 Work Plan

- 2 initiatives focused on quality of care
  - Reliability of quality reporting
  - Serious medical error
- Commitment to investigate health care fraud related to quality of care, i.e. billing for unnecessary services or for substandard care (“failure of care”)
- ROI – for 2008, recovered $17 for each $1 invested
Overcoming Obstacles to Quality of Care – Align Physicians and Hospitals
Hospitals need to enlist physician support to meet quality targets and earn the pay for performance incentive payments
- It is often difficult to enlist physician support by simply coaxing, cajoling, scolding, etc.
- Particularly true if you do not (or cannot) employ physicians

Physicians need to enlist hospitals to help with systems to drive quality across the continuum of care

CMS recognizes need for ACOs to reach goals of quality and efficiencies
Align Physicians and Hospitals

- Independent medical staff structure is not conducive to drive quality under new paradigm BECAUSE
  - Peer review/quality management is retrospective and often incident-based
  - No mechanism to standardize care processes or require evidenced based medicine

- Service Line Co-Management, Gainsharing and “Pay for Quality” are structures designed to align medical staff with hospital to achieve quality of care
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)
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
Service Line Co-Management
Direct Contract Model

Payors → Hospital → Service Line → Specialty Group I → Specialty Group II → Other Specialty Group (s)

- Facility
- Equipment
- Staff
- Hospital licensed
- Quality improvement process
- Clinical protocols
- Clinical oversight/enforcement
- Budget process
- Quality initiatives
- Strategic/business plans
- Other?

Designees

Operating Committee

Services contract
- Allocates effort and reward between groups
- Multi-party contract
Gainsharing

- Shared savings from identified activities to reduce costs
- OIG has approved multiple gainsharing models, all under the same structure
- CMS and OIG recognize importance of gainsharing as a component of VBP
  - Demonstration projects
  - New proposed Stark exception
- Guidance available to structure a program to meet hospital/physician needs
Gainsharing Model

Identifies cost savings opportunities, sets thresholds based on national benchmarks, monitors qualify of care

Cost savings initiatives may be product standardization, product substitution, “open as needed,” and others but cannot withhold or limit care

Shared cost savings from meeting initiatives

Implement cost savings initiatives
What is “Pay for Quality”?

- New legal entity to which medical staff members can join
- Hospital pays the entity (i.e. physician-owners) to meet quality targets. Includes a broad array of services necessary to achieve compliance
- Pay for Performance dollars may provide funding source
- Payments made based on achievement of targets (CMS quality indicators) set annually
- Preamble to new proposed Stark exception recognizes benefits to be achieved through quality incentive program
What is the Rationale for New Structure?

- National mandates for safety/quality and price transparency are difficult to meet without physician/hospital collaboration
- “Carrot vs. Stick” approach
- Pay for Performance ties reimbursement to achievement of quality outcomes
- Manage legal risk arising from quality of care (liability for failing to comply with evidence based guidelines, corporate liability; false claims liability for poor quality or unnecessary care, negligent credentialing)
What are the Benefits of New Structure?

- Integrate physician and hospital clinical practice to meet safety/quality goals
- Establish structure to provide quality across the continuum
- Standardize clinical practice
- Eliminate waste and reduce cost (may include gainsharing)
- Creates a financial “win/win” for physicians and hospitals, but keeps physicians and hospitals focused on their respective core business
How is “Pay for Quality” Structured?

- A new legal entity is created to which all physicians who have been on the active medical staff in relevant departments for at least one year can join.
- Each physician who joins pays an equal capital contribution to provide for the entity’s working capital.
- The physicians joining the entity commit to practice in compliance with certain quality targets established by CMS that form the basis for pay for performance awards under contracts with private insurers (and CMS in the future when Value Based Purchasing is implemented).
The entity contracts with the hospital to provide a variety of tasks and services to improve quality.

Payment to the entity is based on a percentage of pay for performance dollars earned by the hospital (up to 50%) and then distributed to the physicians on a per capita basis.
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- 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
Assessments to Enhance Quality and Compliance
Why are Assessments Critical for Hospitals Today?

- Quality is now the top compliance issue for hospitals today.
- Many hospitals are unaware of their compliance vulnerabilities related to quality because they have not subjected their quality of care processes to the same scrutiny they devote to other compliance concerns (i.e. billing/claims submission; physician financial relationships).
- OIG 2009 Work Plan emphasizes quality as an enforcement priority.
- Data Mining, RAC Medical Integrity Program and other government initiatives increase the risk of enforcement based on quality failures.
- Do you know where you may have risks?
The Foley/Huron Team

- Recognizing that Assessments to enhance quality of care require both legal/compliance and clinical/operational expertise, Foley and Huron have teamed together to develop a streamlined approach.
- Assessments must be done under Attorney/Client Privilege.
- The team is comprised of experts in healthcare regulatory and clinical/operational issues with a specific focus on the compliance risks raised by quality issues.
- The team can help organizations adjust structures and processes to address quality of care and compliance issues proactively to avoid costly and public enforcement actions.
What Does the Assessment Accomplish?

- Streamlined approach to assess quality controls and legal risks
- Looks at Medicare COP requirements, fraud and abuse risks, quality data reporting processes, HAC and Never Events compliance, Medical Necessity requirements and processes, OIG work plan, data mining, state Medicaid enforcement, etc.
- Bring together billing and quality issues and filter through compliance lens to provide global risk assessment and compliance endeavor
What is the Post-Assessment Process?

- The Assessment will identify specific areas of process gaps, quality control weaknesses and fraud and abuse risks (if any).
- The client will be in a position to develop a structured plan to address the issues.
- Results of the Assessment are immediately available.
- Foley and Huron are available to help with corrective action planning or implementation as requested.
Integrating Quality and Compliance

- Policies and education to address compliance risks associated with quality.

- Need to investigate compliance implications of quality failures. Reporting procedures need to be established. Be careful to maintain the privilege.

**SILO Approach**

**Integration**
Questions & Answers
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William L. Abalona is a partner with Foley & Lardner LLP. A member of the firm's Health Care Industry Team and the Public Affairs Practice, his practice is devoted largely to complex transactions, regulatory and legislative matters.

Mr. Abalona works with hospitals and integrated health systems on a variety of transactional and regulatory matters. He works extensively with hospital associations in policy, legislative and regulatory matters. His regulatory practice encompasses antitrust and anti-referral law counseling, licensing and state building permit issues for health facilities, and Knox-Keene Act filings on behalf of health plans. His transactional experience includes structuring and negotiating the private management of a city-owned hospital, handling a variety of sale/acquisition transactions and joint ventures involving clinics, advising on the conversion of a county hospital to private operation/management, and liquidating a captive off-shore insurance company. Mr. Abalona also has been lead counsel in the affiliation or merger of several nonprofit hospitals into large, integrated health care systems, and has created several types of physician-hospital organizations. He served as general counsel for a large, acute hospital for seven years. Most recently, he has helped to develop Foley's Public Affairs Practice Group in Sacramento. This practice group provides a full range of public affairs services to the firm's
clients, including legislative and administrative agency lobbying; public and media relations, policy analysis and issue management; and grass roots organizing. Prior to entering the practice of law, Mr. Abalona was extensively involved in health legislation. He served for more than eight years as a consultant to the California Assembly, principally as the health and welfare consultant to the Assembly Ways and Means Committee. In addition to serving as the Assembly’s main advisor in the formulation of the state’s health and welfare budget, Mr. Abalona was heavily involved in the development of significant legislation in the health field, including the Waxman-Duffy Prepaid Health Plan Act, the Knox-Keene Health Care Service Plan, the health planning legislation that created the certificate of need program, and a number of legislative initiatives to reform the medical program. After leaving the legislature in 1980, Mr. Abalona spent four years heading up the government relations program for the California Hospital Association prior to entering the private practice of law. Mr. Abalona is a graduate of McGeorge School of Law (J.D., 1978) and California State University, Sacramento (B.A., 1967; M.A., government, 1969). He was admitted to the California Bar in 1979.
Janice A. Anderson is a partner in the Health Care Industry Team of Foley & Lardner LLP with 25 years’ experience focusing on health regulatory and compliance issues and over 30 years’ experience working in the health care industry. Ms. Anderson is a participating member of Foley’s Business & Transactions, Payments, Compliance & Government Programs, Regulatory & Strategic Counseling and Medical Devices Focus Groups as well as a participant in a working group dealing with Medicare Reimbursement. She serves on the governing council of the Health Law Section of the State Bar of Michigan; is a member of the Michigan Health & Hospital Association’s Quality, Compliance & Patient Safety Committee; and is a member of the American Bar Association, the Health Care Compliance Association (HCCA) and the American Health Lawyers Association (AHLA). She is admitted to practice in both Illinois and Michigan. Ms. Anderson’s practice focuses on:

- Legal and regulatory compliance, including:
  - The development and implementation of corporate compliance programs
  - Legal/compliance risks, including enforcement risks arising from quality of care and patient safety issues
  - Stark, anti-kickback, HIPAA, EMTALA, False Claims Act, reimbursement, and civil money penalty laws
- Corporate health care and transactional law, including:
  - Mergers and acquisitions
  - Hospital/physician and other joint ventures
  - Physician relationships and contracting
- Development of health care business structures to achieve strategic goals
- Legal/regulatory issues arising in health care transactions such as certificate of need, licensure, tax-exempt status, reimbursement, etc.

- Medical staff issues, including:
  - Legal advice and counsel on medical staff and peer review structures
  - Development of medical staff bylaws and policy and procedures
  - Medical staff disciplinary procedures

- Clinical research
- Advising nonprofit governing boards on a wide range of issues, including those related to the proper discharge of their fiduciary obligations

Prior to joining Foley, Ms. Anderson was the general counsel, vice president and corporate compliance officer for Borgess Health, a regional health system comprised of eight owned or affiliated hospitals, where she also provided administrative oversight to several facilities and corporate service departments. In that position, she developed the first in-house legal department, led numerous merger and acquisition transaction teams, and created and implemented the Borgess Health Corporate Compliance program.

Articles/Publications/Presentations:

- Presented "Legal Issues in Quality of Care" for Patient Safety Audioconferences (January 2009)
- Co-authored "Hospital Systems Today - Valuable Integration or is it Time to Cut the Cord?," AHLA’s Health Lawyers News (October 2008)
- Presented "The Buck Stops with the Board - What the
Board Needs to Know About Quality of Care," for the Michigan Health and Hospital Association’s (MHA) 2008 Health Care Leadership Forum (October 2008)

- Presented "Patient Safety, Quality and Compliance - New Developments" for HCCA’s Quality of Care Compliance Conference (September 2008)
- Presented via booth on "Legal Issues in Quality of Care: Payments, Public Reporting, and Enforcement" at Harvard Quality Colloquium (August 2008)
- Co-authored "Legal Issues in Quality of Care: A Primer for Consultants, Experts," The Medical-Legal News (April 2008)
- Presented "Quality of Care: Transforming Health Care Through Payment Reform, Public Reporting and Enforcement" for HCCA’s Compliance Institute (April 2008)
- Presented "CMS Data Mining Implications" for HCCA’s Master Class in Hospital Reimbursement Compliance Web Conference Series (March 2008)
- Presented "Emerging Enforcement of Quality of Care and Compliance Solutions" for AHLA’s Physicians and Physician Organizations Law Institute (February 2008)
- Presented "Government Focus on Quality Compliance" for HFMA’s Colorado Chapter Compliance Law Conference (February 2008)
- Co-authored "High Quality, Efficient Care for Medicare Beneficiaries - But at What Cost?" HCCA Compliance Today (November 2007)
- Co-authored "Compliance and the Quality of Care Revolution: Fitting the Pieces Together in the Government’s New Enforcement Landscape," Health Lawyers News (September 2007)
- Presented "Grappling with the Reimbursement Implications Associated with Off-Label Medical Devices" at the American Conference Institute’s (ACI) Medical Device Pricing & Reimbursement in Chicago, Illinois (June 2007)
Presented "The Quality Revolution, Government Enforcement, and Compliance" at the Health Care Compliance Association (HCCA) Upper North Central Annual Conference in Detroit, Michigan (June 2007)

- Authored "The Board’s Fiduciary Role: Legal Responsibilities of Health Care Governing Boards" monograph published for the Center for Healthcare Governance (December 2006)

Ms. Anderson received her law degree, *summa cum laude*, from Michigan State University College of Law (1984) and earned a bachelor’s degree, *summa cum laude*, from the University of Detroit/Mercy in nursing (1973).
Larry Harrison was appointed Scripps Clinic Chief Executive in February 2003. Formerly, he was Chief Operating Officer of Scripps Clinic. He joined Scripps in 1998 and has been president of Scripps Clinic Health Plan Services, executive director of Scripps Physicians Medical Group, and executive director of the Scripps Medical Foundation.

Harrison is responsible for planning and managing the daily operations of Scripps Clinic. He directs the Scripps Clinic physician vice presidents and oversees the operations of all Scripps Clinic regional facilities, including the main facility at Scripps Clinic Torrey Pines. Additionally, he manages the Scripps Clinic departments of marketing and communications, patient appointment scheduling/training and health information/transcription.

Prior to joining Scripps, Harrison served as executive director of Cleveland Clinic Florida Health Network, where he was responsible for the redevelopment and implementation of contracting strategy. Prior to that, he was executive vice president of operations for Health Partners, Inc. in Norwalk, Conn., where he directed all clinical operations for multiple physician organizations. Harrison received a Masters of business administration from the University of Southern California, a Masters of health science from Johns Hopkins University and a Bachelor of Science in microbiology from Michigan State University.
Ms. Jacobs is a senior vice president with The Camden Group and has been with the firm since 1990. She has more than 25 years of experience in the areas of physician-hospital relationships, physician group development and management, performance improvement, healthcare strategic planning and marketing, physician compensation, and payer strategy.

She has assisted hospital and physician organizations throughout the country with strategic planning, operational assessment and performance improvement, and merger facilitation. She has led the strategic, financial, and operational redesign of medical groups, IPAs, and physician-hospital relationships. She has directed the strategic and business planning process for hospitals, medical groups, IPAs, academic practices, and integrated delivery systems. She has facilitated the development of integrated medical groups and IPAs, guiding the design of their structure, governance, strategy, and management. She has led the redesign of physician compensation and incentive structures for medical groups and faculty practice plans. She is a frequent speaker for hospital and physician groups regarding current trends in healthcare, payer strategies, consumer expectations, physician compensation, hospital-physician relationships, and optimizing performance.

Prior to joining The Camden Group, Ms. Jacobs held administrative positions at St. Vincent Medical Center and Orthopaedic Hospital in Los Angeles and Presbyterian Intercommunity Hospital in Whittier, California. She is the co-editor of Medical Group Management: Strategies for Enhancing Performance, and a Board Member of the Medical Institute of Little Company of Mary in Torrance, California.

Bachelor’s degree: Stanford University; human biology/public policy

Master of public health: University of California, Berkeley; corporate management
Dr. McEvoy is the Chief Executive Officer with Memorial Health Systems. Memorial is a 714-bed level II trauma center with three hospitals - Memorial Hospital Central, Memorial Hospital North and Memorial Hospital for Children in partnership with The Children's Hospital - and outlying clinical facilities throughout Colorado Springs, Colorado. Memorial is in the emerging phases of its transformation from a city hospital to a physician-led, patient-centered health system.

Dr. McEvoy is committed to producing patient-centered results with a mission aimed at restoring the energy and vitality to healthcare professionals. Larry’s perspective as an emergency physician and physician leader render him a powerful speaker, mentor, and healthcare strategist.

After earning a BA in English Writing from Carroll College (MT), Larry graduated from the Stanford University Medical School in 1992. He completed his training in emergency medicine at Hennepin County Medical Center in Minneapolis, MN, in 1995.

He is the Founder of Bedside Project, President and founder, Cove Canyon Grasslands, (a 3000-acre LLC dedicated to restoration of indigenous biodiversity and protection of open space) and an active coach of little leaguers.
SHIRLEY P. MORRIGAN

Shirley P. Morrigan is a partner with Foley & Lardner and has an A/V rating (the highest ranking possible) by Martindale-Hubbell. A member of the firm’s Health Care and Senior Living Industry Teams and co-chair of the Regulatory and Strategic Counseling Work Group, Ms. Morrigan represents hospitals, medical groups, integrated delivery systems, home health agencies, and skilled nursing facilities in matters relating to licensure, certification, accreditation, medical staff governance and patient care. Ms. Morrigan’s experience includes bylaws, credentialing, corrective action, hearings and appellate reviews, and writ of mandate proceedings at the Superior Court, Court of Appeal and California Supreme Court levels. Her practice also encompasses bioethics, consent, confidentiality, medical records, Joint Commission accreditation, Medicare certification and state licensure. She has defended numerous health care providers in actions taken by the Centers for Medicare and Medicaid Services to terminate Medicare certification.

In addition, Ms. Morrigan has lectured on a wide variety of topics, including bioethics, privacy, patient self-determination, informed consent, HIV/AIDS issues, the Emergency Medical Treatment and Active Labor Act, peer review, risk management, impaired health care professionals, and medical errors. She is currently a member of the board of directors for
the Los Angeles Free Clinic. She has previously served as a member of the board of directors of both the American Academy of Physician Assistants and the California Academy of Physician Assistants.

Ms. Morrigan's memberships include the Los Angeles County Bar Association (LACBA), the LACBA/Los Angeles County Medical Association Joint Committee on Biomedical Ethics, the California Society for Healthcare Attorneys, the American Society of Law Medicine and Ethics, the American Academy of Physician Assistants, and the California Academy of Physician Assistants. She serves on a variety of bioethics committees. She has been named a "Super Lawyer" by the publishers of *Law & Politics* and *San Francisco Magazine*.

Ms. Morrigan is a graduate of the University of Southern California Law Center (J.D., 1990), the University of California, Davis (M.H.S., 1979), Yale University School of Medicine (P.A., 1977) and Stanford University (A.B., 1974). She was admitted to the California Bar in 1990.
Charles B. Oppenheim is a partner with Foley & Lardner LLP and serves as co-chair of the 40+ lawyer Health Care Payments, Compliance & Government Programs Group. As a member of the firm’s Health Care Industry Team, his practice includes all aspects of transactional, operational and regulatory health care law, including acquisitions, joint ventures and integrated delivery systems. Among his clients are many of the largest health care companies in the United States. With a focus on fraud and abuse issues, he provides counseling on the anti-kickback and Stark laws, creates and implements compliance programs, investigates compliance issues, responds to government enforcement actions, and negotiates settlements for many types of health care providers. He also has substantial experience assisting managed care entities, including representing both health plans and providers in a variety of transactional and regulatory matters.

Mr. Oppenheim is a nationally recognized expert on Stark law issues, having written the 2008 American Health Lawyers Association (AHLA) monograph on Stark Law, the fourth (and latest) edition of a treatise he first wrote in 1998. Mr. Oppenheim has served as an expert on the Stark law and anti-kickback laws in arbitration and litigation, in both civil and criminal proceedings. He also lectures frequently on Stark law developments, as well as other health care law subjects and related
topics, to organizations including AHLA, HFMA and HCCA, and has recognized expertise in the evolving field of health care gainsharing.

Mr. Oppenheim has served as a guest lecturer at the UCLA School of Law and at the UCLA School of Public Health and was recently appointed to the Health Law Committee of the Business Law Section of the State Bar of California. He is a member of the California Society for Healthcare Attorneys, the American Health Lawyers Association, the Healthcare Law Section of the Los Angeles County Bar Association, and Executive Committee of the Editorial Board of the California Health Law News, and donates time and legal services to a number of Los Angeles charities. He is listed in Who’s Who in American Law and Who’s Who in America, was included in Guide to the Leading U.S. Healthcare Lawyers, has been named one of Los Angeles Magazine’s Southern California Super Lawyers and was honored as a medallion recipient at the 2001 National Philanthropy Day in Los Angeles for his volunteer work as chair of the finance committee and member of the board of trustees of The Accelerated School, a charter school in South Central Los Angeles.

Mr. Oppenheim is a graduate of Fordham University School of Law (J.D., 1988), where he was a member of the Fordham Law Review, and Cornell University (B.A., 1984). He was admitted to the California Bar in 1988.

Mr. Oppenheim has contributed to numerous publications, including:

• Co-author *Los Angeles Daily Journal*’s health law column
• Author of numerous health care articles published in *California Medicine*, and national publications such as BNA’s Health Care Fraud Report, *House Counsel Magazine*, *Journal of Health Care Compliance*, *Health Law Digest*, *Health Systems REVIEW*, *Inside Health Law*, and *Health Care Law Newsletter*
• Co-author *Physician Organizations and Medical Staff: Contracts, Rights & Liabilities*, published by Aspen Publishers, Inc.
• Author "Providers Are At Risk Under Many Purchase and Sale Arrangements" Vol. 7, No. 1, *Journal of Health Care Compliance* 37 (Jan./Feb. 2005)
Dr. Procci joined Cedars-Sinai in 1996 as the Vice President for Women's & Children's Services. In her current role as Vice President of Service Line Operations, she has full responsibility for the planning, growth and operational management of the programs and services provided in the departments of Medicine, Surgery, Pediatrics, Obstetrics & Gynecology, Radiation Oncology, Psychiatry, Rehabilitation, Emergency Medicine, Neurosurgery, Anesthesia, Heart Institute, and Samuel Oschin Cancer Institute.

Dr. Procci also serves on the Board of the American Psychoanalytic Foundation, is a past President of the Board of the Los Angeles Free Clinic, President of the Board of Wise and Healthy Aging, and is Co-Chair of the Building Campaign for the University of Wisconsin School of Nursing.

As a graduate of the University of Wisconsin, Bachelors and Masters programs in Nursing program, Dr. Procci started her healthcare career at LA County/USC as a pediatric clinical nurse specialist. Dr. Procci has a Doctorate of Philosophy in Education from the University of Southern California. At Good Samaritan Hospital in Los Angeles, Dr. Procci held numerous leadership positions including Chief Operating Officer.
Mark T. Schieble is a partner at Foley & Lardner LLP. He is a member of the firm’s Tax and Public Finance Practice Groups and its Health Care Industry Team. His practice encompasses both nonprofit and for-profit tax law. Representative matters include qualification and ongoing activities of tax-exempt organizations, tax-exempt finance, joint ventures, business reorganizations, employee benefit and deferred compensation arrangements, and real estate transactions. In addition to federal income tax matters, Mr. Schieble also routinely counsels clients on issues relating to sales tax, property tax and other state and local taxes. Mr. Schieble is a frequent speaker and writer on tax matters relating to health care organizations. He is a member of the Tax Section of American Bar Association, the National Association of Bond Lawyers, and the Bar Association of San Francisco. Mr. Schieble is a graduate of Temple University School of Law (J.D., cum laude, 1980), where he was associate editor of the Temple Law Quarterly, and the University of California, Berkeley (B.A., with honors, 1975). He was admitted to the Pennsylvania Bar in 1980 and the California Bar in 1984.
Daniel P. Stech, MBA, CMPE, Executive Director, Pinnacle Group

Mr. Stech is a health care business expert with 20 years of experience in settings ranging from the health policy arena and health services research to physician practice management, association management and technology development. His professional focus is on the advancement of health care organizations through analytical methods and the implementation of innovative improvement solutions.

Before joining the Pinnacle Group in 2006, he spent 11 years with the Medical Group Management Association where he held leadership positions in government affairs, consulting and from 2001 to 2006 was director of Survey Operations. He led numerous organizational initiatives, assisted countless physicians and practice management professionals in solving business problems and firmly established MGMA as the industry leader in physician performance data.

Dan’s background includes legislative service for a member of Congress where he specialized in issues related to health system reform, regulation and reimbursement. He earned a masters degree in business administration from Marymount University, and maintains a commitment to expanding his knowledge and skills through the continual study of health system change and industry movement. Dan is a board certified member of the American College of Medical Practice Executives where he is currently pursuing fellowship designation.
Cheryl Wagonhurst is a partner with Foley & Lardner LLP and she is a Certified Compliance and Ethics Professional (CCEP). She is a member of the firm’s Health Care Industry Team and the White Collar Defense & Corporate Compliance Practice, and focuses primarily on internal investigations, compliance, and health care regulatory matters.

Ms. Wagonhurst designs and implements compliance programs, including assessment of appropriate infrastructures, policy and procedure development, training, development of monitoring and reporting systems and processes. She has worked closely with government enforcement agencies and she has extensive experience in corporate integrity agreement design and implementation. She has conducted over 400 internal investigations and has participated in the negotiation of settlements with the Department of Justice and the Office of Inspector General. She has extensive experience in negotiating with the Center for Medicare and Medicaid Services (CMS) on a wide variety of issues. She has been instrumental in the development and implementation of a utilization review process (auditing and training) and other quality of care improvements for one of the largest hospital healthcare providers in the country.

Prior to joining Foley, Ms. Wagonhurst was the chief compliance officer at the second largest for profit hospital company in the United States. She designed and implemented one of the
largest compliance programs consisting of a multidisciplinary team of over 100 professionals nationwide and was also a member of their new senior management team. Ms. Wagonhurst also previously served as senior counsel on numerous legal and regulatory matters, including EMTALA, licensing, CMS and state surveys, fraud and abuse issues and Medicare/Medicaid billing requirements. She also has experience in managing complex civil litigation and government investigations.

Ms. Wagonhurst is a member of the advisory board of the Society of Corporate Compliance and Ethics and is a former member of the board of directors of the Health Care Compliance Association. She also serves on the editorial board of *Compliance Today* (Health Care Compliance Association) and the editorial advisory board of *Healthcare Auditing Strategies* (Hcpro, Inc.). She is a member of the American Health Lawyers Association, the American Bar Association, the California Bar Association and the State Bar of California.

Ms. Wagonhurst is a frequent lecturer and author on compliance programs, fraud and abuse issues, integrating quality of care and compliance, and internal investigations. Over the past decade, she has lectured at several national conferences for the Practicing Law Institute; the American Bar Association, the American Health Lawyers Association, the Healthcare Compliance Association, and the Society of Corporate Compliance and Ethics, and was recognized by *Nightingale Healthcare News* in "People to Watch - 2004 Healthcare Professionals Making Their Mark" and "Outstanding Healthcare Fraud & Compliance
Lawyers - 2008.

Ms. Wagonhurst is a member of the State Bar of California and is a graduate of the Whittier Law School (J.D., 1986), where she was a member and editor of the Whittier Law Review. She served as an extern to Judge A. Andrew Hauk, Chief Judge Emeritus, U.S. District Court, Central District of California. She earned her bachelor’s degree at the University of Minnesota (B.A., journalism, 1982).

Ms. Wagonhurst’s speaking engagements include:

- "Innovative Approaches to Improve Quality of Care," part of Foley’s Friday Focus Web Conference Series (November 3, 2008)
- "Emerging Enforcement of Quality of Care and Compliance Solutions," HCCA Quality of Care Compliance Conference, Philadelphia, PA (September 28, 2008)
- "Introduction to Compliance for Cities and Municipalities," SCCE 7th Annual Compliance & Ethics Institute, Chicago, IL (September 14, 2008)
- "Large Hospital & Health Systems" and "Governance, Leadership, and Quality: Moving the Whole Organization Forward," HCCA Compliance Institute, New Orleans, LA (April 14, 2008)
- "Quality of Care: An Enforcement Priority for Health Care Regulators," TAANA Teleseminar (December 4, 2007)
- "Business Ventures and Contracts in Healthcare," HFMA CFO Educational Program, Universal City, CA (November 14, 2007)
- "Emerging Enforcement of Quality of Care and Compliance Solutions," HCCA Quality of Care Compliance Conference, Philadelphia, PA (September 30, 2007)
- "OIG/AHLA Guidance for Boards on Quality of Care"
Oversight: What Your Board Needs to Know Today," HCCA Web conference (September 13, 2007)
- "Rethinking the Internal Investigation: What to do When General Counsel is in the Hot Seat," Corporate Wavelength Web conference (September 5, 2007)
- "Internal Investigations A - Z," HCCA West Coast Local Conference, Long Beach, CA (June 29, 2007)
- "Compliance: Government Enforcement of Quality: Merging Quality and Compliance," Honolulu, HI (April 3 - 4, 2007)
- "Quality of Care, Outcomes and Failure of Care," AHLA Hospital & Health Systems Law Institute, Las Vegas, NV (February 6-7, 2007)
- "Emerging Enforcement of Quality of Care," HFMA Region 11 Healthcare Symposium, Las Vegas, NV (January 30, 2007)
- "Quality of Care as an Emerging Fraud and Abuse Enforcement Issue," LEI 24th Annual National CLE Conference, Aspen, CO (January 7, 2007)
- "Tried and True Tips for Determining the Truth," SCCE 5th Annual Compliance & Ethics Institute Conference, Chicago, IL (September 12-13, 2006)
- Legal Panel Discussion HFMA San Diego/Imperial Chapter (May 18, 2006)
- "Industry Immersion Session: Hospitals and Large Health Systems," HCCA 10th Anniversary Compliance Institute, Las Vegas, NV (April 24-26, 2006)
- "Quality of Care and False Claims Act Liability," ABA 7th
Articles/Publications

- Co-authored, "Quality of Care and Compliance: Existing Challenges and First Steps for Hospitals," published in HCCA’s Compliance Today (October 2008)
- Co-authored, "CMS’ Special Focus Facility Initiative and Nursing Home Compare," published in HCCA’s Compliance Today (February 2008)
- Co-authored, "Compliance and the Quality of Care Revolution: Fitting the Pieces Together in the Government’s New Enforcement Landscape," AHLA’s Health Lawyers News (September 2007)
• She recently completed a chapter titled "Emerging Government Enforcement for Quality of Care," *2007 Health Law and Compliance Update*
• Co-authored, "Government Enforcement of Quality: Merging Quality and Compliance," published in HCCA’s *Compliance Today* (November 2006)
David V. White, MBA, Executive Director,
Pinnacle Group

Mr. White’s professional focus has been geared toward building stronger provider relationships and identifying shared opportunities for healthcare businesses. David has over 17 years experience in health organization management and consulting.

His areas of expertise include new business development, health services valuation and financial analysis, healthcare market research (population based analysis), medical staff partnership planning, and physician practice management consulting.

David has worked with hospitals, physicians, health plans, publicly traded healthcare companies, pharmaceutical companies and medical device companies across the country. He is passionate about making positive change in the healthcare industry. He holds a BS, University of Colorado, Boulder and a MBA with an emphasis in Healthcare, Cleveland State University.
Meet

Linda Donoghue
Chief Nursing/Operating Officer, Jewish Geriatric Services

The Economy!

By Roy Snell, CEO, HCCA

OIG ISSUES GREEN LIGHT TO HOSPITAL “PAY FOR QUALITY” ARRANGEMENT

HCCA is going green
HCCA conference attendees will NOT automatically receive conference binders. If you would like to purchase conference binders, please choose that option on your conference registration form. Attendees will receive electronic access to course materials prior to the conference as well a CD onsite with all the conference materials.
Affinity Group Meetings

Hold your own meeting in conjunction with HCCA’s 2009 Compliance Institute!

Planning on attending the Compliance Institute? Need to hold a meeting of your own? Affinity group meetings are now available in conjunction with the Compliance Institute.

Not only do you get the benefit of holding your meeting alongside the most comprehensive compliance conference for compliance professionals, but you also receive complimentary meeting room space at the conference site, your choice of a complimentary continental breakfast or an AM or PM break, and registration at the HCCA Member rate for your attendees.

Affinity Group Meetings may be held on one of the following days:

Saturday, April 25, 2009
Wednesday, April 29, 2009 (afternoon)
Thursday, April 30, 2009

To apply, please visit www.compliance-institute.org (conference tab) and fill out the Affinity Group Meeting form. Please return the completed form to the HCCA office.

Questions? Contact Beckie Smith at 952.405.7913 or email her at beckie.smith@hcca-info.org

OIG issues green light to hospital “Pay for Quality” arrangement

By Janice A. Anderson, Richard K. Rifenbark, and Anil Shankar

Editor’s note: Janice A. Anderson is a partner in Foley and Lardner, LLP in Chicago. She is a member of the Health Care Industry Team with 25 years’ experience focusing on health regulatory and compliance issues and over 30 years’ experience working in the health care industry. She may be contacted by phone at 312/832-4500 or by e-mail at janderson@foley.com.

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Anil Shankar is an associate with Foley & Lardner LLP in Los Angeles, California, and is a member of the firm’s Health Care Industry Team. He may be reached by phone at 213/972-4584 or by e-mail at ashankar@foley.com.

This is the fourth in a series of articles by Foley & Lardner LLP published in Compliance Today designed to address the compliance risks associated with quality of care in the hospital setting.

In Advisory Opinion 08-16, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services approved, for the first time, a hospital program to pay physicians for achieving quality of care by sharing the financial benefits received by the hospital through pay-for-performance (P4P) programs offered by third-party payers. This P4P arrangement allows hospitals to align financially with their medical staffs to drive quality of care improvements at the hospital.

The approved arrangement consists of a Quality Enhancement Professional Services Agreement (Agreement) between a hospital and a physician-owned professional limited liability corporation (PLLC), which all active staff members in relevant departments can join after they have worked at the hospital for more than one year. Under the Agreement, physicians who participate in the PLLC will commit to practice in compliance with hospital quality targets and will provide specific quality-related services to the hospital in order to improve the quality of care provided to the hospital’s patients. These services include:

- developing policies and procedures,
- reviewing and monitoring quality of care in the hospital,
- providing care in accordance with hospital quality targets,
- ensuring adequate peer review if quality targets are not achieved, and
- auditing medical records to track compliance with quality activities.

In exchange for these services, the hospital will pay the PLLC (which then distributes the payment(s) to the member physicians on a per capita basis) a percentage of the P4P award received by the hospital for achieving specific quality targets established by the payer under a P4P incentive plan. This arrangement permits the physicians to participate in the proceeds received by the hospital for providing high quality care, which benefits the hospital, physicians, and patients.
The importance of alignment

The approved P4P arrangement comes at a time when trends in health care reimbursement and regulation underscore the need for new business models that align the financial incentives of hospitals and physicians. Today, the relationship between hospitals and physicians is often marked by distrust, conflicts of interest, and the erosion of the belief in mutual dependence. Historically, hospitals and physicians operated symbiotically, with physicians relying on hospitals as a place to provide services to their patients, and hospitals relying on physicians to refer and care for patients. Declining reimbursement and increasing costs, however, have led many physicians to compete directly with the hospital for business, for example, by owning and operating ambulatory surgery centers or imaging centers. These efforts by physicians to bolster income often increase the financial strain on hospitals and can place the hospital and its physicians in direct competition.

The advent of P4P as a dominant trend in health care reimbursement makes alignment with physicians a business necessity for hospitals. P4P programs reward hospitals that meet target quality metrics, and high scores on these metrics are necessary for hospitals to remain competitive in markets where P4P dominates. High scores, however, are almost impossible to achieve without the full cooperation of the medical staff. Physicians must cooperate with the hospital by providing care in accordance with the targets for the hospital to succeed. The misalignment occurs because hospitals receive the P4P payment, yet physicians must be the ones to earn it.

Medicare has announced its intent to move to a P4P payment methodology called Value Based Purchasing (VBP). The Centers for Medicare and Medicaid Services (CMS) was charged by Congress to reform its payment methodology when the Deficit Reduction Act was passed in 2005. CMS spent 2007 developing its VBP model by holding industry listening sessions, and CMS submitted to Congress a final report describing the program on November 21, 2007. On September 25, 2008, the Quality FIRST Act was introduced for the purpose of implementing many of the principles of VBP recommended by CMS. Notably, the Act would begin paying hospitals for their performance on quality targets in four specified conditions currently reported to CMS (i.e., acute myocardial infarction, heart failure, pneumonia, and surgical care improvement and infection prevention) in 2011 based on the hospital’s 2010 data. This means that hospitals will be paid based on performance beginning with data generated on or after October 1, 2009, the beginning of the government’s 2010 fiscal year. The Act further phases in the amount at risk based on performance. For 2011, the amount is 0.5% of Medicare payments, with graduated increases until a full 2% of Medicare payments are based on performance.

As the government focuses on quality to drive its payment policies, regulators are more willing to hold providers accountable for unnecessary or poor quality care. As a result, quality has become a top compliance issue for hospitals and other health care providers. Today, quality-of-care violations are often enforced under the False Claims Act, resulting in multi-million dollar payments to the government for alleged substandard quality of care and unnecessary procedures. The 2009 OIG Work Plan highlights the fraud and abuse risks associated with quality and has identified two specific enforcement initiatives focused on quality of care: a review of the reliability of hospital reported quality measurement data and a review of incidence of, and payments for, serious medical errors or “never events.” The serious compliance risk based on quality of care cannot be managed appropriately by hospitals unless the medical staff is engaged to develop and implement quality improvement for the care delivered at hospitals.

Advisory Opinion 08-16 describes a business model that addresses these adverse trends by creating an opportunity for the hospitals and a broad group of physicians on the medical staff to align financial incentives to achieve common interests around quality. Unlike other physician/hospital alignment strategies of the past, the “Pay for Quality” structure creates a win/win for hospitals and the physicians. For hospitals, the active alignment of physicians around quality allows hospitals to perform better under P4P methodologies, thus maximizing payment for care delivered to patients. For physicians, sharing in the P4P awards with hospitals allows physicians to supplement declining reimbursement by cooperating, instead of competing, with the hospital.

The approved P4P arrangement successfully aligns the interests of the hospital and participating physicians. By sharing the financial rewards for achieving quality metrics with physicians, the hospital shares the incentive to maintain high levels of compliance with specific quality standards. Moreover, the structure encourages physicians to take the lead in developing and policing the methods to be used to ensure quality compliance. Although physicians are under no obligation to join the arrangement, the physicians who do have strong incentives for encouraging non-participating physicians to meet the quality metrics, because P4P awards are tied to the hospital’s overall performance outcomes, not the participating physicians’. Participating physicians thus have a vested interest in encouraging the recommended medical practices and in engaging in meaningful peer review. These incentives place physicians in the lead in ensuring quality of care.

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Hospitals that have a structure in place to align physician performance around quality will have a marked advantage in seeking out additional P4P programs from payers and attracting business to the hospital. The Medicare demonstration projects focusing on P4P have proven that the programs can generate significant savings, creating a large pool of dollars to share with providers. Hospitals that have a structure in place to achieve top performance under P4P will be significantly advantaged, because they can seek out P4P contracts with third-party payers and know that they can perform well under them. Thus, both physicians and hospitals are likely to perform well under the arrangement, increasing revenue while maintaining focus on their respective core business.

For the same reasons, the arrangement provides the added bonus of minimizing the compliance risks for both hospitals and physicians now associated with quality of care. By providing a structure in which hospitals can engage physicians proactively to improve quality, hospitals can avoid costly public enforcement actions based on quality failures.

Structuring the P4P arrangement

Although there are clear benefits to structures that align the incentives of physicians and hospitals to improve the quality of patient care, such as the P4P arrangement reviewed in Advisory Opinion 08-16, these structures must comply with federal health care fraud and abuse laws, including the Civil Monetary Penalty Law (CMPL),\(^6\) federal Anti-kickback Statute,\(^7\) and federal Physician Self Referral law (commonly referred to as the Stark laws).\(^8\)

The CMPL prohibits hospitals from knowingly making payments directly or indirectly to physicians as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician’s direct care. Violations of the CMPL are punishable by monetary penalties of $2,000 per patient.

The federal Anti-kickback Statute prohibits any person from “knowingly and willfully” paying, offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service covered by a federal health care program, or in exchange for arranging for or recommending purchasing, leasing or ordering any good, facility, service or item covered by a federal health care program, including Medicare and Medicaid. Violation of the Anti-kickback Statute is punishable by a $25,000 fine or imprisonment for up to five years, or both; may subject a violator to civil monetary penalties; and results in exclusion from participation in the Medicare and Medicaid programs.

Stark prohibits a physician from referring Medicare beneficiaries for designated health services, including inpatient and outpatient hospital services, to entities with which the physician has a financial relationship (and prohibits billing for services provided pursuant to such a referral), unless an exception applies. Violations of Stark may result in penalties that include denial of payment, civil monetary penalties of up to $15,000 per service (and $100,000 for schemes that are designed to circumvent Stark), and exclusion from the Medicare and Medicaid programs.

Although OIG found that the Agreement does raise issues under the CMPL and the Anti-kickback Statute,\(^9\) the parties included several safeguards designed to reduce the risk of federal health care program abuse:

- First, only physicians who have been members of the hospital’s active medical staff for at least one year are eligible to become owners of the PLLC; a requirement intended to reduce the risk of physicians joining the medical staff of the hospital (and moving their patients there) in order to join the PLLC and participate in the potential quality-bonus payments.
- Second, the physician owners of the PLLC receive distributions on a per capita basis; no payments are made to induce patient referrals to the hospital.
- Third, the payments by the hospital to the PLLC are capped, based on historical activity levels of the payer(s) at the hospital (adjusted for inflation) to ensure that physicians are not provided a financial incentive to refer additional patients to the hospital.
- Fourth, the hospital will provide written disclosure of its arrangement with the PLLC to its patients.
- Fifth, the hospital will monitor both the quality of care provided and the volume and case mix of its patients to ensure that the financial rewards of the program do not reduce quality or inappropriately change referral patterns of the physician participants.
- Finally, the quality targets that can be incentivized under the program without raising the need for further analysis by the OIG are limited to those listed by CMS and the Joint Commission in the Specifications Manual for National Hospital Quality Measures, which represents the consensus of the medical community as to the appropriate standard of care.

The OIG deemed these safeguards sufficient to approve the P4P arrangement, and they can serve as a guide for future arrangements as well. The OIG’s approval of the P4P arrangement demonstrates a willingness to allow hospitals to pursue this promising method of aligning hospitals and physicians so that they can better work together to drive quality of care improvements.

As to Stark compliance, there presently exist Stark exceptions that can be utilized when
structuring a Pay for Quality arrangement. The fair market value, personal services, and indirect compensation exceptions all can be considered when structuring this type of physician alignment strategy. When CMS finalizes its proposed new Stark exception for shared savings and incentive programs, another more detailed exception also may be available to allow Stark compliance for this type of arrangement.

Although the OIG approved the P4P arrangement in Advisory Opinion 08-16, there are limitations on the reach of the OIG’s Advisory Opinion. First, the OIG’s approval extends only to those parties who submitted the OIG Advisory Opinion request, and, technically, only they may rely on it. This means that parties seeking to replicate the P4P arrangement should consider whether to pursue their own Advisory Opinion. Legal counsel should be consulted to assist in making that determination.

Second, the OIG Advisory Opinion does not analyze the P4P arrangement under Stark or under state fraud and abuse laws, which must also be considered when entering into financial relationships with physicians. As a result of these limitations, manifestations of this model must be structured carefully with the advice of legal counsel to survive regulatory scrutiny.

Conclusion
The primary benefit of the P4P arrangement is that it will likely improve quality of patient care by sharing the rewards for high quality care with the medical staff that are primarily responsible for delivering it, and who are better suited to initiate, innovate, or carry out required actions. The OIG Advisory Opinion recognized that some of the actions proposed by the P4P arrangement could conceivably violate fraud and abuse laws; its decision not to seek enforcement of these literal violations expresses an understanding of the importance of hospital/physician alignment around quality in the modern health care industry. By providing a structure that financially rewards hospitals and physicians for working together to raise the quality of care at a hospital, the P4P arrangement should benefit hospitals, physicians, and patients alike.
Hospital-Physician Alignment Models in California

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INTRODUCTION

Discussions of the long-term success of California's health care industry have increasingly emphasized the need for greater hospital-physician alignment. At its core, the idea of alignment refers to the ability of hospitals and physicians to pursue common goals while limiting conflicts of interest, lack of trust, or other impediments to success. Whether to increase alignment, how, and to what extent, is a business decision for both hospitals and physicians. This article presents six alignment models available in California's unique marketplace and regulatory regime, and describes the advantages and legal considerations for each.

INCENTIVES FOR ALIGNMENT

The recent emphasis on hospital-physician alignment coincides with the increasing financial pressure on both hospitals and physicians. Historically, hospitals and physicians have shared a mutually beneficial relationship, with hospitals relying on physicians to refer patients and perform professional services, and physicians relying on hospitals to furnish the space, equipment, and personnel necessary for them to provide their professional services. Declining reimbursement and growing consumerism among patients have led many physicians to seek opportunities which directly compete with hospitals, straining this relationship, even as shifts in reimbursement and regulation have encouraged hospitals and physicians to collaborate.

These trends have occurred nationwide, but are exacerbated by the pinch of California's highly competitive health care market. California's low Medicaid reimbursement, high cost of living, and significant population of uninsured patients create pressure on hospitals and doctors to pursue their separate financial incentives. Physicians seeking to offset their declining reimbursement have begun to set up outpatient clinics and ambulatory surgery centers that directly compete with local hospitals for business. This competition may undermine the willingness of physicians to refer to the hospital and make them less likely to serve on necessary emergency call coverage panels, provide management or oversight functions for the hospital, or otherwise assist the hospital with meeting its goals.

The decline of a mutually beneficial relationship harms both hospitals and physicians, as well as patients. The long term success of the industry depends upon finding adequate room for both to thrive. Physicians cannot provide the full continuum of health care without the resources and assistance of hospitals, which provide facilities, management expertise, and access to resources and infrastructure that can promote efficiency and reduce cost. Most physician groups simply cannot competitively emulate the information technology systems or staff training programs of hospitals. Similarly, hospitals need physicians to deliver care and refer patients to their facilities.

Other trends in reimbursement and regulation have also created substantial incentives for cooperation. One emerging trend in hospital reimbursement is the pay-for-performance movement, which rewards providers that meet target quality metrics. Achieving consistently high scores on quality measurements is almost impossible without the assistance of the medical staff. Regulators have also begun aggressively pursuing quality-of-care violations through regulatory tools like the False Claims Act, potentially exposing hospitals to enormous financial risk if poor quality or medically unnecessary services are provided by physicians at their facilities. These movements connect hospital finances with the quality of services provided by physicians, making business models that provide opportunities and incentives for hospital-physician collaboration on quality initiatives a business necessity in competitive markets.

In addition, hospitals and physicians have much in common and share many goals. Both are adversely affected by increasing shortages of physicians in many specialties, and are challenged to recruit and retain physicians to practice in communities throughout California. Both are facing greater regulatory and administrative burdens, and have the need to invest substantial sums to maintain, upgrade and replace medical equipment and information technology, including electronic medical record systems. Often it is by joining forces that hospitals and physicians can best overcome these challenges and achieve their common goals.

GOALS OF ALIGNMENT

A well-crafted alignment model can bring together some of the financial incentives of hospitals and physicians. Alignment creates opportunities for hospitals and physicians to pursue common goals and values, allowing their mutual expertise to develop innovative solutions to common problems.
An effectively aligned business model should promote the following goals: (1) align the financial incentives of the hospital and the physician; (2) provide a means for physicians to supplement declining reimbursement; (3) keep physicians and hospitals focused on their core businesses; (4) integrate clinical practices to meet quality and safety goals; and (5) standardize work processes and simplify documentation.

Complete alignment may be neither possible nor desirable. The six models described below provide varying kinds and degrees of integration. Which model, if any, is most beneficial depends on situational factors and a priority among goals. In addition, each model raises specific legal issues which affect the implementation and operation of the model.

LEGAL LIMITATIONS

California’s strong corporate practice of medicine prohibition is the starting point for any discussion of the legal challenges to hospital-physician alignment in the state. Originally designed to protect the practice of medicine from inappropriate influence and commercial exploitation by non-physicians, the doctrine mandates the separation of the business models of hospitals and physicians. Unlike most states, California generally prohibits hospitals from employing physicians, eliminating the simplest method of integrating hospitals and physicians and aligning their financial interests. The prohibition of direct employment preserves the independence of physicians and their judgment when providing care, but frustrates attempts to encourage cooperation on financial and operational matters. Accordingly, some of the business models described below create structures intended to approximate an employment relationship while maintaining the legal separation of hospital and physician.

Federal and state fraud and abuse regulations also shape the contours of these models. Financial relationships between hospitals and the physicians who refer to them may generate scrutiny under federal and state prohibitions on kickbacks and self-referrals. Numerous exceptions and “safe harbors” to these laws exist, but the financial arrangements described below must be structured carefully to meet these exceptions, as and when necessary. Other laws can also be implicated in hospital-physician alignment, e.g., antitrust laws and the laws governing tax-exempt organizations, depending on the parties to the transaction and its nature.

HOSPITAL-PHYSICIAN ALIGNMENT MODELS

1. AFFILIATED PROFESSIONAL CORPORATIONS

In states that allow hospitals to employ physicians, hospitals have increasingly turned to direct employment to encourage hospital-physician alignment. The affiliated professional corporation model allows hospitals in California to approximate this relationship by creating an “affiliated” professional corporation that can employ physicians.

In this model, a physician is selected to serve as the sole shareholder of the affiliated professional corporation (PC). In many cases, this physician is an executive or medical director of the hospital. The hospital, the physician shareholder and the PC then enter into a shareholder agreement in which the physician agrees to seek the approval of the hospital before taking certain actions for the PC, such as declaring dividends or transferring ownership. The PC enters into employment agreements with one or more physicians. In addition, the hospital and the PC may (i) enter into a Medical Director Agreement with the physician owner, (ii) contract with the PC to obtain professional services and coverage from the employed physicians, and (iii) contract for the hospital, or a management company affiliated with the hospital, to provide management services to the PC. These contracts grant the hospital some limited control over the operation of the PC’s business. The PC’s employed physicians continue to provide medical services, but can offload certain management, marketing, and acquisition of capital functions to the hospital, thus allowing them to spend their time seeing patients instead of focusing on the business and operational side of a medical practice.

The affiliated PC model is a relatively simple and potentially efficient method of achieving hospital-physician alignment. The model depends upon physician willingness to agree to the arrangement, in which the physicians may surrender some control over business relationships to the hospital. However, many physicians are attracted to the relative simplicity of the relationship, which frees them from administrative headaches and allows them to focus on providing care to their patients. Hospitals may also provide financial support to the PC for hospital-based physician coverage, thus removing some financial risk from the physicians.

This model is faster and less expensive to develop than other models, and does not require additional regulatory approval or licensure. Relevant costs include forming the PC, securing Medicare and Medicaid supplier numbers, and obtaining professional liability insurance. The minimum number of physicians required for the PC is one, so the model may operate even on a small scale.

Although the affiliated PC model has many advantages, it also has certain potential drawbacks. As discussed below, although the model is common throughout California, it is relatively untested under the corporate practice of medicine doctrine, and thus the degree to which a court would be willing to enforce restrictions in the shareholder agreement against the physician shareholder remains uncertain. Also, despite some recent leniency in the federal physician self-referral regulations, it is also unclear whether a hospital can permissibly subsidize an affiliated PC’s losses in its private medical office locations (as opposed to subsidizing the PC’s losses incurred providing physician services at the hospital, which generally is considered permissible, assuming fair market value compensation and other requirements are met).
a. Corporate Practice of Medicine

California's corporate practice of medicine doctrine forbids unlicensed individuals or entities, including hospitals, from interfering with or influencing a physician's professional judgment. The doctrine has been expansively applied in court decisions and opinions of California's Attorney General, and generally forbids direct employment of physicians by lay entities (including hospitals) as well as arrangements that give a lay individual or entity excessive control over the physician's practice. When courts find that an arrangement violates the corporate practice of medicine doctrine, they may refuse to enforce it, and may enjoin the continuation of the conduct.

The limits imposed by the corporate practice of medicine doctrine remain uncertain in the context of affiliated PCs. Shareholder agreements that provide corporate control over core aspects of the practice of medicine, such as the prescription of drugs, ordering of diagnostic tests, or establishment of treatment protocols, are presumably impermissible. On the other end of the spectrum, contracts to provide administrative services or "back office" functions such as billing and collection or patient record storage systems clearly do not constitute unauthorized practice of medicine. In between are a host of issues that remain untested, including control over hiring of staff, setting hours of physicians may work and productivity targets, and decisions to purchase equipment, as well as restrictions on the shareholder's rights to sell his/her shares or take other corporate action.

In 1993, the California Medical Association published a document that describes the core interests of physicians in maintaining professional autonomy and distinguishes between interests physicians must have sole control over, those which hospitals may perform, and those which should best be pursued jointly. This document provides some practical guidance, although it is not legally binding. In spite of the potential risk generated by this uncertainty, affiliated PC models are fairly common in California.

b. Anti-Kickback Statutes

The financial relationship between the hospital and the affiliated PC may raise concerns about illegal kickbacks. The federal anti-kickback statute prohibits knowingly and willingly offering or receiving remuneration, directly or indirectly, in exchange for or to induce referrals of patients for which payment can be made under a federal health care program. The statute has been interpreted expansively to include any kind of compensation, and to apply so long as one purpose of the compensation is to induce referrals. Violation of the statute is punishable by a $25,000 fine and up to 5 years imprisonment, may subject the violator to civil monetary penalties, and is grounds for exclusion from participation in the Medicare and Medicaid programs. The statute and accompanying regulations contain several "safe harbor" provisions that, if met, guarantee compliance with the statute. Failure to meet the safe harbor provisions, however, does not mean the arrangement violates the law.

California also has fraud and abuse laws that are somewhat comparable to the federal anti-kickback statute. For example, one statute prohibits licensed health care professionals from offering, accepting, or receiving consideration (in the form of money or otherwise) as compensation or inducement to refer patients, clients or customers. This provision is broader than the federal statute, for it applies to patient referrals irrespective of the payor, whereas the anti-kickback statute regulates only referrals of patients whose bills are paid by government health care programs, such as Medicare and Medicaid. California's statute does not contain regulatory safe-harbors, but does include several broad statutory exemptions, such as the payment of fair market value compensation for services other than the referral of patients. Violations of the provision are criminal offenses punishable for first-time offenders by up to one year in jail or fines up to $50,000. In addition, civil actions can be undertaken by California's Attorney General seeking

2 See, e.g., San Joaquin Community Hospital v. San Joaquin Valley Medical Group, 2004 Cal. App. Unpub. LEXIS 5957 (Cal. Ct. App. 2004) (disapproving of an affiliated PC model under corporate practice prohibition). Although this case is unpublished, and thus may not be cited or relied on in any action or proceeding (except in very limited circumstances), it potentially offers insights into how a court might view these types of arrangements.
4 42 U.S.C. § 1320a-7(b).
6 42 U.S.C. § 1320a-7(b).
7 42 U.S.C. § 1320a-7(b)(3); 42 C.F.R. § 1001.952.
9 Cal. Bus. & Prof. Code § 650(g).
injunctions to stop any payments for referrals. Generally, steps necessary to ensure compliance with the federal anti-kickback statute will also mitigate risk under California’s equivalents.

The financial arrangements between the hospital and the physicians in an affiliated PC will generally constitute remuneration under the anti-kickback statute and the California equivalents. Thus, each agreement should be scrutinized individually, including any contracts for medical coverage, leases of space or equipment, or contracts for management services. To minimize the possibility of sanctions under the statutes, these arrangements generally should be consistent with fair market value, commercially reasonable, and not take into account referrals or other business between the parties. Compliance with additional requirements may potentially ensure these arrangements fall within a federal safe harbor.

Many hospitals in the affiliated PC model provide some type of financial support or subsidies, or guarantee the collections in the PC. While it is generally believed that hospitals may guarantee collections of the PC for hospital coverage by the PC’s hospital-based physicians (to the extent consistent with fair market value, etc.), these guarantees raise different, and greater concerns as applied to the PC’s provision of medical office-based physician services. Because the hospital has no direct financial stake in the operations of physicians performing outside the hospital, the physicians’ services in a private medical office do not necessarily or directly benefit the hospital or its patients. As such, the attempt to shoulder some of the financial risk of the physicians in a private office setting could potentially be viewed as exceeding the fair market value of the services to the hospital, and could generate greater scrutiny under both federal and California fraud and abuse law.

On the other hand, it could be argued that if the PC’s physicians only “remuneration” is in the form of fair market value compensation from their employer (the PC), then their compensation may qualify for the employment safe harbor under the federal anti-kickback statute, and ought to be low risk under California’s equivalents. Under this line of reasoning, because the hospital is permitted to provide a broad range of health care inside and outside of its acute facility, it should be permitted to facilitate the delivery of complementary physician care in the community, through an affiliated PC, without regard to the setting where the care is delivered (i.e., hospital outpatient department or medical office), so long as any remuneration received by the physicians is neither excessive nor linked to their referrals to the hospital.

**c. Self-Referral Laws**

The federal physician self-referral act (commonly known as “Stark”) also may apply to the financial relationship between hospitals and an affiliated PC. Stark prohibits physicians from referring Medicare patients to a hospital with which they have a financial relationship, unless the arrangement fits within an exception. Hospitals in the affiliated PC model often engage in contractual relationships related to the leasing of equipment or space or the provision of management services, and may subsidize the physicians’ services to hospital inpatients or outpatients through compensation paid in physician services agreements. These relationships may constitute remuneration under Stark, in which case an exception must be satisfied if the physician will refer any patients to the affiliated hospital.

Recent changes to the Stark regulations provide favorable treatment for hospitals in the affiliated PC model. To understand the benefits of these changes, one must step back and look at how Stark applies to physician compensation arrangements generally. As a starting point, Stark divides compensation arrangements into two kinds, direct and indirect. A direct compensation arrangement is one in which compensation passes directly between the referring physician and the entity to which she refers. An indirect compensation arrangement involves compensation that passes through one or more intermediate entities interposed between the referring physician and the entity receiving referrals. When an indirect compensation arrangement exists, the parties can use the indirect compensation arrangement exception, which is more streamlined and easier to satisfy than most “direct” compensation arrangement exceptions. However, not all such indirect arrangements create a financial relationship under Stark. Depending on how the physician is compensated, and other factors, such arrangements may not even meet the definition of a financial relationship, and no Stark exception is even needed.

Starting in 2007, CMS has sought to limit use of the indirect compensation arrangement construct, by providing that physician owners of a medical practice or other physician organization may not use it when the physician organization contracts with an entity to which the physicians refer. Instead, the physician owners must “stand in the shoes” of their physician organization, are deemed to have whatever direct compensation arrangements the physician organization has, and thus must satisfy the more rigorous direct compensation exceptions.

However, CMS issued a rule which created an exception to the “stand in the shoes” concept for physicians whose ownership interest in a PC is titular only. This rule went into effect on October 1, 2008. A titular ownership interest is one that does not confer the ability or right to receive

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the financial benefits of ownership, such as the distribution of profits, proceeds of sale, or similar returns on investment. The exception was crafted with the affiliated PC model in mind, and allows physicians who own a PC under the affiliated PC model to not stand in the shoes of the PC. If they do not, they have either no financial relationship with the hospital, or only an indirect compensation arrangement with the hospital, in which case they may utilize Stark’s indirect compensation exception. The indirect compensation is available if the physicians’ compensation from the PC is set forth in writing, represents the fair market value of their services, and is not determined in any way that takes into account the volume or value of referrals they generate for the hospital (if the physicians are employees of the PC, their agreements do not need to be written).

This change brings significant flexibility, because now hospitals can subsidize the PC with less concern that these subsidies must fit an exception under Stark. Instead, as long as the physicians’ compensation from the PC is fair market value, the funds flowing from the hospital to the PC are not subject to any specific requirements under Stark.

California law also prohibits physician self-referrals through the Speier Act (“Speier”). Speier is broader than Stark in that it applies to all patients, whereas Stark applies only to Medicare beneficiaries. However, Speier also contains a broad exception allowing physicians to refer patients to a hospital with which they have a financial relationship, so long as the hospital does not pay the physician for the referral and any equipment lease between the parties satisfies certain requirements. Other exceptions mirror Stark, e.g., for certain personal service arrangements, leases of space or equipment, and loans.

While Speier has not incorporated the “stand in the shoes” or the “titular owner” provisions, it does encompass indirect financial relationships and would therefore apply to the physicians and the hospital in the affiliated-PC model. However, participants in this model should be able to utilize the broad exception allowing physicians to make referrals to hospitals, so long as they are not paid for their referrals and any leases between the parties are appropriately structured.

### 2. 1206(D) CLINICS

In California, unless a specific exception applies, organized outpatient health facilities (clinics) must obtain a license from the state. However, §1206(d) of the California Health and Safety Code waives this requirement for clinics that are conducted, operated, or maintained as outpatient departments of a hospital. A hospital may add a clinic to its license even if the clinic is located on premises separate from the main hospital campus, provided that the clinic and hospital have a single governing body, administration, and medical staff. The hospital typically contracts with a physician to oversee the clinic as a Medical Director, and enters into a professional services agreement with a medical group to provide services at the clinic. The hospital may also consider purchasing the assets of a medical practice and converting the physician’s offices into an outpatient department of the hospital.

The hospital’s ownership of the 1206(d) clinic creates opportunities for greater alignment between the hospital and physicians. While the clinic must still be staffed by physicians, the hospital can (and, in fact, is required to) exercise greater practical control over a 1206(d) clinic than it would a medical office or independent clinic operating under its own license. Also, the hospital may have greater leeway in this model (compared to the affiliated PC model) to supplement the physician’s collections for their professional services, because the physicians who provide service at a 1206(d) clinic are providing coverage for a licensed department of the hospital. (This concept is discussed in greater detail in the self-referral laws section, below.)

The greatest disadvantage of the 1206(d) clinic is the cost and complexity of setting one up. Acquiring a physician practice can be costly, and the requirements for licensing space as an outpatient department are extensive. Outpatient departments are licensed as supplemental services of a hospital, and must meet many specific requirements. For example, the clinic must have written procedures regarding outpatient services that are developed and approved by the hospital’s governing body, a committee of the medical staff must periodically evaluate...
the services provided at the clinic, all physicians at the clinic must be members of the medical staff, and the clinic must contain appropriate equipment and supplies. In addition, Medicare's Conditions of Participation require outpatient services to be integrated with inpatient services at the hospital (e.g. medical records, anesthesia services, surgical services, etc.). The clinic may need to comply with applicable building and safety codes as well. The process for adding an existing, freestanding outpatient clinic to a hospital's license can be quite lengthy, taking months to complete.

**a. Corporate Practice of Medicine**

California’s corporate practice of medicine remains a potential concern for 1206(d) clinics, but is less likely to present problems than it might in some of the other arrangements. Because the 1206(d) clinic is operated as an arm of a hospital, the clinic will not enter into lease arrangements or management agreements with the physicians or physician groups, nor will there be restrictions on the shareholders’ rights to dividends or to sell shares, which can raise the question of impermissible control over a physician practice by the hospital. The physician services agreements at a 1206(d) clinic are likely to be similar to those made with other hospital-based physicians, which generally have not been found to violate the corporate practice doctrine. So long as the hospital does not employ or exert excessive control over the physicians providing care in the 1206(d) clinic, this model presents little risk.

**b. Anti-Kickback Statutes**

The financial relationships between the hospital and the physicians providing services at the 1206(d) clinic may be scrutinized to see if they constitute illegal remuneration for referrals. Hospitals may purchase a physician practice to operate a 1206(d) clinic, provide compensation for services through a professional services agreement, or enter into a contract with a Medical Director. To limit risk, these arrangements should be consistent with fair market value, be commercially reasonable, be pursuant to written agreements, and should not take into account referrals or other business between the parties.

In addition, hospitals must be careful to avoid bestowing a windfall benefit to physicians practicing at a 1206(d) clinic by allowing them free use of the clinic’s facilities to see private patients. This issue arises because private payors typically do not pay a facility fee to hospitals for outpatient visits, thus only the physicians collect fees for visits from these patients. Thus, hospitals operating 1206(d) clinics should consider whether they might need to charge physicians for the use of the clinic to treat private patients.

**c. Self-Referral Laws**

In locations with an unfavorable payor mix, hospitals may need or wish to supplement physicians’ compensation in order for them to receive a reasonable level of compensation and remain in the area. These attempts, in the context of a physician’s private office practice, may run afoul of fraud and abuse laws, which scrutinize payments that exceed fair market value. However, because the physicians who provide service at a 1206(d) clinic are providing coverage for a licensed department of the hospital, the hospital may compensate physicians for the fair market value of this coverage, even if the hospital is required to supplement the physicians’ professional collections. These payments generally should fit within the Stark and Speier exceptions for personal service arrangements. These exceptions require the payments to be fair market value, for reasonable business purposes, set down in writing, and not to take into account the value or volume of referrals or other business generated by the parties. The payments provide physicians with additional income that supplements their professional collections, and allows them to receive fair market value income.

**3. 1206(l) MEDICAL FOUNDATIONS**

Like the 1206(d) clinic, 1206(l) clinics are statutorily exempt from obtaining a clinic license. To qualify for the 1206(l) exemption, the clinic must be a large, multi-specialty outpatient health care facility that is owned and operated by a non-profit, tax-exempt medical foundation. The clinic must conduct medical research and health education, and provide care through at least 40 independent contractor physicians and surgeons, at least 2/3s of which practice at the clinic full-time. The physicians and surgeons must together represent at least 10 board-certified specialties.

1206(l) clinics can be formed by, and affiliated with, a hospital. Because the 1206(l) must be a nonprofit corpora-

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20  Cal. Code Regs., Tit. 22 § 70525-70533.
21  42 C.F.R. § 482.54.
22  See Cal. Code Regs., Tit. 24 §§ 7-2100(a), 7-2103.
23  42 C.F.R. § 411.357(d)(1); Cal. Bus. & Prof. Code § 650.2(b)(6).
25  Id.
26  Id.
tion that is exempt from taxation under Internal Revenue Code § 501(c)(3), it cannot be "owned" by a hospital. However, the hospital may create a § 501(c)(3) corporation to serve as the medical foundation that owns and operates the clinic, and the hospital can serve as a "corporate member" of the medical foundation. Unlike shareholders in a for-profit corporation, the hospital, as a corporate member, would not have an ownership interest in the medical foundation and would not receive dividends or share in the profits, but it could elect the board of directors and would have the right to approve mergers, reorganizations and other significant corporate events.

Meeting the requirements of a 1206(l) clinic can be onerous, as it requires a large, diverse and committed group of physicians. If established, however, 1206(l) clinics offer significant advantages. 1206(l) clinics are exempt from clinical licensing requirements, which results in a significant reduction in facility and personnel costs, particularly compared to 1206(d) hospital outpatient clinics. Hospitals also can attract quality physicians by offering the prestige of association with a large clinic that conducts research and education in addition to patient care. Moreover, the clinic benefits by being able to obtain tax-exempt capital financing and to accumulate income for reserves without paying taxes.

The hospital's corporate control over the 1206(l) clinic also creates substantial opportunities for alignment. The non-profit medical foundation may operate the clinic as part of an integrated health delivery system, with coordinated case management between the clinic and the hospital facilities. The hospital's control over the clinic also allows the clinic to take advantage of the hospital's financial backing, resources for information technology and electronic medical records, existing business office infrastructure, and assistance in securing managed care contracts.

Some hospitals also guarantee collections of the medical group for coverage at the 1206(l) medical clinic, to the extent consistent with the fair market value of such services. While the hospital does not receive profits from the clinic, it benefits from the prestige and goodwill surrounding the clinic, and can use the clinic to expand its referral network into areas that have a need for local physician services.

a. Corporate Practice of Medicine

§ 1206(l)'s exemption of clinics operated by § 501(c)(3) non-profits from the clinic licensing requirements marks a limited exception to California's prohibition on the corporate practice of medicine. This exception allows the medical foundation to provide medical care to the public, own medical records, enter managed care contracts, establish its fees, and bill patients and other payors in its own name.

However, California's corporate practice of medicine doctrine forbids the medical foundation from employing physicians. Typically, clinics arrange for physician services through a professional services agreement with one or more medical groups, and the physicians are employees of the group, rather than employees of the clinic.

b. Tax-Exempt Status

Two IRS determination letters issued in 1993, one regarding Facey Medical Foundation and the other regarding Friendly Hills Healthcare Network, clearly indicate clinics can be granted tax-exempt status in appropriate cases. The IRS letters emphasize that the organizations involved would be controlled by a board of directors that was broadly representative of the communities served. Specifically, the letters stated that more than 20% of the board positions would be held by persons representative of the physicians involved in the arrangement. These rulings suggest the IRS will require that a significant majority of the board of directors be independent community members, unaffiliated with either the hospital or the medical group.

The medical foundation must also carefully structure its relationship with physicians and the parent hospital to preserve its tax-exempt status. While some well-known 1206(l) clinics have existed for many years with 501(c)(3) status, the IRS has never promulgated specific, definitive guidance for establishing or maintaining tax exempt medical clinics. Presumably, the IRS will apply the general exemption guidelines established for hospital organizations in Rev. Rule. 69-545. This was the approach taken in earlier IRS determination letters issued to 1206(l) clinic organizations.

The hospital guidelines, however, are not a perfect fit. For example, an "open medical staff" is one of the hallmarks of tax exemption for hospitals, but 1206(l) clinics must contract with a medical group populated with minimum numbers of physicians, a requirement at odds with an "open" medical staff. To compensate, the IRS has previously insisted on specific and significant indigent care obligations. More recently, our experience has been that adoption of a general indigent care policy without bright line minimums, similar to what exempt hospitals typically adopt, has been sufficient.

The earlier IRS letters also limited contracting physician participation on the foundation board of directors to 20%. That maximum presumably was borrowed from the limit for interested directors under Rev. Proc. 97-13, applicable to facilities financed with tax exempt bonds. Certainly if a clinic facility is financed with tax exempt bonds, that 20% limit would be applicable and should be observed. If clinic facilities are not financed with tax exempt bonds, however, the IRS's "less than a majority" of interested directors guideline, adopted more recently, presumably would be the applicable limit, so long as the foundation also adopted a conflict of interest policy consistent with the IRS model policy.

Likely the area of greatest IRS scrutiny will be physician compensation. Physician compensation should be approved by a board or board committee composed solely of disinterested directors, who approve all physician compensation arrangements based on objective criteria of reasonableness. It is good practice to follow the excess benefit regulation guidelines for establishing a presumption of reasonableness, including contemporaneous minutes of the approving meeting that reflect the voting and state the objective criteria relied on and the board or board committee's deliberative processes.

In addition, if any incentive compensation will be part of the physician compensation package, the various incentive compensation factors that the IRS has identified from time to time should be carefully considered, and followed as appropriate. These factors attempt to remove incentive compensation that can encourage conduct inconsistent with tax exempt status. For example, while bottom line profitability may be an element taken into account in awarding incentive compensation, it should not be the sole factor, but should be considered alongside other measures, such as quality standards. Finally, as a means of assuring that an incentive compensation formula does not result in total compensation that is unreasonable in amount, the IRS is likely to insist on some form of total compensation cap.

c. Anti-Kickback Statutes

The acquisition of physician practices to form a 1206(l) clinic raises potential concerns under the federal anti-kickback statute and California's equivalents. When a medical foundation purchases a physician practice, the physicians are employed by the foundation's contracting medical group and remain in a position to refer patients to the foundation as well as to any affiliated hospital. Accordingly, hospitals should be sensitive to whether the purchase price for a physician practice group constitutes remuneration intended to induce referrals. To reduce the likelihood of sanctions, the clinic should utilize arm's-length negotiation, require fair market value consideration, and obtain an independent third-party appraisal for any payment.

4. Joint Ventures

Under Speier, a physician may continue to refer to a hospital with which they have a financial relationship, so long as the hospital does not compensate the physician for the referral and any equipment leases between the parties satisfy certain requirements.

Under Speier, physician joint ventures are business enterprises between hospitals and physicians that are characterized by joint funding, sharing of profits and losses, and control of common resources by the participants who define the enterprise's operations and govern the enterprise in an agreement (or similar document, such as articles or bylaws) among the investors. These joint enterprises are generally conducted through a new entity, such as a corporation, partnership, or limited liability company, although a hospital may also choose to syndicate to physicians, thus bringing them in as direct investors in the hospital. Joint ventures frequently provide health services, but may restrict their scope solely to the provision of management services or leasing arrangements.

Joint ventures can provide strong alignment for hospitals and physicians with respect to the joint venture's business and operations. This alignment helps avoid unnecessary duplication of costs and underutilization of expensive equipment, and can improve the quality and efficiency of health services by drawing on physicians' medical expertise and hospitals' management expertise. Physicians are attracted to joint ventures because they can supplement their medical practice income with profits from their

30 42 C.F.R. § 411.357(p).
31 Cal. Bus. & Prof. Code § 650.2(c).
investment in the joint venture. Joint ventures can also provide access to a hospital’s greater financial resources, lack of which can hinder physicians from developing their own enterprise. Hospitals should benefit as well, for physicians can help raise additional capital for new equipment and provide new services or expertise to a community.

While joint ventures are frequently attractive both to hospitals and physicians, their availability is limited by fraud and abuse laws. Also, their ability to align hospitals and physicians may be confined to the joint venture’s business, and have little or no “spillover” effect on other aspects of the parties’ businesses and practices.

a. Self-Referral Laws

Stark constitutes a significant hurdle for joint ventures between hospitals and physicians. As discussed above, Stark prohibits physicians from referring Medicare patients for certain “designated health services” to entities with which the physician has a financial relationship, and prohibits entities from billing for services provided pursuant to prohibited referrals. Joint ventures that do not provide designated health services, or that do not provide them to Medicare patients, need not comply with Stark. The options for those which do, however, are very limited. Stark contains numerous compensation exceptions, but few exceptions allow for physician ownership interests in entities to which they refer. Inability of physician investors to refer patients to the joint venture may negate much of the incentive to enter into the joint venture. Thus, Stark seriously constrains the way hospital/physician joint ventures are constructed.

The types of hospital/physician joint ventures that provide designated health services and can satisfy ownership exceptions are: (1) hospitals and joint ventures that qualify as a “rural provider” under Stark. Other options include joint ventures which are vendors to providers but are not themselves health care providers (e.g., leasing joint ventures, or management companies), joint ventures which do not see any Medicare patients, or those which have only non-referring physicians as investors (e.g., radiologists, radiation oncologists, pathologists, or physicians who perform solely administrative functions and no longer see patients). Finally, the joint venture may provide ambulatory surgery center services, end stage renal dialysis services, pain management services, and sleep disorder diagnostic testing services, among other services, which are not “designated health services” covered by Stark (unless they are provided and billed as a hospital service, in which case they are covered by Stark).

b. Anti-Kickback Statutes

If one purpose of offering physicians an opportunity to invest in the joint venture is to induce the physician to refer patients to the joint venture, then the federal and California prohibitions on payments to induce referrals might be violated. Similarly, a hospital’s investment in a joint venture might constitute a disguised kickback to the physician investors.

However, the federal anti-kickback statute contains multiple regulatory “safe harbors” that exempt certain types of joint ventures from prosecution under the statute if they meet the requirements of the safe harbor(s). As described above, hospital/physician joint ventures that provide designated health services under Stark can either (1) own a hospital or (2) qualify as a rural provider. With respect to the anti-kickback statute, hospital/physician joint ventures that own hospitals may qualify for the “small entity” safe harbor, which places limits on (among other things) the investment interests held by investors in a position to make referrals and the amount of gross revenue coming from referrals made by such investors.

Hospital/physician joint ventures that qualify as rural providers may also qualify for the “underserved area provider” safe harbor, which requires (among other things) that the entity be located in a Medically Underserved Area (MUA), and have generated at least 75% of its business in the prior year from patients who reside in an underserved area or are members of a medically underserved population.

Failure to satisfy each element of a safe harbor means the joint venture is outside the safe harbor and potentially could be subject to scrutiny and federal prosecution. However, many joint ventures do not or cannot satisfy a safe harbor, but nonetheless come as close to compliance as possible in an effort to reduce their risk of liability. While there is no statutory immunity for “substantial compliance,” a federal court has concluded that a physician’s ownership interest in a jointly owned health care provider does not violate the anti-kickback statute so long as: (1) the return on investment is based on each physician’s ownership interest and not their referrals, (2) eligibility to invest does not depend on an agreement to refer, (3) the size of the investment is not based on referrals, and (4) physicians who do not refer are not pressured/required to divest.

52. 42 U.S.C. § 1395nn.
54. 42 C.F.R. § 1001.952(a).
55. 42 C.F.R. § 1001.952(a)(3).
California’s equivalent statute does not contain regulatory safe harbors, but does include a statutory exception for physician ownership in entities so long as the physician’s return on investment is based on the capital investment or proportional ownership of the physician and not based upon the number or value of any patients referred, and so long as there exists a valid medical reason for the referral.\textsuperscript{37}

c. Securities Laws

Federal and state laws regulate the offering of ownership and investment interests in joint ventures. These laws generally seek to assure that appropriate written disclosure of the facts regarding the investment is provided to potential investors. Generally, provisions of federal and state laws permit the offering of joint venture securities to “qualified” investors, who meet income and net worth tests, if appropriate notice is given to state regulators. The venture may also have up to 35 investors who do not meet the “qualified investor” standards. If nonqualified investors are included, it will be important to document their ability to understand the risks and benefits of the joint venture.

5. SERVICE LINE CO-MANAGEMENT AGREEMENTS

Service line co-management agreements are used by hospitals to contract with medical groups to manage and improve the quality and efficiency of a hospital service line (e.g., orthopedics, cardiovascular surgery). The hospital enters into a contract with a medical group or a joint venture which is owned by the hospital and a medical group. The contract provides for a base payment consistent with the fair market value of the time that the medical group’s physicians dedicate to service line management, development, implementation and oversight. The contract may also provide bonus payments of pre-determined amounts for meeting specific, mutually agreed upon, and objectively measurable quality improvement and efficiency goals. These agreements are also known as service line management, center of excellence, or service line institute arrangements.

Service line co-management agreements can effectively align hospitals with the physicians responsible for managing the service line. Physicians undertake these management opportunities both as a way to supplement declining reimbursement and as a means to have greater voice in the operation of the service lines related to their particular field of expertise. Hospitals gain from this expertise as well. By granting the physicians greater responsibility for the oversight of the work done at the hospital, the hospital encourages the physicians to use their technical knowledge and familiarity with staff to innovate and implement new procedures for ensuring efficient, high quality care.

These agreements can offer significant opportunities for alignment. Service line co-management agreements allow hospitals and physicians to cooperate to achieve commonly shared goals of efficiency and quality. The agreements thus create a working relationship with shared economic incentives. The agreements also may contain, under certain circumstances, a noncompete provision (e.g., to prevent the physician groups from providing similar management services for other hospitals), subject to applicable legal restrictions on such provisions.\textsuperscript{38}

a. Anti-Kickback Statutes

Service line co-management agreements raise concerns under federal and state anti-kickback prohibitions if the physicians’ compensation exceeds the fair market value of their services, thus potentially allowing the inference that the payment is intended to induce the physicians to make referrals to the hospital. Under federal law, service line co-management agreements may not quite fit any of the available safe harbors, leaving the contract open for potential scrutiny and prosecution. The “personal services and management contracts” safe harbor requires the aggregate compensation given to physicians to be set in advance, which service line co-management agreements will not meet if they include conditional bonus fees.\textsuperscript{39} If a joint venture management company is formed, the “small investment” safe harbor will not be met if more than 40% of the interests are held by persons in a position to refer to the hospital, which typically will be the case.\textsuperscript{40}

Failure to satisfy the safe harbors does not mean the service line co-management agreement violates the anti-kickback statute. The hospital and physicians should be well positioned to argue that the purpose of the compensation was not inducing referrals, particularly if compensation is keyed to the fair market value of services. Further, the structure of the agreement may provide a clear intent to improve quality and efficiency. Absent evidence of an improper intent, the relationship should not be found to violate the anti-kickback statute. Similarly, the ability to demonstrate that compensation was limited to the fair market value of the management services provided for the service line.

\textsuperscript{36} Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

\textsuperscript{37} Cal. Bus. & Prof. Code § 650(d).

\textsuperscript{38} See, e.g., Cal. Bus. & Prof. Code § 16600 et seq.

\textsuperscript{39} 42 C.F.R. § 1001.952(d).

\textsuperscript{40} 42 C.F.R. § 1001.952(a)(2).
would help to ensure compliance with California’s Business & Professions Code § 650.41

b. Civil Monetary Penalty Law

Service line co-management agreements that provide bonuses to physicians who achieve an increase in the efficiency of services may be scrutinized under the civil monetary penalty law. This law prohibits hospitals from making payments to physicians as an inducement to reduce or limit services to Medicare/Medicaid beneficiaries who are under the direct care of physicians.42 Violations of the law are punishable by fines of $2000 per patient. According to the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG), whether the services are medically necessary or prudent is irrelevant under the civil monetary penalty statute.

Arguably, not all incentives to reduce or limit care, however, should be held to be a violation. OIG advisory opinions have suggested such arrangements are permissible if specific cost lowering activities can be tied to actual, verifiable cost savings, there are no incentives to change the volume or steer away sicker or more costly patients, there are assurances that quality will be maintained, and the arrangement is disclosed to patients. While advisory opinions cannot, technically, be relied upon by anyone other than the requestor, they suggest service line co-management agreements may be permissible if they incentivize specific, verifiable methods of cost-saving, as long quality is not adversely affected and volume and case mix changes are not rewarded.

c. Self-Referral Laws

Service line co-management agreements may create a financial relationship between the hospital and physicians under Stark and Speier. Under Stark, the physicians' relationship with the hospital may be characterized as either direct or indirect. Physicians who contract directly with a hospital will clearly have a direct relationship, but often groups of physicians will form an entity responsible for contracting with the hospital.

If the group of physicians responsible for managing a hospital’s service line pursuant to a service line co-management agreement is a “physician organization,” then the physician owners of the group will stand in its shoes and be deemed to have a direct compensation relationship with the hospital. However, it is unclear how far the definition of physician organization extends. In some cases, physicians may form an entity which shares only the management responsibilities under the service line co-management agreement, but which is unaffiliated with the physicians’ individual practice. These arrangements should not be considered “physician organizations,” and the physicians should not be deemed to stand in the shoes of the management entity they formed. In this case, the physicians will have only an indirect relationship with the hospital or perhaps none at all.

If the physicians are deemed to have a direct financial relationship with the hospital, they may nonetheless rely on exceptions to Stark’s prohibition on referrals. The fair market value exceptions apply to commercially reasonable relationships, set down in writing, whose payments are consistent with fair market value, and which meet certain other requirements.43 The personal services exception applies to arrangements between a hospital and physicians which are set down in writing, relate to services which are reasonable and necessary for a legitimate business purpose, have a term of at least a year, and pay compensation which does not exceed fair market value.44

If the relationship is deemed indirect, then the hospital and physicians should rely on the indirect compensation exception.45 This exception requires payments to be set out in writing, signed by parties, not exceed the fair market value for the services and items actually rendered, and not be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring hospital for the hospital.

Speier does not distinguish between indirect and direct relationships, but contains a broad exception for referrals to a hospital, if the hospital does not compensate physicians for any referrals and any lease between the parties satisfies certain requirements.46

6. Pay-for-Performance Agreements

As with service line co-management agreements, pay-for-performance agreements create a financial structure which rewards physicians for their effort to improve service at a specific hospital. Many third-party payors offer pay-for-performance (P4P) programs that reward hospitals for achieving higher scores on designated quality metrics. Studies have shown that P4P programs can gener-

42 42 U.S.C. § 1320a-7b.
43 42 C.F.R. § 411.357(f).
44 42 C.F.R. § 411.357(d).
45 42 C.F.R. § 411.357(p).
46 Cal. Bus. & Prof. Code § 650.2(c).
ate significant savings, and they are an undisputed trend in hospital reimbursement. Hospital/physician P4P agreements allow physicians the chance to share in the rewards these programs offer to hospitals.

A P4P agreement is a contractual relationship between a hospital and a group of physicians who provide service at the hospital. The agreement typically provides that the physicians will receive a negotiated percentage of the P4P rewards the hospital receives in exchange for providing specific quality-related services to the hospital. Unlike service line co-management agreements, P4P agreements generally do not pay physicians for management services, but instead they create incentives for the physicians to take steps to help the hospital achieve higher scores on the designated quality metrics. Unlike the bonus payments made to service line co-management agreements, these target metrics are generally established by outside payors, not by the parties to the agreement.

On October 14, 2008, the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG) approved a P4P agreement for the first time. While the approval was expressly limited to the parties involved and did not analyze the agreement under state fraud and abuse laws, the model analyzed in the OIG’s opinion can be used to structure future efforts. The opinion creates the possibility of a relatively simple and efficient model of alignment for California providers.

Under the recently approved agreement, a physician-owned special purpose entity receives a portion of a hospital’s P4P awards and is responsible for developing policies and procedures, reviewing and monitoring quality of care in the hospital, providing care in accordance with hospital quality targets, ensuring adequate peer review if quality targets are not achieved, and auditing medical records to track compliance with quality activities. After receiving the agreed-upon percentage of the pay-for-performance awards from the hospital, the physician group distributes the money on a per capita basis to its physician members.

P4P agreements create cooperative relationships between the hospital and physicians which creates strong alignment. The programs will frequently be a win-win for both the hospital and the physician group. As with service line co-management agreements, physicians are attracted to the program as a way to supplement declining reimbursement. Even more so than service line co-management agreements, P4P agreements allow physicians to earn greater compensation without deviating from their core business of providing care to patients. Hospitals also benefit. While the hospital loses a negotiated portion of its P4P award, the cooperation gained by physicians' financial participation should allow the hospital to reap greater overall sums. Achieving high scores on P4P quality metrics requires the cooperation of the entire medical staff responsible for delivering care at the hospital. Absent incentives for physicians to participate, hospital management can only exert limited influence on the practices of its medical staff to comply with specific protocols necessary to achieve high scores.

P4P agreements pass on incentives to physicians and encourage them to develop, implement, and maintain efficient protocols that achieve desired outcomes. Thus, like service line co-management agreements, P4P arrangements increase efficiency by enlisting the expertise and cooperation of physicians to achieve quality goals. Meeting these goals will not only increase P4P payments, but also have the potential to boost quality performance at the hospital, help ensure higher scores on The Joint Commission’s surveys, and reduce the risk of litigation for quality of care violations.

a. Anti-Kickback Statutes

Because the physicians in a P4P agreement with a hospital will typically refer patients to the hospital, the P4P agreement might generate scrutiny under the federal anti-kickback statute and California’s equivalents. Like service line co-management agreements, P4P agreements will not typically meet any of the available federal safe harbors. Failure to satisfy a safe harbor does not mean the agreement violates the statute, however, to violate the statute one purpose of the arrangement must be to induce a participating physician to refer to the hospital. Since P4P arrangements are entered into for other, legitimate business reasons, they generally should not be found in violation of the statute, particularly if the safeguards found in Advisory Opinion 08-16 are incorporated into the arrangement.

In Advisory Opinion 08-16, the OIG expressly referred to several details of the considered arrangement, which can serve as models for developing future P4P agreements. First, only physicians


48 Advisory Opinion No. 08-16 (Oct. 14, 2008).

49 42 U.S.C. § 1320a-7(b); Cal. Bus. & Prof. Code § 650.
who have been members of the hospital’s active medical staff for at least one year were eligible to join the participating physician group. This requirement reduces the risk of physicians joining the medical staff of the hospital (and moving their patients there) in order to participate in the potential quality-bonus payments. Second, the participating physicians received distributions on a per capita basis, bearing no relation to how many or few patients a particular physician has who are covered by the program. Third, the program was transparently designed to improve quality, not to reward referrals, and physicians are paid only for meeting quality targets published in advance. Fourth, third party payors help ensure payments are based solely on achieving quality targets. Fifth, the agreement was for a limited, three-year period. As a result of these safeguards, the OIG declared the specific arrangement under consideration a “low risk of fraud or abuse under the anti-kickback statute.” These same safeguards present a strong argument for compliance under California law as well.

b. Civil Monetary Penalties Law

P4P agreements can raise concerns under the civil monetary penalties law if the agreements encourage providers to limit the amount of care given to a Medicare or Medicaid beneficiary. There is no requirement that the limited care be directed at a specific patient or, according to the OIG, that it be medically necessary. The OIG has asserted that providing general incentives to avoid medically unnecessary care may still violate the statute. On this broad reading, providing incentives to meet quality target measures may violate the law. The agreement considered by the OIG in opinion 08-16, for example, contained specific quality targets which arguably provided incentives to physicians to limit care, such as the discontinuing of certain antibiotics within specific times after surgeries.50

In its Advisory Opinion, the OIG reiterated its broad reading of the civil monetary penalties law and asserted the potential for sanctions. However, the OIG also declared that it would not seek sanctions under the statute, since the proposed arrangement contained “sufficient safeguards” against abuse. First, the OIG recognized there was credible medical support for believing the arrangement would improve patient care and would not have adverse effects. Second, the agreement provided no incentive for physicians to apply specific standards in inappropriate cases. Third, the quality targets were reasonably related to the practices and patient populations of the entity requesting the advisory opinion. Fourth, the performance measures that could result in compensation were clearly and separately identified, and could generate public scrutiny and individual physician accountability should problems occur. Fifth, the requesting entity had certified it would monitor the quality targets and their implementation throughout the terms of the agreement. Finally, the OIG emphasized that the quality targets being considered had been endorsed by CMS and The Joint Commission through the Quality Measures Manual.

These considerations provide a model for future P4P models can use to avoid sanction under the civil monetary penalties law. Agreements which rely on approved, medically sound quality targets, and which allow for appropriate oversight and do not create incentives for limiting care in inappropriate circumstances presumably should pose little risk of sanction.

c. Self-Referral Laws

P4P agreements may create a financial relationship between the hospital and the physicians under Stark and Speier. As described above for service line co-management agreements, under Stark this relationship might be characterized as indirect or direct,51 and the personal service,52 fair market value,53 and indirect compensation54 exceptions to Stark may be available. The broad exception to Speier for financial relationships that do not compensate for referrals may also be satisfied.55

In addition, the Center for Medicare and Medicaid Services (CMS) has proposed a rule which would provide an exception specifically tailored for P4P agreements. On July 7, 2008, CMS proposed a new exception to Stark for “incentive payment programs” that explicitly acknowledged the importance of obtaining physician cooperation with P4P agreements.56 The proposed rule notes the increasing popularity of P4P and the importance of obtaining physician collaboration to meet quality targets, while also recognizing that improperly structured P4P programs can encourage physicians to steer unhealthy patients from the hospital or can become vehicles for disguised payments for referrals.

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50 OIG Advisory Opinion No. 08-16 (Oct. 14, 2008).
51 See text accompanying notes 42-43, supra.
52 42 C.F.R. § 411.357(d).
53 42 C.F.R. § 411.357(l).
54 42 C.F.R. § 411.357(p).
55 Cal. Bus. & Prof. Code § 650.2(c).
The proposed rule contains numerous restrictions which P4P agreements must meet before the exception applies. To qualify for the proposed exception, for example, the P4P program must: (1) make payments to physicians as part of a documented incentive payment program to achieve the improvement of quality of hospital patient care; (2) identify patient care quality measures that use an objective, verifiable, and credible methodology listed in CMS’ Specification Manual for National Hospital Quality Measures; (3) establish baseline and target levels for the quality measures using the hospital’s historical and clinical data; (4) not restrict or condition physicians’ access to technology or supplies; (5) give effective prior written notice of the arrangement to patients; and (6) set out the arrangement in writing, with the amount of remuneration set in advance and unvarying during the term of the arrangement.\textsuperscript{57} Notably, the rule does not require physician compensation in the P4P program to be consistent with fair market value, presumably based on the view that determining the fair market value of these payments can be difficult.

If finalized, the proposed rule would provide a detailed model that would guarantee compliance under Stark and would allow hospitals to dispense with having to determine the fair market value of the physician’s services in improving the hospital’s quality scores. However, the proposed rule may contain too many additional requirements to justify this one advantage. Thus, unless and until it is promulgated, P4P arrangements must make use of the currently available exceptions, and unless the proposed regulation is simplified, they may continue to use other exceptions, even afterwards.

CONCLUSION

The preceding six business models entail varying strategies available for aligning hospitals and physicians. In practice, the models may be modified to accommodate the specific needs of hospitals and physicians, and many hospitals and their medical staffs are likely to mix and match and expand upon the strategies discussed. The success of each model in achieving alignment, and the ability of alignment to meet the unique challenges of California’s health care market, will continue to be tested and evaluated for years to come.

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\textsuperscript{57} Proposed 42 C.F.R. § 411.357(x), 73 Fed. Reg. 38604-06.