

Getting Aligned: Strategic Affiliations for Community Providers

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I. Overview: Drivers, Benefits, and Challenges to Strategic Affiliations

A “community provider” generally refers to an organization or individual that provides services to a community and may include entities like hospitals and clinics.

A. Key Challenges Faced by Community Hospitals

- Low patient volumes
- Workforce recruitment and retention
- Payment program dependence
- Federal hospital support
- Medicaid-funded patient base

B. Community Provider Strategic Affiliations: Benefits

- Branding and patient draw
- Economies of scale
- Leadership and management training and support opportunities
- Improved ability to manage defined populations and coordination of patient-centric care
- Alignment for quality and efficiency
- Shared resources, risks, and rewards
- Opportunity to improve clinical and financial data systems
- Access to specialists
- Access to clinical trials and other research opportunities

C. Community Provider Strategic Affiliations: Challenges

- Cultural differences, which can be significant, particularly when dealing with a smaller and geographically remote community provider (clinical care and business practices)
- Difficult to elevate the community hospital credentialing requirements to academic standards
- High costs of specialists
- Loss of autonomy for community provider
- Difficulty integrating disparate systems
- Mismatch of expectations
- Overestimation of partner capabilities
- Lack of buy-in from key stakeholders
- Misunderstood governance
- Trusting partner versus creating contractual obligations
- General misalignment of values, mission, strategy, and goals

II. Strategic Affiliations: Principal Business and Regulatory Considerations

- A. Principal Business Considerations
- Scope of contractual arrangement or venture
 - Name use rights
 - Governance structure and decision-making
 - Capital contributions and distributions and financial relationships
 - Fraud and abuse considerations
 - Bond restrictions
 - Obligated group issues
 - Dilution
 - Tax-exemption considerations
 - Noncompetition and other restrictive covenants
 - Term/termination
 - Buy-in/buy-out
 - Dispute resolution
 - Succession planning
- B. Principal Regulatory Compliance Considerations
- Fraud and Abuse
 - Stark Law
 - Anti-Kickback Statute (AKS)
 - False Claims Act and Civil Monetary Penalties
 - State Fraud and Abuse
 - Antitrust Considerations and Unfair Competition
 - Licensure and Certificate of Need/Determination of Need
 - Reimbursement Considerations, Including the Anti-Markup Rule
 - Provider-Based Rules and Colocation Requirements
 - Privacy and Security (HIPAA)
 - Tax and Tax Exemption Issues
- C. The Stark Law (Physician Self-Referral Act)

The Stark Law is a strict liability¹ statute that generally prohibits a physician from making a referral of a Medicare patient for certain enumerated designated health services (“DHS”) to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies.² The entity that receives the prohibited referral under the Stark Law may not bill Medicare for the services furnished as a result of the referral.³ However, the Stark Law contains several statutory and regulatory exceptions that set forth permissible financial arrangements between a referring physician and a DHS entity.

¹ As a strict liability statute, any technical violation of the Stark Law requires repayment of all “tainted” referrals, regardless of the parties’ intent. The Stark Self-Referral Disclosure Protocol (“SRDP”) allows providers the option to self-disclose actual or potential violations of the Stark Law, with the intention of resolving any overpayment liability exposure for the identified conduct for a lesser amount.

² See 42 U.S.C. § 1395nn; 42 C.F.R. § 411.353.

³ Under the Stark regulations, “[a]n entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis...” 42 C.F.R. § 411.353(d); see also 42 U.S.C. § 1395nn(g)(2). Penalties for violating the Stark Law include the denial of payment by Medicare to an entity for the impermissible provision of DHS, the refund of any amounts collected in violation of the Stark Law, and civil monetary penalties. 42 U.S.C. § 1395nn(g). Further, the failure to refund may potentially trigger false claims liability or even a criminal reporting obligation. See 31 U.S.C. § 3729; 42 U.S.C. § 1320a-7b(a)(3).

Notably, DHS includes outpatient prescription drugs and accordingly, Amazon Pharmacy is a “DHS entity” under the Stark Law and must ensure that any financial relationship involving referring physicians complies with the Stark Law.

Penalties for violating the Stark Law are harsh and include the denial of payment to the DHS entity, the refund of any amounts collected related to referrals made in violation of the Stark Law, and civil monetary penalties.⁴ Furthermore, violations of the Stark Law may also expose an individual or entity to liability under the FCA, including via *qui tam* action, for knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment or approval.

The Stark Law defines a “financial relationship” as an indirect or direct compensation arrangement with a DHS entity, or an indirect or direct ownership or investment interest in a DHS entity.⁵ A “compensation arrangement” is further defined as any arrangement involving remuneration—direct or indirect—between a physician (or a physician’s immediate family member) and the DHS entity.⁶ For purposes of direct and indirect compensation arrangements, a physician is deemed to “stand in the shoes of his or her organization” (and thus is deemed to have the same compensation arrangements as the physician organization itself) if the physician has an ownership or investment interest in the physician organization.

D. Federal AKS

The federal AKS prohibits providers from knowingly and willfully soliciting, receiving, offering, or paying, directly or indirectly, any remuneration in return for either making a referral for a service or item covered by a federal healthcare program (including Medicare and Medicaid) or ordering any covered service or item.⁷ For purposes of this statute, remuneration includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly. The AKS is intent-based, which means remuneration for referrals is only subject to liability if the requisite intent to induce or provide referrals is present.⁸ Notably, however, multiple federal circuit courts have held that the federal AKS is violated if one purpose (as opposed to a primary or sole purpose) of a payment or remuneration to a provider is to induce referrals.⁹

AKS regulations have been promulgated to provide “safe harbor” protection for certain activities falling within defined parameters that might otherwise potentially be subject to scrutiny under the AKS. Each requirement of an applicable safe harbor must be met in order to receive safe harbor protection. Nonetheless, the failure to fit within a safe harbor does not mean that the arrangement is *per se* illegal, but rather failure to fit entirely within a safe harbor merely means that the arrangement would be subject to a case-by-case review of the particular facts and circumstances. In this regard, as a general matter, we recommend compliance with as many elements of a safe harbor as possible as the attempt to comply with the safe harbor supports that an illicit intent to induce referrals is not present.

⁴ 42 U.S.C. §1395nn(g).

⁵ See 42 C.F.R. §411.354(a)(1).

⁶ See 42 C.F.R. §411.354(c).

⁷ See 42 U.S.C. § 1320a-7b(b); 42 C.F.R. §§ 1001.952 *et seq.*

⁸ Pursuant to the Patient Protection and Affordable Care Act, P.L. 11-148 (2010) as amended by P.L. 111-152 (2010) (“ACA”), a defendant does not have to have actual knowledge of, or a specific intent to commit, a violation of the federal AKS in order to be found guilty. *See id.*

⁹ See *U.S. v. Borrasi*, 639 F.3d 774 (7th Cir. 2011); *U.S. v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *U.S. v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *U.S. v. Kats*, 871 F.2d 105 (9th Cir. 1989); *U.S. v. Greber*, 760 F.2d 68 (3rd Cir. 1985).

Violation of the AKS is a felony and may be punished by substantial fines of up to \$100,000 and/or ten years imprisonment for each violation.¹⁰ In addition, violations may lead to civil monetary penalties and exclusion from federal healthcare programs. Finally, violations of the federal AKS subject an individual or entity to liability under the FCA, as described above.

E. Federal AKS Safe Harbors

Several AKS safe harbors are available to protect strategic affiliation and joint venture financial arrangements, including:

- Personal and Management Services¹¹
- Equipment Lease¹²
- Space Lease¹³
- Small Entity Investment¹⁴
- Ambulatory Surgical Center¹⁵
- Value-Based Arrangements¹⁶

OIG advisory opinions provide regulatory guardrails to guide the implementation of arrangements when safe harbor protection is not available.

F. AKS Safe Harbors: Common Features

The Personal and Management Services, Equipment Lease, and Space Lease Safe Harbors

- In writing, signed by the parties
 - Covers all services to be furnished
 - At least a one-year term
- Commercially reasonable services
- Compensation methodology
 - Set in advance
 - Consistent with FMV
 - Not determined in a manner that takes into account the volume or value of referrals

G. AKS Safe Harbors: Common Features

Small Entity Investment and Ambulatory Surgery Center Safe Harbors

- Investment Terms
 - Specific requirements for how investment interests are offered and structured
- Investment Returns

¹⁰ 42 U.S.C. § 1320a-7b(b). Note that the penalties for violations of the federal AKS significantly increased under the Bipartisan Budget Act of 2018, as the maximum penalties for violating the federal AKS quadrupled.

¹¹ 42 C.F.R. § 1001.952(.).

¹² 42 C.F.R. § 1001.952(d).

¹³ 42 C.F.R. § 1001.952(b).

¹⁴ 42 C.F.R. § 1001.952(c).

¹⁵ 42 C.F.R. § 1001.952(r).

¹⁶ 42 C.F.R. §§ 1001.952(ee)-(gg).

- Return on investment (equity distributions) must be proportional to capital contributions
- Financial Arrangements
 - Specific requirements regarding services provided by the invested entity, ensuring compensation is FMV and does not incentivize referrals

H. OIG Special Fraud Alert on JV Arrangements¹⁷

Features of Suspect JVs

- Investors are chosen because they are in a position to make referrals.
- Physicians expected to make a large number of referrals are offered a greater investment opportunity in the JV than those anticipated to make fewer referrals.
- Physician investors are actively encouraged to make referrals to the JV and may be encouraged to divest their ownership interest if they fail to sustain an “acceptable” level of referrals.
- The JV tracks its sources of referrals and distributes this information to investors.
- Investors are required to divest their ownership interest if they cease to practice in the service area (e.g., if they move, become disabled, or retire).
- Investment interests are nontransferable.

I. OIG Special Advisory Bulletin: Contractual JVs¹⁸

Features of Suspect Contractual JVs

- A healthcare provider in one line of business (the “Owner”) expands into a related healthcare business by contracting with an existing provider of a related item or service (“Manager/Supplier”) to provide the new item or service to the Owner’s existing patient population.
- The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services.
- In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

III. **Common Affiliation Models: Model Structures and Principal Considerations**

A. Range of Community and Rural Provider Affiliation Models

- Clinical affiliation agreement
- Clinically integrated network
- Management services agreement
- Service line joint operating agreement
- Hospital JV, JOA or merger
- Member substitution/acquisition

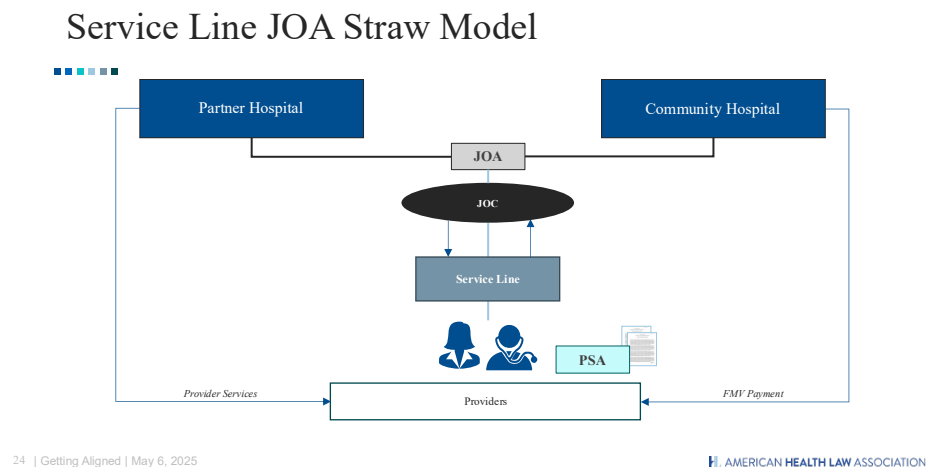
¹⁷ OIG, Special Fraud Alert

¹⁸ OIG, Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23,148 (April 30, 2003).

B. Service Line JOA

- The value of each hospital's contribution to the service line JOA determines "ownership."
- The JOA board (or joint operations committee [JOC]) consists of representatives from both hospitals and has authority over the service line, including strategic planning, development of operating and capital budgets, and determination of new service offerings or locations.
- The scope may vary depending on the service offerings of each organization, but the parties agree on which services should be included in the partnership and how those are defined.
- Each hospital maintains its own operations.
- While JOA facilitates increased clinical coordination (e.g., care pathways and transfer protocols), organizations continue to bill for services under their own licenses, payer contracts, and provider numbers.
- Income and loss from each hospital's service line is combined and allocated based on the hospitals' respective ownership percentages.

C. Service Line JOA Straw Model



D. Benefits of Service Line JOA

- Leads to improved patient care as the community hospital gains the experience of the partner hospital
- May allow for independence while being able to offer a previously out-of-scope service
- Optimizes clinical and administrative processes
- Improves patient experience and outcomes
- Enhances patient access as the service line is kept in the community
- Coordinated care with specialists from the partner hospital

E. Challenges of Service Line JOA

- Lack of engagement from the partner organization due to looser alignment
- Hesitancy to share data
- Complexity of accounting

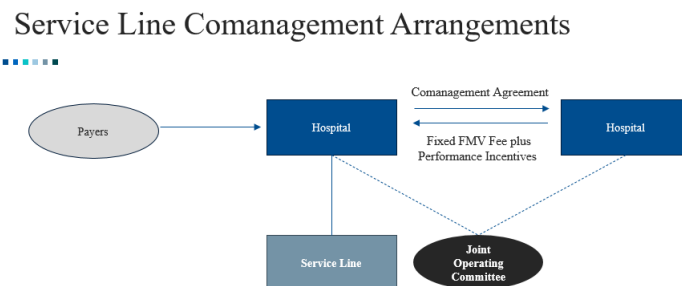
- Arrangement compliance
- Determination of responsibility for future capital commitments
- Governance structure that satisfies both parties involved

F. Management/Comanagement Arrangements

Service Line Comanagement and Management Arrangements

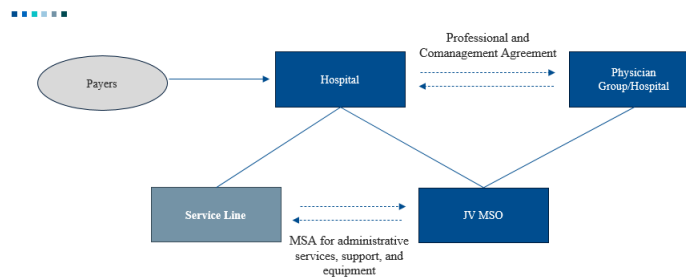
- These are contractual arrangements that provide shared responsibility for a service line by recognizing and appropriately rewarding participating hospitals through their physicians for efforts in managing and improving the quality and efficiency of a hospital service line (e.g., oncology).
- They are generally meant to ensure service line quality improvement, patient access, and sustainability.
- Typically, funds flow through:
 - (a) A fixed FMV annual base fee for the time the medical groups/physicians dedicate to the service line management, development, implementation, and oversight processes.
 - (b) Predetermined incentive payments associated with the achievement of specified, mutually agreed upon, and objectively measurable quality improvement and efficiency goals.
- Governance is through a JOC consisting of representatives from the hospital and physician group/partner hospital, but the hospital that owns the service line must have ultimate control.

G. Service Line Comanagement Arrangements



H. JV MSO

JV MSO



I. Benefits of Service Line Comanagement and Management Arrangements

- Relatively quick to execute and implement as a mechanism for using physician competencies to manage a variety of service lines
- Align hospital and physicians around service line quality and efficiency
- Optimize service lines while maximizing physician engagement
- Optimize clinical and administrative processes
- Improve patient experience and outcomes
- Maintain hospital reimbursement for service lines
- If a JV management company formed: low capital investment, minimal investment risk, and financial returns

J. Challenges of Service Line Comanagement and Management Arrangements

- Need for active participation and real-time effort by physicians
- Gaps in communication and lack of stakeholder engagement
- Lack of adequate long-term benefits for the community provider (if financial motivations are primary driver versus efficiency, cost, and patient experience)
- Onerous target setting and continual resetting of quality targets relative to baseline levels
- Need to reevaluate and replace metrics that are fully optimized or achieved for multiple consecutive years
- Some irreducible regulatory risk

IV. **Valuations: Approach to FMV and Financial Considerations**

A. Standards of Value: When performing a valuation of a business, services, or fixed assets, the standard of value must be determined.

- FMV
 - The price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing-and-able buyer and a hypothetical willing-and-able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts

- Cannot consider downstream referrals
- Cannot consider synergies among entities
- Fair Value
 - The price that would be received for an asset or paid to transfer a liability in a transaction between marketplace participants on the measurement date
 - FASB definition
 - For financial reporting purposes
 - Certain litigation or shareholder dispute valuations require the standard of value to be fair value
- Strategic (Investment) Value
 - The value to a particular investor based on individual investment requirements and obligations
 - Can consider downstream referrals
 - Can consider synergies among entities

B. JOA Valuation: Existing Service Line (one sided)

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- One hospital contributes a service line
- The income stream from that service line is valued so the other party knows how much cash to contribute
- Tangible assets are often leased to the JOA
- The partner organization often provides cobranding or management services

C. JOA Valuation: Existing Service Line (two sided)

- Ensure both sides are contributing an equal amount of something to the affiliation (e.g., assets, knowledge).
- If one party's services are larger, the entity with the smaller service line will need to contribute cash, or else the JOA funds flow should be adjusted so it is not 50/50 and representative of each service line's value.
- The valuation is based on the income stream from both service lines.

D. Management and Comanagement Valuation

- If one party will manage the services going forward, the management fee should be consistent with the market.
- Management services vary widely per arrangement and are not always comparable with market data.
- The manager should try to estimate the time that each individual at the company will spend operating the service line to better support the fee.
- Instead of the larger health system/AMC providing typical management services (finance, HR, marketing, etc.), the services might focus on quality and protocols and could include the following:
 - Care experience
 - Physician recruitment
 - Accreditation, certificates, and licenses

- Protocols, policies, and procedures
- Quality

E. Cobranding and PSA Valuations

- Cobranding
 - Typically, part of an MSA arrangement.
 - If the partner hospital's brand will be utilized, they are often compensated for it.
 - It is important to clearly establish the restrictions with cobranding, if any, and how the name will be utilized.
- PSA
 - This is a multipronged approach.
 - Review FTE, WRVUs, and collections of providers.
 - Determine whether it is a coverage-based versus volume specialty.
 - Understand all the payment arrangements for the provider.
 - If APPs are involved, consider whether the overall payment is still reasonable.