Health Care Joint Ventures: What's the Big Deal?

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Your Presenters

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Partner

Foley & Lardner LLP

- Partner in the Health Care Practice Group in LA
- Extensive experience representing health care providers, focusing on health care mergers and acquisitions, health care joint ventures, data privacy, and health care regulatory matters.
- Recognized by Chambers USA as a leading health care attorney in California (2020 – 2023) and Trusted Advisor of the Year from the LA Business Journal (2023)

David Sanders

Partner

Foley & Lardner LLP

- DC Office Managing Partner
- Former Chair of Transactions and Securities Practice Group (2011 – 2017)
- Business Law Department Vice Chair
- At least 200 Health Services Transactions, including M&A, JVs, strategic alliances, technology license agreements, etc.
- Commercial agreements in health services and medical devices, including supply, distribution, manufacturing
- Chambers and Legal500 recognized
- **Go Blue!**

Angela Smith

Associate General Counsel and Assistant Corporate Secretary

Veradigm

- Practical, solution-focused attorney with over 20 years of transactions experience in healthcare information technology and corporate finance
- Drives legal strategy as lead counsel for Veradigm's patient engagement and revenue cycle services business units
- Supports compliance with regulatory filing and disclosure requirements, subsidiary governance matters and annual shareholder meeting process

Agenda

- What is a Health Care Joint Venture?
- Why Engage in a Joint Venture?
- Health Care Regulatory Concerns
- Mission Control
- Management & Management Structure
- Brand and Reputation Management
- Ownership of Business
- Transactional Considerations/Exit
- Intellectual Property
- 2024 Predictions and Tips

What is a Health Care Joint Venture?

- **General Definition** – An arrangement between two or more parties, combining their respective resources and collaborating in carrying on a business activity, with a shared vision and mutual desire for profit.

- **What do the parties mean?** Helpful to have certainty of terms at the outset between all parties involved, their respective counsel and any consultants.

- **What's the difference between a "real" and a "contractual" joint venture?**

Why Engage in a Health Care Joint Venture?

- Lower Cost Opportunity to Grow Brand and Business than:
  - M&A
  - Greenfielding
- Grow market share geographically
- Access to complementary IP/products
- Access to new and different patient/provider populations
- Monetize IP, technology, and products with significantly less investment
- Negotiable terms on brand management
  - But you’re sharing mission control

- **Note**: Cash or lack thereof is often impactful in the reasons for entering into a JV and the negotiations between the parties.

Health Care Regulatory Concerns

- **Federal Anti-Kickback Statute (AKS)** – Criminal statute prohibiting any person from knowingly and willfully offering or paying any remuneration, directly or indirectly, in cash or in kind, to induce a person to make referrals for items or services that are covered by Medicare or another federal health care program.
  - There are statutory exceptions and regulatory safe harbors, promulgated by the Office of Inspector General of the Department of Health and Human Services (OIG) that specify the arrangements that will not be subject to prosecution under the AKS.

- **OIG Guidance**
  - OIG has issued various forms of guidance concerning joint venture arrangements, including the 1989 Special Fraud Alert: Joint Venture Arrangements (reprinted in 1994), and the 2003 Special Advisory Bulletin on Contractual Joint Ventures.
  - Advisory Opinions – OIG has issued several advisory opinions on health care joint ventures.

Health Care Regulatory Concerns

- **Key compliance concepts health care joint ventures:**
  - Independent legitimate business
  - True investment with a bona fide risk to investors, and under commercially reasonable terms
  - Income distributions are proportional to ownership interest
  - Concerns around exclusivity and market competition
  - No requirement for referrals
  - Safeguards on physician compensation
  - Underlying contracts meet an AKS safe harbor or a Stark exception

Health Care Regulatory Concerns

- **Federal Physician Self Referral Law (Stark)** – Civil statute prohibiting a physician from referring Medicare patients for designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.
  - Applies to contractual or ownership interests.
  - Stark will be implicated if a physician is in a position to refer designated health services to an organization in which the physician has a financial interest, and needs to be considered if there will be physician ownership in the joint venture entity.
  - Arrangements between the joint venture entity and physicians must satisfy a Stark exception.

- **State Law Considerations**
  - Many states have state versions of the Stark or AKS which may have similar, although often identical elements of applicable exceptions.
  - Prohibitions on the corporate practice of medicine

Mission Control

- **Shared Management**
  - Case by case basis – negotiated

- **Outward Facing**
  - How are patients finding the JV? Consider referral sources.
  - Whose name is on the door?
  - Who is employing the physicians? See above.

- **Behind the Scenes**
  - Billing and collections
  - Computer Networks
  - Financial Systems

Management

- **Entity**
  - Usually an LLC, rarely a corporation
  - Management borrows from corporate concepts
    - Operating Agreement/Bylaws
    - Board of Directors
    - Officers
  - Entity has employees
  - Entity owns (or leases) property
  - IP
  - Follow corporate formalities to terminate or separate

- **Contractual**
  - Create a shared management structure
  - Not entity focused
  - Management
    - Management Committee
    - Steering Committee
    - Negotiable (number of people, who nominates, scope of authority, etc.
  - Who owns all of the assets?
  - Termination/separation all need to be contractually defined and described.

Management Structure

- **Flexible, but here is one common structure:**
  - Management Committee/Board of Directors
    - Executives from member companies, meet 3-4 times per year
    - Approve budget proposed by Steering Committee
    - Big picture decisions
    - Chair role can rote
    - Number of members from each member company can be negotiated
  - Steering Committee
    - Operational representatives from member companies
    - Propose Budget
    - Clear scope/limit to authority
    - Operates the business – could be day-to-day or day-to-day could be delegated to a CEO or President
    - Person responsible for management of the JV is usually on this committee.

Brand and Reputational Management

- Negotiable/flexible
- Case by case
- Whose brand name?
  - Trademark/trade name ownership (contractual v. entity)
- Who handles quality control/quality insurance? Credentialing? Licensure
- Risk sharing
  - Indemnity
  - Patient claims
  - Product claims
  - Infringement claims
  - Public relations/crisis management
- Promotional efforts – marketing and advertising

Ownership of Equity/Business

- If JV is an entity, easy to address.
  - Use shares, membership units, etc.
  - Profits and losses should be based on ownership percentages [Regulatory Considerations]
  - Often times, one party provides capital and recovers its investment first before profits are paid out (or there can be a preferred return to that party, expressed as a higher percentage of initial revenues)
- If a contractual joint venture:
  - Contributions negotiated and expressly in contract
    - Not just financial
    - Employees and benefits
    - Systems (accounting, technology)
    - Assets owned by each party?
    - IP – who owns? Who licenses?
    - Compensation for services (in lieu of profits and losses) negotiated and expressed in contract, based on FMV appraisal

Transactional Considerations/Exit

- **Usually an ability to control with whom you partner**
  - Restrictions on transfer to any new partner
  - ROFR/ROFO
  - Drag along
  - Tag along
  - Deadlock provisions
  - Non-Assignment
    - You can be super creative here

- **When you exit:**
  - What about the mission and patients?
    - Extended time to cure a breach
    - Transition Agreement
  - What about the IP?
  - What about the patient files?
  - Other assets (leases, new trade names)

Other Restrictions and Considerations

- **Post Termination:**
  - Noncompetition
  - Patient/customer nonsolicitation
  - Employee nonsolicitation
  - Confidentiality
    - Time periods
    - Scope/geography
- **Tax implications for nonprofit/for profit joint ventures**
- **Ethical Issues**
  - JV Counsel
  - Separate Counsel for the parties
  - Attorney-Client Privilege
- **Antitrust**

More on IP

- **Scenario:**
  - Party A contributes IP
  - Party B contributes IP
  - The JV develops its own IP
    - Who owns when the JV ends?
    - What are each party's rights to use when the JV ends?
- **Not just patents and trademarks**
  - What about ongoing maintenance fees? Protection from infringement by others? Liability for infringement of others IP?
  - Know how/show how
  - Treatment protocols and modalities
  - Newly developed IP
    - **PRECISE DEFINITIONS AND DESCRIPTIONS ARE KEY**

2024 Predictions and Tips

- **Predictions:**
  - Health care joint ventures will continue in 2024 and beyond.
  - The OIG may issue further guidance on suspect joint ventures, and will certainly issue more advisory opinions on joint ventures.

- **Tips:**
  - Use advisors experienced with these types of transactions in your business segment
  - Identify and prioritize the goals of the joint venture early.
  - Ensure meaningful contributions from both joint venture parties.
  - Negotiate in a thoughtful and deliberate manner.
  - Address regulatory hurdles proactively.
  - Establish a process for addressing ongoing operational issues.

Questions?

Thank You!/Contact Info

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