the EDGE

Accelerating Hospital-Physician Collaboration

2008

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McGuireWoods and Sg2 Staff

Project Directors
Jillian Addy
Scott Becker
Elissa Moore
Thomas Stallings
Kristian Werling
Bill Woodson

Editorial Review
Barbara M Bennett, RN
Amy Nolan
Dorothy Scott

Contributors
Laurie Sicaeros, MHA
Vice President, Physician Integration
MemorialCare Medical Centers
MemorialCare Physician Society

Jack Jensen
Chief Operating Officer
WellSpan Medical Group

Thomas McGann, MD
Senior Vice President of Practice Management
WellSpan Medical Group

Don Schreiner
Chief Operating Officer
Rockford Orthopedic Associates

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Executive Summary

Accelerating Hospital-Physician Collaboration 2008

Hospital-physician relationships are entering a new era as changing market conditions drive a new level of differentiation based less on technology and innovation and more on performance.

Physicians will look to the hospital for support as they face increasing practice costs, rising malpractice premiums, continuing reimbursement pressure, more stringent quality standards, and challenges acquiring needed clinical technology and information technology (IT) systems.

Hospitals, facing their own unique set of pressures, seek to strengthen physician alignment to stall escalating physician shortages, competition and call coverage issues as well as declining physician loyalty. To succeed in an increasingly competitive marketplace, hospitals must have the right physicians engaged, and the right alignment structures in place as well as the right leadership and culture to execute effectively.

As hospitals and physicians navigate these new opportunities to strengthen ties with one another, it becomes essential that they understand the types of structures that are available to them and the various benefits and challenges associated with each. Future success and performance excellence require strong integration with the physician workforce on quality, cost and service performance.

Accelerating Hospital-Physician Collaboration 2008 examines the trends driving a shift in hospital-physician relationships and profiles the arrangements that can be adopted to secure successful, long-term alignment with the physician workforce. Steps for developing each arrangement, and its benefits and challenges, are summarized. Leading practices and lessons learned from successful alignment initiatives are also presented.

Key Strategies

- Organize the medical staff for performance improvement.
- Refocus physician strategy on stronger integration.
- Focus on 12 steps to accelerate hospital-physician collaboration.
- Choose from multiple structures to strengthen alignment.

Alignment Structures

- Medical directorships
- Contractual arrangements
  - — Call coverage agreements
  - — Professional services agreements (PSAs)
  - — Comanagement and service line management agreements
- Gainsharing agreements
- Information technology strategies
- Joint ventures (JVs)
  - — True provider joint ventures
  - — Infrastructure joint ventures
- Employment agreements

A companion workbook, *How to Accelerate Hospital-Physician Collaboration 2008*, provides step-by-step guidance for planning, implementing and evaluating physician alignment strategies.

Strategies for Accelerating Hospital-Physician Collaboration

Organize the Medical Staff for Performance Improvement

The next decade of health care will be characterized by performance differentiation on quality, cost and service. Hospitals that are aware of these changing dynamics find the traditional voluntary medical staff model outdated and ineffective in meeting these new standards. A collection of forces, impacting both hospitals and physicians, will drive the formation of new strategies and alignment structures.

Challenges With the Voluntary Medical Staff Create New Opportunities

Hospital leadership, weary of long-standing inefficiencies and frustrations associated with the traditional medical staff model, express growing interest in new strategies that better strengthen physician alignment.

Current Frustrations…

- "The traditional medical staff model is 100 years old and designed for an old era of health care."
- "ED call is by far and away our biggest challenge."
- "We've been doing joint ventures successfully for years and we still have the same problems."
- "Volunteerism is dead. It is increasingly difficult to get physicians to serve on committees."

…Create Opportunities With the Physician Workforce

- "Our end game is explicitly an employed model. It's the only way to truly drive performance improvement. We expect to have 500 employed docs by end of 2006, maybe not quite 1,000 within 5 years."
- "We have a 'shadow leadership' of select medical staff representatives who are empowered to make rapid decisions on performance, growth, technology adoption."

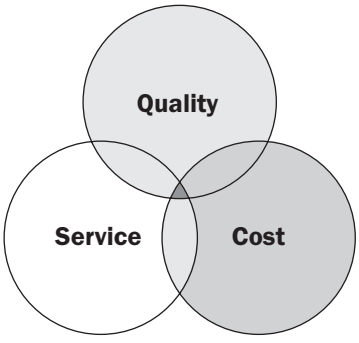
Many Forces Will Create the Alignment Necessary for Performance Improvement

From both physician and hospital perspectives, multiple forces are driving hospitals and physicians closer to one another. To meet and exceed rising performance standards, a new level of collaboration between hospitals and physicians will be necessary.

Alignment Around Quality, Cost and Service Performance

Hospital Drivers

- Performance imperatives
- Call coverage struggles
- Recruiting challenges
- Physician competition
- Changes in physician productivity
- Aging workforce
- Turnover and retention issues
- Strained referral relationships
- Lack of physician leadership



Physician Drivers

- Income insecurity
- Demanding on-call schedule
- Rising practice costs
- Rising malpractice premiums
- Work-life balance
- Technology accessibility
- Turf issues
- Cost and quality transparency imperatives

ED = emergency department.
Sources: Sg2 Analysis, 2008; Society for Healthcare Strategy and Market Development, 2006.

Refocus Physician Strategy on Stronger Integration

Hospitals will increasingly shift from low-integration strategies to those that provide more long-term, stable physician loyalty and engagement.

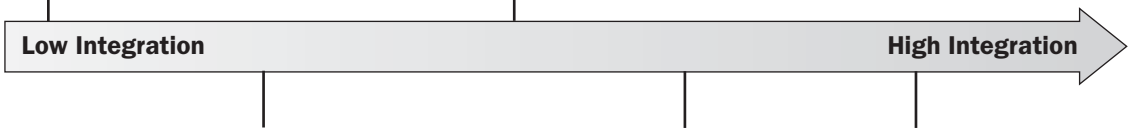
Hospital-Physician Strategies Will Shift Toward High Integration

Hospitals must focus on integration and partnership opportunities that engage physicians more formally in strategies that deliver growth, profitability and quality improvement. The new medical staff organization will be characterized by physician partners, engaged service line leaders and employed physicians.

Physician Alignment Structures Vary From Low to High Integration

Traditional Medical Staff Model
- Independent physicians with hospital privileges
- Physician volunteers on committees
- Physician volunteers for call coverage

Equity and Contractual Relationships
- True provider JV
- Infrastructure JV for technology and real estate
- Comanagement and service line management agreements
- Professional services agreement



Paid Positions
- Medical directorship
- Committee participation
- Call coverage stipend

Expansion of Hospital-Based Specialists

Employment or contracting with:
- Hospitalists
- Intensivists
- Surgicalists
- Laborists

Employment and Similar Models
- Employment of select specialists and primary care physicians (PCPs)
- Foundation model
- Multispecialty clinic model

Low Integration
- Short-term solutions that generally do not require the development of a partnership or extensive capital outlay
- Examples: medical directorships*, gainsharing agreements* and management contracts

Medium Integration
- Collaborations that require more effort to create and sustain, often involving capital contributions and partnership agreements
- Examples: true provider joint ventures* and infrastructure joint ventures*

High Integration
- Employment arrangements with physician groups or individual physician specialists
- Examples: traditional employment, foundation models* and clinic models

*See Appendix 4: Glossary of Terms.

Accelerate Hospital-Physician Collaboration

Hospital leadership must continually assess performance within core service lines to identify new opportunities and strategies that strengthen physician alignment. The companion workbook, *How to Accelerate Hospital-Physician Collaboration 2008,* guides executives through planning, implementing and evaluating the strategies outlined in this report.

Steps for Accelerating Physician Alignment

Step	Description
Initial Planning	
1	**Assemble the core planning team.** ■ Identify hospital administration representatives. ■ Find the right physician partners.
2	**Perform an alignment assessment.** ■ Identify historical alignment structures and evaluate their effectiveness. ■ Review key learnings from current alignment structures.
3	**Create a new compact.** ■ Create a shared understanding of the value of a compact. ■ Engage key stakeholders in identifying expectations.
4	**Review alignment options.** ■ Understand the benefits and challenges of different alignment structures.
Alignment Assessment	
5	**Determine alignment objectives.** ■ Engage stakeholders in identifying objectives.
6	**Assess appropriate level of integration.** ■ Determine whether to pursue low-, medium- or high-integration strategies.
7	**Identify the appropriate alignment structure(s).** ■ Identify alignment structures that provide “win-win-win” opportunities. ■ Conduct scenario testing.
Development and Implementation	
8	**Create a project work plan.** ■ Form a development team to create the work plan and determine key milestones.
9	**Identify performance metrics.** ■ Choose a set of metrics to evaluate performance of the alignment structure.
10	**Communicate agreement to key stakeholders.** ■ Develop a communication plan.
Management and Evaluation	
11	**Establish an accountability structure.** ■ Create a management structure that supports success. ■ Explicitly define roles and decision-making processes for the management team.
12	**Evaluate performance and make adjustments.** ■ Review performance against benchmarks to identify potential performance gaps. ■ Know when to change direction.

Choose From Multiple Structures to Strengthen Alignment

To secure stronger relationships with key physicians on the medical staff and within the larger community, hospitals can choose from multiple alignment structures.

Several Alignment Structures Advance Hospital-Physician Alignment

Determining which structures are most appropriate requires careful examination of current physician relationships, changing market conditions and the support of key physician leaders.

Potential Structures to Strengthen Hospital-Physician Alignment*

Alignment Structure	Description
Medical Directorships	■ Medical directorships involve key physician leaders more directly in the management and operations of the service line. ■ Payment to physicians must be for services actually needed by the hospital.
Contractual Agreements	■ Contractual agreements between a hospital and physician or physician group exist to provide a service on the hospital's behalf, including call coverage† and professional services agreements†. ■ Comanagement or service line management agreements† offer opportunities to engage physicians more directly in service line growth and quality improvement.
Gainsharing Agreements	■ Gainsharing, although limited in scope and duration, improves alignment with specific specialists based on reductions in hospital costs.
Information Technology Strategies	■ The Department of Health and Human Services and others are reducing barriers to physician EMR adoption through relaxed donation rules. ■ Hospitals and health systems can gain significant first-mover advantages by connecting with community physicians before the competition does.
Joint Ventures	**True Provider Joint Ventures** ■ Hospital and physicians partner to create a company as the provider of services. ■ Joint ventures are governed by several state and federal regulations. **Infrastructure Joint Ventures** ■ Hospital and physicians partner to create a company that owns equipment or real estate.
Employment Agreements†	■ Physicians are directly employed by the hospital or a subsidiary company to provide services for the hospital and/or health system. ■ This strategy is typically pursued to manage physician shortages, improve recruiting efforts, minimize physician competition and strengthen long-term physician alignment.

The remainder of this report considers the benefits and challenges of each of these structures and outlines the steps for developing them.

EMR = electronic medical record.
*Under arrangements models and per-click lease models are not covered in this report since these involve substantial regulatory risks.
†See Appendix 4: Glossary of Terms.

Medical Directorships

Medical Directorships: Benefits and Challenges

As the level of physician involvement in leadership, management and clinical oversight has increased, hospitals continue to use medical directorships and similar agreements to fill these needs.

Medical Directorships Provide Compensation to Physicians for Leadership Services

Medical directorships remain common structures for compensating designated physicians within core service lines for their time and involvement in leadership roles. Medical directorships must be for services truly needed by the hospital. Medical directorships are receiving growing attention from both the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG).

Medical Directorship Description	■ Hospital retains the physician to provide direction and guidance on certain clinical, operational and patient care activities within the facility. ■ Academic medical centers may consider department directorships.

Benefits and Challenges of Medical Directorships

	Benefits	Challenges
Hospital	■ Involves physicians directly in clinical priorities of the service line ■ Invests physicians in hospital and service line success	■ Actual physician availability to provide input and to be involved is limited. ■ Payment is restricted to fair market value for physician services.
Physicians	■ Offers stronger hospital support of physician needs ■ Provides physicians with additional income in exchange for leadership services	■ Explicit expectations are needed to clarify the scope of responsibilities. ■ Physicians bear the regulatory burden of maintaining time records.

When Is the Medical Directorship Strategy Appropriate?

Hospitals must consider several factors prior to establishing medical directorship agreements. These include determining which physicians (or nonphysicians) can best serve in the role and defining the time commitment and commensurate compensation for their services.

Key Factors for Determining Appropriateness

- Physician leaders who are skilled and appropriate for the role must be identified. Hospital leadership may also consider nonphysician leaders.
- Medical directorship services must be actually required by the facility for the service line to operate effectively.
  - — Medical directorships should not be created solely to provide additional compensation for physicians.
  - — Clear expectations and defined responsibilities are necessary to ensure payment for actual work performed.
  - — The compensation arrangement must be directly aligned with the responsibilities and time that the physician actually provides.

Medical Directorships: Steps for Development

Medical directorships must be compliant with anti-kickback statute* requirements and satisfy a Stark law* exception in order to meet regulatory requirements.

Specify Medical Director Services, Responsibilities and Compensation

The agreement between the physician and the hospital must explicitly define the services to be provided by the physician to the hospital.

Key Step in Developing a Medical Directorship

Key Step	Description
Design the Agreement	■ Clearly define: — Medical director responsibilities and obligations — Hours per week per year that will be devoted — Compensation to be paid to the physician by the hospital — Term and termination provisions (must be longer than 12 months) — Specific time schedule for the physician and documentation method

Carefully Design Agreements to Meet Regulatory Standards

Because medical director arrangements can vary widely, they can raise significant regulatory issues. Three federal statues impact the payment of fees for medical director roles.

Federal Regulations Impacting Medical Directorships

Stark Law	■ Prohibits physicians from having a financial relationship with an entity that they make referrals to for designated services ■ Includes exception for personal services, including medical director services ■ Requires that compensation: — Be set in advance — Not depend on the volume or value of referrals provided
Anti-Kickback Statute	■ Prohibits remunerating physicians to induce, or in exchange for, Medicare or Medicaid referrals ■ Offers a safe harbor for medical director compensation if: — Payments are made for services that are actually needed — Payment amount is fixed on an annual basis — Payment amount reflects fair market value for services actually provided
Internal Revenue Code Section 501(c)(3)	■ Requires that no contract be entered into or compensation be paid for the purpose of providing private benefit or private inurement. The contract must further community benefits. ■ Requires that the contract be: — Product of an arm's length negotiation* — Approved independently by an independent compensation committee of the board of directors — Supported by independent data indicating the appropriateness of the compensation amount

*See Appendix 4: Glossary of Terms.

Contractual Agreements

Call Coverage Agreements: Benefits and Challenges

Under the federal Emergency Medical Treatment and Active Labor Act (EMTALA)* of 1986, hospitals are required to keep a roster of on-call physicians, institute policies and procedures for call coverage and ensure timely, appropriate care of patients admitted to the emergency department.

Call Coverage Agreements Increasingly Include Compensation

A variety of strategies, both financial and nonfinancial, can be pursued to ensure adequate call coverage in key specialty areas.

Call Coverage Agreement Description	■ The hospital enters into an agreement with a physician or physician group to provide coverage for the ED. ■ Call coverage has typically been uncompensated, but hospitals are increasingly offering remuneration to various specialists in exchange for call coverage support.

Benefits and Challenges of Call Coverage Agreements

	Benefits	Challenges
Hospital	■ Ensures emergency call coverage and fulfillment of community need ■ Creates goodwill with physicians by supporting their financial needs	■ Some call coverage agreements may present risk of fraud and abuse. ■ Agreements may not engage physicians sufficiently in organizational priorities.
Physicians	■ Supports a physician's lost opportunity costs due to the inability to provide patient care on both the day of and day after being on call ■ Reduces physician concerns over the costs they must absorb and liability risks they incur when treating uninsured ED patients	■ On-call requirements may conflict with work-life balance preferences. ■ In exchange for call coverage compensation, hospitals may require more time to be spent on specific committees that meet hospital priorities around quality improvement.

When Is a Call Coverage Agreement Strategy Appropriate?

Call coverage agreements can be simple arrangements involving a set fee in exchange for services. Hospitals must also evaluate these arrangements with respect to their tax-exempt bonds and Internal Revenue Service (IRS) Revenue Procedure 97-13 on longer-term relationships.

Key Factors for Determining Appropriateness

- Ensure that all fees paid are at fair market value and do not take into account the volume or value of referrals between the parties.
- Ensure that reasons for call coverage are legitimate for the compensation provided (eg, compliance with EMTALA obligations, demonstrated shortages of physicians within the service area).

*See Appendix 4: Glossary of Terms.

Consider a Range of Models for Call Coverage Agreements

A variety of strategies, both financial and nonfinancial, can be pursued to ensure adequate call coverage. Choosing the right approach typically depends on the hospital's patient mix, physician culture, competitive environment, and state and federal laws.

Multiple Payment Options Exist for Call Coverage Agreements

In 2006, 78% of organizations surveyed reported providing some form of payment to physicians for call coverage. Call coverage payments must be at fair market value, requiring careful documentation.

Payment Options for Call Coverage Agreements

Option	Description
Daily Stipends	■ Per-diem payment rates are calculated based on: — Specialty — Frequency of call while on call — Hospital payer mix — Professional liability risks — Number of physicians participating in call rotation
Retirement Plans	■ Hospitals can design an "attending faculty plan" (AFP), a non-qualified defined contribution plan that uses the "deferred compensation plans of state and local governments and tax-exempt organizations" that the IRS provides in 457(f). ■ Under an AFP, the hospital makes tax-deferred payments to the physician's 457(f) account, and the physician invests it in a 401(k) or 403(b) retirement plan. ■ The physician is vested 100% after a period of time during which the physician was on the medical staff and performed the required call duties.
Minimum Thresholds	■ A stipend is set for a minimum number of call nights per month (usually 1 or 2).
Tiered Payment Levels	■ A higher stipend is set for specialties with greater relative burden or intensity of providing call coverage.
Maximum Payout	■ A maximum payment limit is set at the physician or medical staff level; the hospital allocates a defined portion of its annual budget for on-call compensation.
Activity-Based Payments	■ Payment is tied to the amount of activity required of physicians (eg, answering ED-related phone calls, providing in-person consultations, procedures, follow-up visits).
Guaranteed Payment Rates	■ Payment is made per service at Medicare rates for indigent patients.
Deferred Payments	■ Payment is tied to a specific number of years on medical staff; deferred payment is usually per diem.
Alternative Payouts	■ Provider costs, such as malpractice insurance premiums and billing services, are covered.

Sources: Healthcare Financial Management Association (HFMA), 2007; BNA's Health Law Reporter, 2007; Sullivan & Cotter, 2006.

Carefully Structure Call Coverage Agreements

When structuring call coverage agreements, hospitals must consider key safeguards to ensure the agreements meet legal and regulatory requirements. The unmet need for on-call services must be clearly identified, payments to physicians must be at fair market value for services provided, and the agreement must minimize the risk of fraud and abuse.

OIG Advisory Opinion Identifies Key Characteristics of Call Coverage Agreements

The OIG advisory opinion released in September 2007 provides guidelines for providers and counsel when drafting compensated call coverage agreements. The OIG has voiced concern that these agreements could create considerable risk if physicians demand call coverage compensation in exchange for providing services at the hospital.

OIG-Stipulated Considerations for Call Coverage Agreements

Challenges to On-Call Payment Agreement	■ The OIG advisory opinion notes that payment for call coverage may violate the anti-kickback statute: — There is a "considerable risk" that physicians will demand on-call pay in return for patient referrals to the hospital. — Payment for call coverage could entice physicians to join or remain on the hospital's medical staff or to generate additional business for the hospital. — Covert kickbacks could take the form of payments that exceed fair market value or payments for call coverage not actually provided. Problematic compensation structures may disguise kickback payments. ■ The opinion concludes that call coverage compensation should be scrutinized to ensure that it is not a vehicle to mask payments for referrals.
Safe Harbor for Personal Services	■ Safe harbor protection is granted to those agreements that precisely meet all conditions described in the safe harbor: — Agreement is set out in writing and signed by all parties involved. — Agreement covers and specifies all of the services provided. — If the services are periodic or part-time, the agreement must exactly specify the schedule, length and charge for the intervals. — Agreement is not for less than 1 year. — Amount of compensation is determined in advance, is consistent with fair market value and does not take into account the volume or value of any referrals generated between the parties for which payment may be made by Medicare or Medicaid. — Services performed do not involve counseling or the promotion of a business arrangement. — Aggregate contracted services do not exceed those that are reasonably necessary.

How to Comply

- Structure call coverage agreements to meet the personal services safe harbor standards.
- Work closely with legal counsel throughout the development steps to ensure that compensated call coverage agreements are structured properly.

Source: OIG Advisory Opinion 07-10. September 27, 2007.

Consider Noncompensation Models for Call Coverage

Policy-based and technology-based approaches offer hospitals options other than payment relationships for managing call coverage needs.

Consider Policy-Based Approaches for Managing Call Coverage

According to a recent survey, 46% of hospitals have implemented or are considering implementing policies and procedures for addressing physician on-call pay.

Policy-Based Options for Managing Call Coverage

Option	Description
Mandatory Call Coverage	■ Medical staff bylaws include on-call responsibilities and requirements.
Designated OR	■ One operating room (OR) is identified for ED cases.
Hospitalists	■ Employed or contracted physicians who treat ED patients reduce the burden on specialists and attending physicians.
Physician Assistants	■ Highly trained physician assistants perform on-call duties, relieving call coverage demands on physicians.
Regional Pools	■ A shared pool of specialists for high-demand, limited-supply services rotate call coverage.
Transfer Agreements	■ Formal agreement is made to transfer stable patients to a nearby facility when a hospital cannot provide on-call services.
Regional Competitive Contracting	■ Group purchasing organization is created by 2 or more hospitals in a regional market to bid contracts with medical groups for call coverage.

Explore Technology-Based Approaches to Alleviate Call Coverage Issues

EMR, telemedicine and remotely monitored ICU (eg, eICU®) are among the technology-based approaches to mitigate call coverage challenges.

Technology-Based Approaches for Ensuring Call Coverage

Option	Description
Electronic Medical Records and Physician Portals	■ Physicians can quickly access patient records and make informed medical decisions from outside the hospital.
Teleradiology	■ Radiologists are relieved of after-hours reads by contracting with radiology firms staffed 24/7 to read images sent via the Internet.
Remotely Monitored ICU	■ Real-time data and visual images of ICU patients are sent via the Internet to pulmonary and critical care specialists. ■ Providers remotely monitor patient status and make treatment recommendations to ICU staff over the phone.
Telehealth or Telediagnosis	■ Local providers are linked digitally with remote specialists who assist them in evaluating, diagnosing and treating patients.

ICU = intensive care unit.
Sources: HFMA, 2007; Sullivan & Cotter, 2006.

Professional Services Agreements: Benefits and Challenges

For adequate coverage of specific services, hospitals frequently develop professional services agreements (PSAs)* with physician groups in the market.

PSAs Engage Physician Groups to Ensure Needed Coverage

By contracting with physician groups to deliver services, the hospital gains consistent and reliable coverage for key specialty areas.

Professional Services Agreement Description	■ Hospital enters into an exclusive or nonexclusive arrangement with a group of physicians who deliver all services for a specific specialty area in the hospital. ■ The most common examples are pathology and anesthesia; however, the arrangement may also be applied to surgical specialties.

Benefits and Challenges of Professional Services Agreements

	Benefits	Challenges
Hospital	■ Ensures coverage and the availability of services	■ Compensation can be difficult to structure within the confines of regulatory standards. ■ Overreliance on business from a single physician group can impact growth if the relationship is terminated.
Physicians	■ Enables physicians to rely on the hospital as a committed source of referrals to assist the group's business and position for recruiting	■ The arrangement may limit physician options with other hospitals due to its exclusive nature.

When Is a Professional Services Strategy Appropriate?

PSAs are valuable for specific specialty areas in which the hospital requires 24/7 physician coverage that is delivered consistently and reliably.

Key Factors for Determining Appropriateness	■ Appropriate when consistent availability and coverage are required for the specialty area, including pathology and anesthesiology ■ Requires that a large physician group is available, interested in pursuing the arrangement and willing to enter into an exclusive relationship

*See Appendix 4: Glossary of Terms.

Contractual Agreements: Steps for Development

Developing call coverage agreements and professional services agreements involves creating a contract with the physician or physician group.

Involve Legal Counsel in Contract Development

Legal counsel should assist in all aspects of developing the contract, particularly determining the compensation model and performing a careful review to ensure compliance with regulatory standards.

Key Steps in Developing Contractual Agreements

Key Steps	Description
Identify Physician Group	■ Choose a physician group large enough to provide the services and resources desired for the specialty area. ■ Determine that the group is interested in developing an exclusive relationship.
Create a Written Contract	■ Clearly define the responsibilities of the physician group, obligations, compensation and duration of the agreement. ■ Engage legal counsel in determining the appropriateness of the contract.
Choose the Compensation Methodology	■ Engage legal counsel in determining the appropriateness of the compensation methodology. ■ Ensure the methodology meets restrictions defined by the Stark law, anti-kickback statute, restrictions on the use of tax-exempt financing proceeds and state law.
Analyze Fair Market Value	■ Obtain an independent fair market value analysis in order to validate the approach and methodology of the compensation agreement.

Ensure Regulatory and Legal Standards for Contractual Agreements Are Met

The OIG and IRS are increasingly scrutinizing the physician compensation provided in hospital-physician relationships, specifically issues related to fair market value. Ensure that contractual arrangements meet both federal and state regulatory requirements.

Success Factors

- Obtain a fair market value analysis and ensure that compensation is not influenced by the volume or value of referrals between the parties.
- Document the need for the relationship and the justification for compensation.
- Structure the arrangement to meet the personal services safe harbor of the anti-kickback statute. This is possible if the aggregate amount of compensation can be set in advance.
- Ensure compliance with restrictions defined by the Stark law, anti-kickback statute, restrictions on the use of tax-exempt financing proceeds and state laws governing these arrangements.
- Determine the impact of this agreement on the larger medical staff and independent physicians.
  - — Understand and mitigate potential points of contention with the medical staff in advance of implementing the agreement.

Comanagement and Service Line Management Agreements: Benefits and Challenges

Comanagement—involving a group of physicians in partnership with the hospital—allows physicians to become more directly involved in leading and directing the operations and growth of a service line.

Comanagement Agreements Engage Physicians in Service Line Performance

The agreements allow hospitals to align more closely with their physicians by formally involving them in the management of the service line.

Comanagement Agreement Description	■ A group of physicians form a management company and enter into a services agreement with a hospital. The physician entity manages the service line for a set management fee. ■ The hospital owns the service, bills the patient and/or payer for services, and performs collections. ■ Compensation may include incentive-based bonuses for meeting quality targets.

Benefits and Challenges of Comanagement Agreements

	Benefits	Challenges
Hospital	■ Provides opportunities to align more closely with a group of physicians ■ Directly engages physicians in the management of the service line ■ May provide opportunities for cost savings and other efficiencies	■ Broad participation of the physician group is required. ■ Careful documentation of physician time and ongoing involvement of legal counsel in monitoring the agreement are necessary. ■ Payments to physicians must be at fair market value.
Physicians	■ Allows physicians greater sense of control over the service line ■ Allows physicians to maintain independent practice	■ Compensation and return-on-investment possibilities for physicians are limited. ■ Physicians may inherit historic service line challenges, such as difficulty securing call coverage.

When Is a Comanagement Agreement Appropriate?

Hospitals and physicians interested in comanagement agreements typically have a joint focus on fostering stronger relationships with one another and more direct engagement in service line management, yet without the investment involved in joint ventures or employment.

Key Factors for Determining Appropriateness

- Comanagement agreements are appropriate when:
  - — The hospital and physicians want to collaborate on service line improvements
  - — Physicians wish to have more input and control over operations
- Comanagement agreements require relatively low levels of investment.
- Services must be reasonably needed by the hospital, and there must be a strong rationale for the physician or group being the right source for these services.

Comanagement and Service Line Management Agreements: Steps for Development

Development of comanagement agreements must take into consideration the length of the agreement and must ensure the structure and compensation specifics meet regulatory standards.

Involve Legal Counsel in Comanagement Agreement Development

As a contractual agreement, a comanagement agreement must comply with Stark law, anti-kickback statute and state laws. Legal counsel must be engaged to ensure regulatory compliance.

Key Steps in Developing Comanagement Agreements

Key Steps	Description
Identify Physician Group	■ Choose a group large enough to provide the services and resources desired to manage the service line and/or department.
Create a Written Contract	■ Develop a contract after both parties agree to an exclusive relationship. ■ Clearly define the responsibilities of the physician group, obligations, compensation and duration of the agreement.
Choose the Compensation Methodology	■ Engage legal counsel in reviewing the contract and compensation methodology. ■ Ensure the methodology meets restrictions defined by Stark law, anti-kickback statute, restrictions on the use of tax-exempt financing proceeds and state laws.
Analyze Fair Market Value	■ Obtain an independent fair market value analysis to determine the management fee. Anything other than a set annual, aggregate management fee raises regulatory risks. ■ Ensure the agreement does not take into account the volume or value of referrals. ■ Document need for the agreement and justification for compensation.

Pay Particular Attention to Regulatory Standards for Comanagement Agreements

The OIG and IRS are increasingly scrutinizing physician-hospital relationships related to compensation, specifically issues related to fair market value.

Success Factors

- Carefully develop the agreement to meet anti-kickback statute requirements.
  - — Physician payments must be based on fair market value for services actually provided and cannot be based on the volume or value of referrals.
- Document why the services are needed by the hospital and the rationale for choosing the physician group. Concern is raised when a group is designated to manage the services for the hospital but then subcontracts a third party to provide a majority of the services.
- Pay attention to legal and regulatory matters, including Stark law and tax-exemption issues.
  - — Structure the relationship to meet the professional services safe harbor of the anti-kickback statute. This is possible if the aggregate amount of compensation is set in advance.

Gainsharing Agreements

Gainsharing Agreements: Benefits and Challenges

Gainsharing emerged in the 1990s as a strategy to incentivize physicians to contain costs by sharing some of the cost savings achieved by more appropriate choice of procedures, supplies and devices.

In 1999, the OIG issued a Special Advisory Bulletin stating it was illegal for hospitals to share savings with physicians who helped reduce hospital costs under the Social Security Act Civil Monetary Penalties Law. The OIG also suggested that gainsharing arrangements could violate the federal anti-kickback statute. Hospital-physician gainsharing arrangements were abandoned until 2001 when the OIG reversed its stance and issued an advisory opinion allowing a limited gainsharing agreement between a hospital and group of cardiovascular surgeons. Since then, the OIG has issued multiple advisory opinions permitting gainsharing with specific specialists.

Gainsharing Is Limited but May Improve Alignment With Specific Specialists

Although gainsharing offers stronger alignment, these agreements require considerable time to develop. The arrangements are limited by the type of specialist that can be involved and duration of the agreement.

Gainsharing Agreement Description	■ Hospital and physician group enter into a cost-sharing arrangement to encourage product standardization and cost savings.

Benefits and Challenges of Gainsharing Agreements

	Benefits	Challenges
Hospital	■ May increase physician loyalty ■ May allow a reduction in expenses and increase utilization	■ The departments and specialties in which gainsharing can be implemented are limited. ■ Agreement duration is restricted.
Physicians	■ Provides physicians with clear expectations and payment based on cost reductions	■ Income potential for physicians is limited. ■ Agreement duration is limited.

When Is Gainsharing Appropriate?

Gainsharing is most appropriate when hospitals and physicians are interested in an agreement that supports cost reduction and quality improvement without a capital investment from either party

Key Factors for Determining Appropriateness

- Determine the specialties for which gainsharing would be applicable.
- Consider requesting an advisory opinion from the OIG.
- Rewrite the agreement as necessary if the program will continue past its original duration to ensure it meets the latest performance standards of OIG advisory opinions.

Source: *The Gray Sheet* 2008.

Gainsharing Agreements: Steps for Development

When developing gainsharing arrangements with specialists, hospitals are advised to follow the OIG advisory opinion process to ensure important regulations are closely followed.

Carefully Evaluate Possible Benefits of Gainsharing

The OIG has not stated that gainsharing is legal, only that certain types of gainsharing programs would be allowed under close scrutiny.

Key Steps in Developing Gainsharing Agreements

Key Steps	Description
Evaluate Opportunities	■ Analyze and evaluate cost-saving opportunities in the key specialty areas of cardiology, cardiovascular surgery, orthopedics and anesthesiology.
Develop and Negotiate the Agreement	■ Engage key specialists in determining the focus of the gainsharing agreement. ■ Consider the following areas: — Open as Needed: opening items only as needed — Use as Needed: using certain devices only as needed — Product Substitution: substituting certain less costly items — Product Standardization: standardizing certain devices
Submit to the OIG Advisory Opinion Process	■ Submit the agreement to the OIG advisory opinion process after it has been negotiated and finalized to confirm that there are no administrative sanctions. ■ Ensure that all specialists are treated equally in the gainsharing agreement.

Adhere to OIG Standards When Developing a Gainsharing Agreement

The OIG has supported several structural guidelines for developing gainsharing agreements. Several additional factors are important to consider when developing gainsharing agreements in order to ensure success.

OIG Recommendations

- Demonstrate a direct connection between individual actions by physicians and any reduction in hospital out-of-pocket costs.
- Specifically identify individual actions that result in savings.
- Implement sufficient safeguards to minimize the risk that other unidentified actions (eg, premature hospital discharges) may account for any savings incurred.
- Ensure that quality-of-care indicators are valid and statistically significant.
- Independently verify cost savings, quality-of-care indicators and other aspects of the arrangement.

Additional Success Factors

- Limit agreements in duration and payment. Agreements approved by the OIG are typically for 1 to 2 years, and payments are 50% or less of cost savings.
- Create a written disclosure of the gainsharing agreement for both hospitals and physicians to provide to patients before admission.

Sources: OIG Advisory Opinions 07-21 and 07-22.

Gainsharing Agreements: Leading Practices

A limited number of gainsharing agreements currently exist nationwide, but many believe these programs will gain momentum as hospitals struggle to control costs.

Gainsharing Programs Can Improve Physician Alignment on Quality, Cost Control

Good Samaritan Hospital and Pinnacle Health System are among the organizations and systems exploring the gainsharing agreement as a method to enhance physician involvement in improving quality and reducing costs within core service lines.

Examples of Gainsharing Programs

Hospital	Gainsharing Agreement
Pinnacle Health System Harrisburg, PA	■ Pinnacle started a gainsharing program in 2005 with Harrisburg Hospital and 3 cardiology group practices consisting of 50 physicians. ■ Pinnacle saved approximately $2.5M by using more cost-effective cardiac devices such as bare metal and drug-eluting stents, pacemakers and implantable defibrillators. ■ Cardiac cath lab complication rates have decreased incrementally since the program's inception. ■ Each cardiology group decided how they would distribute shared annual savings based on physician level of involvement in gainsharing activities. ■ Pinnacle's CEO cites the gainsharing program as the impetus for collaborative hospital-physician dialogue that resulted in 2 clinical quality improvement initiatives.
Good Samaritan Hospital San Jose, CA	■ Gainsharing agreement began in 2005 with hip and knee replacement procedures. ■ Contracts were developed with 3 preferred device manufacturers. ■ Participating orthopedists who use prosthetics covered under the contracts can receive gainsharing payments of 15% to 20% of the hospital's cost savings. ■ Seven of the 30 orthopedic surgeons at Good Samaritan enrolled in the program. Physicians were eligible to participate in gainsharing based on the number of procedures they performed in the previous year. ■ The gainsharing program was estimated to reduce the $2M annual orthopedic medical device costs by 10%.

Lessons Learned

- Begin by engaging and educating key physicians on the devices and supplies that create variations in practice patterns and associated costs. Once physicians become knowledgeable and share concern about costs, strategies for containing them, including gainsharing options, can be discussed.
- Build in a focus on transparency and quality when developing gainsharing programs, including disclosure of the practice to patients by both the hospital and physicians, to assist in gaining OIG approval.
- Include safeguards and documentation to ensure that the use of less costly supplies and devices will not compromise quality of care.

Sources: *Sacramento Business Journal* 2005; *Physician's News Digest* 2007.

Information Technology Strategies

Information Technology Strategies: Benefits and Challenges

Hospitals have invested substantially in IT systems and EMR, often without achieving the desired level of physician involvement and implementation. In August 2006, the OIG announced a relaxation of the Stark law and added exemptions to the anti-kickback statute—changes that allow hospitals to donate up to 85% of the cost of an EMR, including software and service, to physicians in their market. Similarly a 2007 IRS ruling allows tax-exempt hospitals to donate IT and related support services to private practice physicians.

IT Strategies Link Physician Practices to the Hospital and Health System

Donations apply only to new systems or major functionality upgrades, thereby limiting the window of opportunity for hospitals to develop connectivity with physician practices as EMR adoption increases.

IT Strategy Description	■ Hospital provides access and equipment that enable community physician practices to implement EMR systems.

Benefits and Challenges of IT Donation Strategies

	Benefits	Challenges
Hospital	■ Allows hospital to secure stronger alignment with physicians and groups ■ Supports coordinated care throughout the community or health system ■ May facilitate improvements in efficiency and quality of care	■ Continual training and retraining are required and are costly. ■ Eligibility for IT support must be determined. ■ HIPAA regulations and patient privacy must be considered.
Physicians	■ Offers physicians an opportunity to access IT systems ■ Provides an opportunity to offer evidence-based and efficient care	■ Time spent in training and retraining may be significant. ■ Switching from one hospital's system to another can be costly.

When Is an IT Strategy Appropriate?

Organizations that use IT to enhance relationships with physicians create competitive advantages. However, as federal and state governments and competing organizations drive widespread adoption, the window of opportunity for hospitals to become central players in community EMR adoption is limited.

Key Factors for Determining Appropriateness

- IT strategies with community physicians are appropriate when the hospital:
  - — Has already implemented EMR and gained the buy-in and support of physician leadership on the medical staff
  - — Has defined a subset of the medical staff who meet eligibility requirements to receive the equipment and services
  - — Can capture a first-mover advantage with physicians in the market

HIPAA = Health Insurance Portability and Accountability Act.

Information Technology Strategies: Steps for Development

Hospitals can gain an advantage by seizing opportunities to donate the costs of EMR systems to eligible physician practices in the market. Physicians are likely to resist switching EMR systems once one has been implemented due to the capital investment and training time involved.

Work With Physicians and Legal Counsel to Craft IT Agreement

Successful implementation of IT agreements begins with physician involvement to identify the vendor as well as steps to define eligibility, determine the scope of the donation and ensure compliance.

Key Steps in Developing IT Agreements

Key Steps	Description
Engage Physician Leadership	■ Gain the support and buy-in of key physician leaders on the medical staff. ■ Gauge the interest level from community physician practices in the market.
Define Eligibility	■ Determine which physician practices are eligible to receive IT support. ■ Work with legal counsel to properly determine physician eligibility that does not directly take into account the volume or value of referrals. Potential eligibility criteria include: — Size of the recipient's practice, eg, total patients or relative value units (RVUs) — Total number of hours that the recipient practices medicine — Recipient's use of automated technology in the medical practice — Whether the physician is a member of the hospital medical staff — Level of uncompensated care provided by the recipient
Create a Written Agreement	■ Define the following in the agreement: — Scope of the donation, cost of equipment and services, amount of the contribution
Ensure Compliance	■ Submit plans to the OIG for approval (recommended, but voluntary). ■ Do not place any restrictions on practices or requirements for referrals, as these can raise regulatory risks. ■ Ensure agreement complies with Stark law exceptions, anti-kickback statute safe harbors, IRS guidelines and any applicable state laws or regulations.

Ensure IT Agreement Success

Involve physician leadership and legal counsel to determine which practices are appropriate for donation.

Success Factors

- Identify the steps needed to meet state and federal regulatory standards.
- Ensure that the agreement does not place restrictions on the physician's practice or any requirements on physicians to refer patients.
- Promote transparency with the medical staff in the development of the agreements, timeline and definition of eligibility requirements.

Information Technology Strategies: Leading Practice

Expansion of EMR use across community practices assists physicians in accessing IT systems while effectively aligning their practices with the hospital.

Successful IT Strategies Are Developing

MemorialCare, a nonprofit, 5-hospital system in southern California, began planning and implementing an inpatient EMR in 2003.

MemorialCare Medical Centers, Long Beach, CA

Key Factors	Description
Leadership and Structure	■ MemorialCare's Physician Society is a partnership on leading practices and outcomes. The Society is governed by a board of directors that includes 16 physicians. ■ Governance structure of the Physician Society, best practice teams and informatics committees were critical for successful EMR adoption. ■ The Clinical Design Group is the physician team formed to design the EMR system.
Development of the System	■ Epic EMR system was chosen to be implemented first for inpatient (IP) care, followed by ambulatory care in April 2008. — 729 physicians are active on the IP EMR system. Two additional campuses began their rollout with 1,250 new physicians live on the IP EMR system by July 16, 2008. ■ Physicians are charged a flat fee for system implementation and training, and a monthly fee for ongoing licensing and support. ■ MemorialCare donates 75% of implementation costs to the physician practice. Individual physicians are responsible for computer and Internet connection costs.

Benefits

- The EMR has been positive for improving efficiency and demonstrating patient safety.
- MemorialCare was able to recruit an orthopedic surgeon and an obstetrician/gynecologist from a health system in Chicago because the physicians specifically wanted to work with Epic.

Challenges

- The system needs continual attention. Training and education for all staff is challenging.

Lessons Learned

- Engaging physicians in the strategic direction of the organization was critical for developing plans for a more integrated physician model (eg, formation of a foundation and medical group).
- The process is not complete after the initial rollout; continuous training, retraining and "at the elbow support" are necessary for physicians and the larger clinical workforce.

Source: MemorialCare Medical Centers, 2008.

Joint Ventures

True Provider Joint Ventures: Benefits and Challenges

True provider joint ventures, including ambulatory surgical centers (ASCs), end-stage renal disease (ESRD) facilities and whole-hospital joint ventures, remain common alignment options with physicians interested in pursuing equity arrangements with the hospital and/or with a third-party management company.

True Provider Joint Ventures Are a Stable Option for Physician Partnership

Most joint ventures involving hospitals and physicians have 50% to 60% hospital ownership, but hospital ownership may be as low as 20% to 30% or as high as 70% to 80%. Typically these joint ventures are structured as limited liability companies (LLCs), and governance is led by a board whose membership is split based on ownership.

True Provider Joint Venture Description	■ Physicians and hospitals partner to create a company that is the provider of services. ■ Variations: Third-party management companies can invest directly in the joint venture (or the provider) and contract directly with the joint venture.

Benefits and Challenges of True Provider Joint Ventures

	Benefits	Challenges
Hospital	■ Assists with recruitment and retention ■ Builds goodwill with physicians ■ Offers opportunity to increase market share and retain income	■ Location may be a point of contention. ■ Physicians have more control over governance and operations. ■ Hospital shares ownership with physicians. ■ Income share depends on the return on investment.
Physicians	■ Realizes potential cost savings by partnering with the hospital ■ Improves contracting strength with payers ■ Provides control over governance ■ Offers greater control over operations (eg, OR schedule, staffing choices, supplies)	■ Hospital is likely to retain significant control over the venture. ■ Bureaucracy associated with the hospital may mean slower decision making. ■ Income share depends on the return on investment.

When Are True Provider Joint Ventures Appropriate?

True provider joint ventures, or traditional joint ventures, are jointly owned entities. The joint venture has its own provider number and license, and typically owns the assets. Profits from the joint venture are divided based on the percentage of ownership.

Key Factors for Determining Appropriateness	■ True provider joint ventures are typical for surgery centers, ESRD facilities, whole-hospital joint ventures and specialty hospital joint ventures. ■ They are also appropriate for imaging ventures with radiologists or radiation therapy joint ventures with radiation oncologists.

True Provider Joint Ventures: Steps for Development

Successful performance of a joint venture begins with careful preparation and planning prior to initiation.

Prepare for an Ambulatory Surgery Center

Several key steps and considerations are necessary for establishing a successful ASC with physicians.

Key Steps in Developing a Successful ASC

Key Steps	Description
Identify the Number of Physicians	■ Choose a minimum of 8 to 10 physicians. ■ Ensure physicians are committed to the joint venture and are ready to proceed. ■ Designate a physician leader to represent the physicians, drive the process forward and collaborate with hospital leadership.
Evaluate Case Volume	■ Accurately analyze the projected year-over-year surgical case volume. ■ Determine case volumes by physician; calculate net case transfer to the ASC or joint venture. ■ Consider issues that discount volume, including insurance contracts, regulatory changes, local politics, scheduling and surgeon behavior. ■ For a conservative analysis, estimate 50% of surgical case volume.
Assess Specialty Mix	■ Identify a dominant subspecialty, such as orthopedics, pain management, ENT, ophthalmology, GI or general surgery, that will give the project its best opportunity for success.
Plan for Reimbursement	■ Anticipate reimbursement and payer contracting before starting construction. ■ Ensure payment for the work performed to secure sufficient cash collections.
Determine Ownership	■ Consider all approaches; there are positives and negatives for each. — Physicians may own the surgery center entirely or partner with a hospital and/or a corporation.
Identify Project Scope	■ Do not build a facility beyond its capacity—this is the main reason for failure. It is easy to overbuild, which creates undue stress on the financial performance of the venture. ■ Underbuild initially and plan future expansion.
Assess Equity and Debt	■ Ensure that enough cash is committed to the project. A lack of cash in the crucial start-up phase is common. ■ Avoid initiating capital calls from the partnership to meet cash needs in the first 12 months to keep the project running. ■ Obtain a commitment for financing before starting the project. Rates may vary.
Analyze Costs	■ Estimate approximately: — $1M per OR — $2M–$3M for a small single-specialty center with 2 surgical suites — $4M–$8M for a large multispecialty surgery center ■ Consider leveraging the majority of costs with debt.

ENT = ear, nose and throat; GI = gastrointestinal.

True Provider Joint Venture: Leading Practice

True provider joint ventures remain common alignment structures for partnering with physicians to improve and grow a service.

Successful Joint Venture Relationships Strengthen Alignment

Rockford Surgery Center opened in July 2004 as a joint venture between Rockford Orthopedic Associates (ROA) and OSF Saint Anthony Medical Center.

Rockford Surgery Center, Rockford, IL

Key Factors	Description
Background	■ ROA owns 65%; OSF Saint Anthony Medical Center owns 35%. ■ ROA offers services in orthopedics, physiatry, podiatry and rheumatology. ■ The venture includes 8 orthopedic surgeons and 1 podiatrist. ■ Currently, ROA has 8 orthopedic surgeons, 2 rheumatologists, 2 podiatrists and 1 physiatrist. ROA is looking to add a third hand specialist, a foot and ankle specialist, and a sports medicine physician. ■ The hospital partnership has helped surgeons navigate equipment purchases, oversee facility construction and get advice on day-to-day operations. ■ The ROA management team has been contracted to manage daily operations.
Performance	■ The joint venture was projected to break even within 4 to 5 years but actually broke even within 6 months. ■ The joint venture has reported a significant annual profit, especially in the second and third years.
Success Factors	■ A slow and deliberate choice of payers has been a key strategy for success. In addition to Medicare, the Center has only 4 contracts. The Center plans to add an additional 1 or 2 payers. ■ Many patients have out-of-network coverage. ■ Efficiency of care has also been important for success. Hiring a nurse manager with surgical center experience has improved operations and overall efficiency of care.

Lessons Learned

- Hospitals exploring joint ventures with surgeons must weigh the benefits and costs of the joint venture. Evaluate whether or not it makes sense to partner and retain a portion of the business or potentially lose business if surgeons go on their own.
- Joint ventures are governed by multiple laws and regulations, requiring involvement of legal counsel throughout all stages of development.
- Ongoing performance measurement and monitoring of the joint venture are necessary in order to ensure objectives are being met.

Source: Rockford Orthopedic Associates, 2007.

Infrastructure Joint Ventures: Benefits and Challenges

Infrastructure joint ventures involve hospital and physician joint ownership of equipment, real estate or staffing. These ventures are common for "Stark services," which physicians cannot own except in a group practice. Infrastructure JVs require close attention as the regulatory environment continues to shift.

Infrastructure JVs Provide Options to Partner on Equipment and/or Real Estate

In equipment JVs, the equipment is leased to the hospital or physician practice, which operates the equipment on either an annual flat-fee basis or a per-click basis. Per-click lease agreements are under growing scrutiny, and if pursued, hospitals and physicians must proceed cautiously.

Infrastructure Joint Venture Description	■ Hospital and physicians partner to create a company that owns equipment or real estate. ■ The joint venture company leases the equipment and/or real estate to the providers. ■ Infrastructure joint ventures can be structured from low to high risk. Low risk is a fixed annual fee payment, medium risk involves lower per-click payments and high risk involves retail per-click payments.

Benefits and Challenges of Infrastructure Joint Ventures

	Benefits	Challenges
Hospital	■ Provides opportunity to partner with physicians ■ Provides assistance with the cost of the equipment or real estate	■ Regulatory scrutiny of lease arrangements is increasing. ■ Hospital may not see as large a return as with true provider JVs.
Physicians	■ May be a less expensive investment and entail less risk than a true provider JV ■ Provides ownership in real estate and/or equipment	■ Increasing scrutiny may make this arrangement less desirable. ■ Physicians may not see as large a return as with true provider JVs.

When Are Infrastructure Joint Ventures Appropriate?

Infrastructure JVs are typically created when hospitals and physicians have a joint interest in purchasing a very expensive piece of equipment or real estate and the hospital has legitimate capital reasons for seeking a partner in the purchase.

Key Factors for Determining Appropriateness	■ May be appropriate when hospitals and physicians want to create a partnership arrangement but physicians are prohibited from owning the entity; examples include: — Imaging JVs with non-radiologists, radiation therapy JVs with urology and oncology practices, stereotactic radiosurgery JVs, lithotripter JVs and HOPD ambulatory surgery JVs, for which the hospital seeks to bill at HOPD rates.

HOPD = hospital outpatient department.

Joint Ventures: Steps for Development

Joint ventures involve a multistep process typically taking 6 months to 1 year from start to finish, depending on the amount of negotiation involved.

Involve Legal Counsel in the Multiple Stages Required of Joint Ventures

Developing a joint venture proceeds from a letter of intent through an operating agreement to a subscription agreement.

Key Steps in Joint Venture Development

Key Steps	Description
Write Letter of Intent	■ Include ownership percentages, capital distributed and covenants. The arrangement is nonbinding, although it contains certain binding provisions.
Establish an Operating Agreement	■ Draft the Operating Agreement after the Letter of Intent is signed. Drafted by counsel, this document governs the rights and obligations of venture partners. — Sets forth capital contributions, membership requirements, buy-out processes, noncompete covenants and management structure
Create Ancillary Documents	■ Include the Management Agreement, if there is one. ■ Include the Lease Agreement: — Hospital may provide management services to the joint venture, in which case there is a stated payment for these services and staff involved. — Physicians may own the real estate and lease it to the joint venture.
Develop Subscription Agreement	■ Create the subscription agreement/private placement memorandum. — Sets forth the risks involved in the investment — Details what the physicians are buying in shares of the joint venture

Consider Several Factors for Successful Joint Venture Development

In some cases, hospitals find they do not see the congruent interests they hoped to see. Consideration of the following factors will help ensure success.

Success Factors

- Ensure physician involvement in the drafting of the Operating Agreement.
- Anticipate points of contention and be willing to compromise.
  - — Covenants can be an issue for physicians, usually on the geographic radius of competing ventures.
  - — Ownership percentages are negotiating points. Hospitals typically want 51% ownership to qualify for tax exemption. Hospitals may take a lower percentage in return for additional powers in the Operating Agreement to protect the tax exemption.
- Carefully assess the volume necessary to ensure profitability to avoid overestimating size and capacity to reach the breakeven point in the time frame specified. Prudence is essential.
- Ensure that the joint venture company has tenants for real estate infrastructure JVs and that the lease satisfies relevant anti-kickback statute safe harbors and Stark law exceptions.

Address Legal Issues During Joint Venture Development

Hospitals and physicians must comply with Stark law, the anti-kickback statute, certificate-of-need laws, antitrust and state self-referral regulations when developing joint ventures.

Traditional Legal Structures May Present Hurdles to Joint Venture Development

If services are not Stark Designated Health Services (DHS), there is greater flexibility to develop a true provider joint venture. Venture models for DHS are limited.

Stark Law

Description	■ Stark law prohibits physicians from referring Medicare or Medicaid patients to an entity for DHS if the physician (or member of the immediate family) has a direct or indirect financial relationship with the entity, unless an exception applies. ■ DHS, as defined by Stark, include clinical laboratory, radiation therapy, physical and occupational therapy, durable medical equipment (DME) and supplies, IP and outpatient hospital services and prescription drugs, and home health.
Safe Harbors	■ Some services provided at an ASC may be DHS (eg, some implant procedures, DME) but are exempt from Stark law when performed within an ASC.

How to Comply

- Ensure your organization is complying with Stark law if:
  - A physician group invests in an HOPD and seeks to convert it into a freestanding surgery center
  - Physicians managing the hospital surgery department are operating in accordance with an "under arrangements"* agreement. Physicians must be paid fair market value for services, and the joint venture must not be intended to induce referrals.

Anti-Kickback Fraud and Abuse Statutes

Description	■ These laws aim to keep any organization that provides Medicare or Medicaid services from providing remuneration to physicians in exchange for referrals.
Safe Harbors and Exceptions	■ Safe harbors exist for single-specialty surgery centers, multispecialty surgery centers and surgery centers within hospitals. ■ Nuances include single-specialty surgery center safe harbors requiring that at least one-third of a physician's practice income from the previous fiscal year or previous 12 months be derived from the physician's performance of certain procedures. For multispecialty surgery centers, physician investors must perform at least one-third of the procedures at the center in which they are invested.

How to Comply

- Ensure that within a true provider joint venture the number of shares offered to physicians is not based on the number of referrals to that venture.
- Establish returns on investment based on ownership of shares, not the number of referrals.
- Pay physicians fair market value for services and ensure that payments are not tied to the volume or value of referrals generated by that physician.

*See Appendix 4: Glossary of Terms.

Anticipate the Impact of Regulatory Changes

As hospitals seek to align with physicians through joint venture relationships, continued attention to the changing regulatory landscape is necessary.

Recent Changes in Regulatory Environment

Regulation	Description	Implication
CMS Physician Fee Schedule	■ The 2008 Physician Fee Schedule, released July 2007, articulated future changes to Stark law, commenting negatively on per-click and under arrangements agreements from an anti-kickback statute perspective. ■ CMS is concerned that per-click payments for the use of the facility or equipment are an inducement to refer.	■ Several risks accompany the under arrangements model for joint ventures. Risks include potential liability under the anti-kickback statute, Stark law, IRS rules and regulations, and the False Claims Act. Hospitals and physicians are discouraged from implementing this model. ■ Without per-click agreements, block lease structures, in which equipment is leased for a specific time period, will be used.
Stark Phase III	■ CMS issued a final rule on Phase III of Part II of the Stark law on September 5, 2007, which went into effect December 4, 2007. ■ Key provisions address "stand in the shoes,"* shared space, independent contractors, physician recruitment and productivity bonuses.	■ These are mainly "clean-up" changes. ■ Expansion of the "stand in the shoes" provision will likely have significant implications for the structure of arrangements between physicians and entities providing DHS.
ASC Payment Changes	■ New CMS rules aim to eliminate financial incentives for choosing one care setting over another for similar services provided in an ASC, HOPD or physician office. ■ Revised ASC payment system will use hospital OPPS weights as a guide. ■ Surgical procedures that are eligible for ASC payment and can be performed safely at a lower cost in physician offices will be capped at the lower physician office rate.	■ Changing reimbursement will have a negative impact on low-acuity cases at these centers, especially pain management and gastroenterology services. — Payments for many orthopedic procedures and more complex cases will increase. ■ Payment changes will force hospitals and physicians to reevaluate alignment options and carefully assess ASC economics.
OIG Opinions	■ The advisory opinion issued June 19, 2007, suggests that hospitals seeking to invest in an ASC by purchasing it from physicians risk violating the anti-kickback statute.	■ Hospitals will be at risk if they purchase interests that include joint ventures that are not safe harbor compliant. ■ This opinion may create challenges for physician investors who are struggling to manage their ASCs and are looking to hospitals for assistance with operational issues and cash infusions.

*See Appendix 4: Glossary of Terms.
OPPS = Outpatient Prospective Payment System.

Employment Agreements

Employment Agreements: Benefits and Challenges

Many hospitals have avoided employment after the outlay of capital to acquire primary care practices in the 1990s that led to considerable financial losses. However, as physicians find alternative investment opportunities today and partnerships face growing scrutiny, hospital administrators are again employing physicians.

Employment Offers High Integration Between the Hospital and Physicians

Employment trends today are unique. Recent employment agreements* largely focus on specialists who directly drive revenue to the hospital, but some are also revisiting PCP employment.

Employment Options

Direct Employment	■ Hospital directly employs the physician. Fraud and abuse employment safe harbor and the Stark law employment exception are satisfied.
Subsidiary Company	■ The hospital creates a subsidiary company and employs physicians through the subsidiary.

Benefits and Challenges of Employment Agreements

	Benefits	Challenges
Hospital	■ Provides greater control of physicians' practice and referrals ■ Reduces physician competition ■ Helps mitigate physician shortages ■ Offers most flexibility under fraud and abuse statutes and Stark law	■ Operational costs can be significant. ■ It is difficult to include certain specialists in income opportunities from ancillary services. ■ Developing compliant productivity compensation models is often difficult. ■ Corporate practice of medicine* doctrine prohibits physician employment in some states. ■ Hospital is liable for physician malpractice.
Physicians	■ Offers greater income security ■ Supports physician work-life balance interests with predictable schedules and shift work	■ Employment may be perceived by physicians as diminishing their control and autonomy. ■ Payment is restricted to fair market value.

When Is Employment Appropriate?

Hospitals increasingly are pursuing physician employment to create greater integration and alignment with their physicians around growth, profitability and performance.

Key Factors for Determining Appropriateness

- When hospitals have plans to employ multiple physicians over the course of several years, this strategy can create strong integration.
- When managing shortages in the community, this strategy offers the opportunity to attract new specialists to the market.

*See Appendix 4: Glossary of Terms.

Employment Agreements: Steps for Development

Development of successful employment agreements requires careful analysis of economics, physician workforce dynamics and compliance with regulatory standards defined by Stark law, the anti-kickback statute and the IRS.

Clearly Define Compensation and Responsibilities

Legal counsel should be involved in the entire development process to ensure regulatory compliance.

Key Steps in Developing Employment Agreements

Key Steps	Description
Set the Compensation Structure	■ Primary care: Determine the percentage of salary to be based on RVUs. Typically the remainder is based on performance with agreed upon quality measurements. ■ Specialists: Agree on a structure that adequately measures productivity, eg, base salary plus a percentage of net collections.
Define Patient Care and Non–Patient Care Duties	■ Clearly define physician activities and responsibilities. ■ Responsibilities may include administrative duties, department-based duties, and research and patient care obligations, including the hours devoted to patient care and call coverage requirements.
Meet Regulatory Standards	■ Meet bona fide employment exceptions to the Stark law by ensuring the agreement describes: — All services to be performed by the physician — Remuneration consistent with fair market value and not determined by the volume or value of any referrals by the employee — Remuneration that is provided pursuant to an agreement that is commercially reasonable even if no referrals are made — Certain restrictions on compensation for ancillary services ■ Ensure the employee safe harbor of the anti-kickback statute is met. ■ Meet the criteria of a bona fide employee as defined by IRS.

Consider Factors for Developing a Successful Employment Agreement

In addition to regulations, important financial and cultural factors must be considered.

Success Factors

- Develop accurate pro formas, taking care not to overextend them.
- Use templates when possible; maintain consistency in the agreements for different specialists.
- Focus on providing a transparent process with no special deals for one specialist over another.
  - Engage specialists in determining the compensation process and performance metrics.
  - Ensure that any restrictive covenants are uniform for all specialists to maintain a fair process and culture.
- Incorporate an analysis of downstream revenue for primary care physicians to gain the support of hospital leadership and board for the employment agreement.

Employment Agreements: Leading Practice

Well-structured employment agreements can support physician recruitment, retention and engagement in organization-wide performance improvement.

Well-Structured Agreements Define Physician Involvement and Incentives

Primary care physicians approached WellSpan Health about employment to improve the standard of health care.

WellSpan Health, Central Pennsylvania

Key Factors	Description
Background	■ In 1993, WellSpan acquired 4 primary care physician groups, and growth continued for 5 years. ■ In the late 1990s, WellSpan began employing specialists to address shortages in the community, recruitment challenges and an aging workforce.
Leadership and Structure	■ WellSpan Medical Group created a unique structure with 50/50 board representation (hospital/physicians). This required special approval from the state. ■ Currently, there are 400 providers at 56 sites, and they are adding 40 to 50 per year. ■ The majority of physicians now find their voice and representation through the Medical Group rather than through the traditional medical staff structure.
Compensation Model and Incentives	■ Developing an analysis for identifying downstream revenue generated by the PCPs was essential for gaining board and hospital administration support of the employment model. ■ Compensation for PCPs is productivity based: 93% based on RVUs and 7% on quality. ■ Surgical specialist compensation includes base compensation plus a percentage of net collections. ■ Compensation for non-surgeon specialists is RVU based.
Benefits	■ In the past, WellSpan struggled with recruiting specialists. Now their employed PCPs control 45% of the referrals, and these referrals are a vehicle for attracting specialists.
Challenges	■ Some physicians have an employee mentality, which has been challenging to overcome.

Lessons Learned

- WellSpan Medical Group leadership is structured to support a collaborative relationship with physicians.
- Transparency on compensation structures is critical for maintaining a healthy culture and fairness.
- Creating a physician-led medical group was necessary for establishing trust, as was the 50/50 board.
- Shared decision making is essential.

Source: WellSpan Health, 2008.

Alignment Structures: Next Steps

Prepare for the Future: Evolution of Alignment Structures

Alignment structures will evolve as hospitals increasingly adopt structures that provide tighter integration to improve organizational performance.

Anticipate Future Changes to Alignment Structures

Considering the evolution of alignment structures is essential for choosing the right structure to establish sustainable and durable physician relationships.

Future of Physician Alignment Structures

Alignment Structure	Future Direction
Medical Directorships	■ Medical directorships will remain common in the near term; however, their structure will become more explicit, with specific requirements for performance improvement. ■ As more hospitals employ larger groups of physicians and identify other structures to develop stronger integration, medical directorships will become less common.
Contractual Agreements	■ Hospitals that continue to pay physicians for call services will require their participation in quality improvement committees and performance improvement initiatives. ■ Performance metrics will increasingly be incorporated in contract renewals. — Radiology contracts will include as key requirements: guaranteed turnaround times, active participation in hospital committees and availability for physician consultation.
Gainsharing Agreements	■ Additional approvals for gainsharing agreements suggest more widespread replication of this model in years to come.
Information Technology Strategies	■ Reduced barriers to EMR adoption offer a small window of opportunity for hospitals interested in first-mover advantage by connecting with community physician practices. ■ Future IT-related alignment opportunities will include virtual care delivery models.
Joint Ventures	■ True provider JVs will remain common where appropriate, including surgery centers, ESRD facilities, whole-hospital JVs, specialty hospital JVs, imaging JVs with radiologists and radiation therapy JVs with radiation oncologists. ■ Infrastructure JVs will remain common; however, equipment JV structures will shift. Although not finalized, CMS has indicated that most of the existing under arrangements and per-click agreements will no longer be legal under Stark III.
Employment Agreements	■ Employment will become the dominant focus for developing strong integration. ■ Hospitals will increasingly embrace integration strategies that involve employment of specialists who drive revenue to the hospital to improve specialist recruitment. ■ In states prohibiting the direct employment of physicians due to the corporate practice of medicine doctrine, expect to see proliferation of the foundation model. ■ As the base of employed physicians grows, the focus for hospitals will be proficiency in building and managing large groups of physicians.

Expand the Integrated Enterprise

The integrated enterprise is a combination of strategy, culture and alignment structures that engage physicians in all aspects of care delivery and performance improvement.

Integrated Organizations Advance Goals

Hospital leadership must identify where along the integration continuum they wish to be. Will a contractual agreement, joint venture, employment agreement or some combination of these best fit the needs of the organization and physicians in the market? Most will find that structures offering the highest degree of integration will best support hospital and physician objectives to improve outcomes, financial performance and service excellence.

Integrated Organizations Share Common Attributes

Organize Around the Patient	■ Focus shifts from delivering discrete services to delivering results across the entire care process; coordination of specialists and locations is seamless.
Align Economics	■ Hospitals and physicians are economically aligned through the business structure and through the emergence of new payment structures, including bundled payment systems. ■ Physician compensation reflects not only productivity in clinical care, but active involvement in leading priorities and committees to improve quality, service and financial performance.
Focus on Performance	■ Physicians and the hospital form a single, unified entity and culture to differentiate care. ■ Physicians are involved in all aspects of process, care delivery and innovation.

Implementation Matters as Much as Structure

As organizations refine physician strategy in a way that meets tomorrow's performance objectives, identifying the right alignment structures is only the beginning. The organization's ability to successfully implement and manage these emerging structures will be just as critical. Successful models of integration engage physicians in leading all major aspects of care delivery: strategy, planning, operations, policy decisions and governance.

Collaboration	Integration	Management
■ Quality improvement ■ Efficiency ■ Patient satisfaction ■ Low-integration alignment structures	Long-term alignment: ■ Employment ■ Partnerships ■ Paid leadership positions ■ Management services agreements	■ Governance ■ Physician leadership ■ Service line management ■ Compensation and productivity incentives ■ Practice management

Get Started: Find the Right Leadership and the Right Approach

Building a successful physician partnership or integration strategy begins with finding the right physician partners and the right leadership. Carefully design the approach to attract these physicians, establish trust and create a winning relationship.

Engage the Right Physician Partners, Develop the Next Generation of Leadership

Hospitals must cultivate a pool of highly engaged physician leaders devoted to developing leading practices, driving performance improvement and spearheading culture change.

Key Priorities of the Physician Leader

Key Priorities	Role of the Physician Leader
Create Leading Practices	■ Initiates and manages multidisciplinary care teams, integrating specialists across service lines and locations of care
Demonstrate Performance Improvement	■ Is deeply knowledgeable about the care continuum and specialists involved ■ Leads process redesign, technology adoption, and ongoing measurement and tracking of outcomes for performance improvement
Focus on Culture	■ Translates metrics and analytics to gain medical staff support and build momentum for cultural change ■ Serves as the master communicator with empathy for multiple stakeholders

Establish Trust With the Right Approach

Before engaging potential physician partners, create a strong approach that demonstrates credibility, careful preparation and planning, as well as sensitivity to physicians' needs and expectations.

Key Steps for Building Physician Trust

Demonstrate Credibility	■ Focus on transparency of principles and processes to demonstrate fairness and trustworthiness as a partner. ■ Engage physicians in identifying the methodology for compensation models and in decision making to encourage buy-in and to establish fair, equitable treatment.
Identify What Is Unique and Different	■ Identify and address past mistakes. Reestablish trust by developing a social compact to define needs and expectations. ■ Ensure that the process gives physicians a voice and clearly articulates the unique roles and responsibilities they will have in the leadership and management of care. ■ Commit to a transparent decision-making process.
Communicate Your Strength as a Partner	■ Identify how the relationship with the hospital would meet physician wants and needs, including work-life balance, income stability, access to capital, quality improvement, and greater involvement in and control over operations and performance. ■ Position the hospital as the strongest partner in the market.
Know When to Bring in the Experts	■ Engage legal counsel in all discussions regarding potential alignment structures and in all phases of development of agreements. ■ Consider involving an independent third party to serve as an interface to strengthen communication and collaboration between the hospital and physicians.

Appendices

Appendix 1: Review of Medical Directorship Agreements

Several questions require further exploration to establish the validity and appropriateness of medical directorship agreements.

Ask Key Questions When Developing Medical Directorship Agreements

Questions to Consider to Ensure Regulatory Compliance

- ☐ Is there a legitimate need for a medical director in the specified service line or department? If so, is the need documented?
- ☐ Which clinicians, including nonphysicians, would be most appropriate for this role?
- ☐ Have the number of hours that the medical director will be needed to provide services annually been estimated?
  - — How many hours will be spent handling administrative responsibilities and not providing professional services?
  - — If a physician is separately billing for professional time, this time should not count toward the calculation of medical director hours.
- ☐ Is the hourly payment amount reasonable for the skills required to serve in this role?
  - — Hourly rates depend on the services provided and the geographical location of the practice.
  - — Only in unusual cases can above-average per-hour rates be justified.
- ☐ Is there a process to ensure physicians maintain time records or time sheets?
- ☐ Is the total compensation amount in line with national and/or regional averages for persons performing similar services?
- ☐ Have multiple sources from independent consultants and surveys (eg, Medical Group Management Association or other public surveys) been consulted to determine appropriate compensation?

Appendix 2: Review of Joint Venture Agreements

Determine whether or not the joint venture is reasonably defensible from anti-kickback statute, Stark law and other tax-exempt law perspectives.

Ask Key Questions When Developing Joint Ventures With Your Physicians

Questions to Consider to Ensure Compliance

- ☐ What structure will the joint venture take? Will it be an entity in and of itself, or will it share profits by contract?
- ☐ Will the venture provide a new and improved service?
- ☐ Who will own the majority of the venture? Will a tax-exempt entity have sufficient control over the venture to ensure that the venture serves community benefits?
- ☐ How much of the venture will physicians own? Will participants generate more than 40% of the venture's business?
- ☐ Will the parties pay equal amounts on a per-share basis for venture interests?
- ☐ Will acquisition rights be provided to referring physicians on an equal basis without taking into account projected referrals to the venture?
- ☐ Will loan guarantees be required? Will they be provided to ownership pro rata? Will a non-referring party be forced to serve disproportionately as the loan guarantor?
- ☐ Will investors, or the entity itself, "finance" the acquisition of interests for any party referring to the venture?
- ☐ Will the joint venture be required to provide indigent care? To treat Medicare/Medicaid patients? To participate in managed care contracts? To abide by compliance policies and programs? Will there be specific conditions for charity care?
- ☐ Will physicians or others be required, pressured or expected to refer business to the venture to retain ownership in the venture?
- ☐ Will physician owners refer patients to the venture but not perform services for the venture?
- ☐ Will physician owners inform patients of their investment interest?
- ☐ Will all venture interests have equal economic rights?
- ☐ Will any payments be made to the investors other than as a return on investment?
- ☐ What events will cause ownership to terminate in the venture?
- ☐ Will the venture be located within the physical location of the hospital? Do state licensing laws permit this? If the state does not permit this, will this allow the services to be Stark designated?
- ☐ Will the venture provide Stark designated health services?
- ☐ Will the venture be located in a medically underserved area?
- ☐ Will the venture comply with safe harbors, such as those for small investment interests or ambulatory surgery centers?

Appendix 3: Review of IT Agreements

When developing IT agreements, ensure that they meet anti-kickback statute safe harbors, Stark law exceptions and IRS exceptions for health care IT subsidies.

IT Agreements Must Meet Regulatory Standards

Requirements for IT Donations to Physicians

Electronic Prescribing Items and Services	☐ Items and services are provided as part of, or are used to access, an electronic prescription drug program that meets Medicare Part D requirements. ☐ Donor does not limit or restrict the use or compatibility with other systems. ☐ Neither eligibility for receiving items and services nor amount/nature of items/services can be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. ☐ Written agreement specifies the items and services, cost of the items and services and the amount of the contribution. — Cannot be conditioned on the physician doing business with the hospital — Cannot restrict the patients for whom the items and services are used
Electronic Medical Record Items and Services	☐ Items and services in the form of software or IT and training are deemed necessary and are provided predominantly to create, maintain, transmit or receive EMR. ☐ Items and services must be given by an individual or entity that provides services covered by Medicare. ☐ Software must be interoperable with other electronic prescribing or EMR systems at the time it is provided to the physician. ☐ Donor cannot restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or EMR systems. ☐ Donation cannot be conditioned on doing business with the hospital. ☐ Neither eligibility for receiving items and services or amount/nature of items/services can be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. ☐ Written agreement specifies the items and services, cost of the items and services, and the amount of the contribution. — Cannot restrict the patients for whom the items and services are used ☐ Donations must be unrelated to the recipient's clinical practice or clinical operations. ☐ Electronic prescribing capabilities must meet the applicable Medicare Part D electronic prescribing standards. ☐ Recipient must pay 15% of the donor's cost of the items and services; the donor hospital cannot finance such payment or loan funds to be used by recipient. ☐ The hospital cannot shift costs of the items or services to any federal health care program. ☐ The donation must occur prior to December 31, 2013.

Source: OIG Advisory Opinion 07-10, September 27, 2007.

Appendix 4: Glossary of Terms

Anti-kickback statute
A provision of the Social Security Act that forbids:

- Any knowing and willful conduct involving the solicitation, receipt, offer or payment of any kind of remuneration in return for referring an individual for any Medicaid- or Medicare-covered item or service
- Recommending or arranging the purchase, lease or order of an item or service that may be wholly or partially paid through the Medicare or Medicaid programs

Violation of the provision can result in fines, imprisonment, exclusion or suspension from government health care programs if convicted.

Arm's-length negotiation
Used specifically in contract law to arrange an equitable agreement that will stand up to legal scrutiny, even if the parties may have shared interests (eg, employer-employee relationship) or are too closely related to be seen as completely independent (eg, the parties have familial ties)

Call coverage agreement
An agreement between a hospital and physician or between a hospital and physician group to provide coverage for the emergency department. Call coverage agreements may include physician compensation or may be policy or technology based.

Comanagement agreement or service line management agreement
A contract between the hospital and a group of physicians that have formed a management company to provide services to the hospital. The hospital pays the management company a fee based on fair market value for the services provided to the hospital.

Corporate practice of medicine doctrine
State laws that prohibit physicians from working for a corporation—physicians can only work for themselves or another physician. A corporation that is not owned by physicians generally is prohibited from practicing medicine. These laws often have a variety of exceptions that permit physicians to work as an employee of a hospital or health plan.

Emergency Medical Treatment and Active Labor Act (EMTALA)
Included in the Consolidated Omnibus Budget Reconciliation Act of 1986 to prevent the discriminatory practice of transferring, discharging or refusing to treat indigent patients in the emergency department because of the high cost associated with diagnosing and treating these patients. EMTALA imposes strict penalties, including fines and exclusion from the Medicare program, for violations.

Employment agreement
Direct employment of physicians or creation of a subsidiary company that directly employs physicians. Direct employment models with physicians satisfy the Fraud and Abuse Statute employment safe harbor and the Stark law employment exception. Under an employment model, payments to physicians meet safe harbor protection under the bona fide employee exception to fraud and abuse statutes.

Foundation agreement
A nonprofit form of an integrated health care delivery system. The foundation model is typically used in response to tax laws that affect nonprofit hospitals or in response to state corporate practice of medicine laws that prohibit direct physician employment. The foundation purchases both the tangible and intangible assets of the physicians' practices; the physicians form a medical group that exclusively contracts with the foundation for services to patients seen through the foundation. The foundation is usually associated with a nonprofit hospital.

Appendix 4: Glossary of Terms (Cont'd)

Gainsharing agreement
A cost-sharing agreement between the hospital and a physician group to encourage product standardization and cost savings. The OIG has issued multiple advisory opinions that permit gainsharing with specific specialists, but there are no safe harbors for these arrangements.

Infrastructure joint venture
A partnership between the hospital and physicians to create a company that owns equipment or real estate. The joint venture company then leases the equipment and/or real estate to the providers.

Medical directorship
Structures for compensating physicians within core service lines for their time and involvement in leadership roles. The hospital retains the physician to provide leadership and other services with respect to certain activities within the hospital.

Professional services agreement
A contract between a physician or medical group and integrated delivery system, hospital or managed care organization for the provision of medical services

Safe harbor
Regulatory or statutory provisions that shield certain designated payment arrangements from criminal prosecution or program exclusion. Safe harbor provisions are contained in the anti-kickback statute and regulations issued by the OIG.

"Stand in the shoes" provision
Initially, certain indirect compensation relationships that did not violate the Stark law. A hospital could own a clinic or foundation, and that clinic or foundation would employ physicians. Under Stark III proposed rules, the hospital owner of the clinic or foundation would "stand in the shoes" of the clinic or foundation. As such, the relationship between the physicians and the foundation or clinic would need to meet a Stark exception, as though the hospital had a direct relationship with the physicians.

Stark law
Includes 3 separate provisions that restrict physician self-referrals:

Stark I: Refers to the physician self-referral prohibitions introduced to Congress in 1998 by California representative Fortney "Pete" Stark. The initial Stark law became effective January 4, 2002 and provides that a physician or immediate family member who has a financial relationship with an entity may not refer a Medicare patient to that entity for clinical laboratory services, unless an applicable exception exists. In addition, the law prevents an entity with which a physician has a financial relationship from billing Medicare or a beneficiary for clinical laboratory services furnished pursuant to a prohibited referral.

Stark II: Amendments to Stark I extend the physician self-referral restrictions to Medicaid services and beneficiaries and expand the referral and billing prohibitions to 10 additional designated health services reimbursable by Medicaid or Medicare. The 10 services include: physical therapy; occupational therapy; radiology services (including MRI, CT and ultrasound services); radiation therapy services and supplies; DME and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient health services. Stark II became effective on July 26, 2004.

Appendix 4: Glossary of Terms (Cont'd)

Stark III: These provisions, effective December 4, 2007: 1) redefine arrangements between hospitals and individual members of group medical practices as "direct" rather than "indirect" compensation; 2) eliminate the "safe harbor" methodology for calculating fair market value for hourly physician services; and, 3) create additional flexibility for rural hospitals in recruiting and retaining physicians. This rule makes no changes to the in-office ancillary services exemption but cites this area as a possible target for future rulemaking. Under arrangements are receiving growing scrutiny and likely will be included under Stark III in the future. Per-use or "per-click" space and equipment leases are likely to receive future limitations under Stark III as well.

True provider joint venture
A partnership between hospital and physicians to create a company that is the provider of services and bills payers for services. A third-party management company may invest directly in the joint venture (or the provider) and contract directly with the joint venture. Typically these joint ventures are structured as an LLC, and governance is led by a board whose membership is split based on ownership.

"Under arrangements" agreements
Historically, hospitals could purchase services that they did not currently provide by outsourcing such services "under arrangements" with a third-party supplier. In such arrangements, the third party provides the care and is paid by the hospital. The hospital remains responsible for the quality and overall scope of the service and bills the appropriate payer under the hospital's provider number for care delivered. These types of agreements currently face growing scrutiny by CMS. It is concerned over the proliferation of these agreements, particularly between hospitals and physicians in joint venture relationships, since they can provide physicians with an opportunity to profit from referring patients for the services.

Sources: American Health Lawyers Association. *Fundamentals of Health Law*, 3rd ed. 2004; McGuireWoods Stark III: 9 Areas of Concern, 2007; McGuireWoods Hospital-Physician Integration: An Alternative to Joint Ventures, 2007.

Notes

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5250 Old Orchard Road
Skokie, Illinois 60077

+1 866 681 3343

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