Health Law Webinar

Innovative Business Models for Health Care Organizations

September 14, 2022



Agenda

- Consolidation vs. Independence
- Innovative Business Models:
 - Physician Supergroups
 - MSOs
 - Physician-Hospital JVs
 - VBE Arrangements
 - Hospital-Payer-Physician Arrangements



Motivations

- Recruitment Challenges
- Overhead and Decreasing Reimbursement
- Health Care Reform
- Access to Capital
- Perception of Greater Security
- Reluctance of New Professionals to Buy-In



Consolidation: Pros And Cons

Pros:

- Protect incomes
- Help with recruitment
- Avoid hassles of owning a practice
- Focus on practicing medicine

Cons:

- Lack of autonomy and independence
- Frustration with inefficiencies
- If the transaction doesn't work, it will be very difficult to "reverse" the deal
- Future financial pressures facing hospitals due to health care reforms and declining Medicaid/Medicare reimbursement; more consolidation likely
- Nonprofit / governmental hospital requirements (e.g., open meeting laws, fair market value compensation)



Remaining Independent

- Practice Basics
- Options:
 - Increase Size
 - Organic growth through recruitment
 - Merge
 - MSOs (to be discussed)
 - Joint Ventures
 - Strategic Alliances
 - PSAs/MSAs



Physician Supergroups



"Supergroups"

- Typically a group of physician practices under a single EIN and legal entity
- Single or multi-specialty
- Structure options vary, but typically include divisions or "care centers"
- May include an MSO structure
- Varying levels of integration



Pros And Cons

Pros:

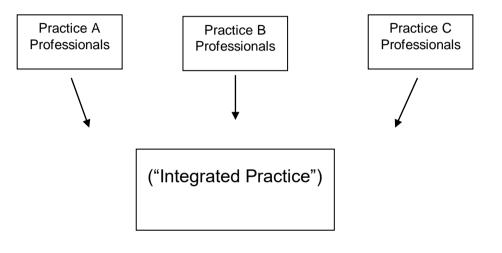
- Better negotiating/political clout
- Economies of scale
- Better administrative help
- Ability to offer more ancillaries
 - more legal flexibility
 - more economic flexibility
- Public may perceive bigger as better

Cons:

- If a division is unable to pay its liabilities, divisional "firewall" might be breached
- Loss of individual autonomy



Divisional Merger Structure



- · Physicians become owners of the Integrated Practice
- Practice assets/liabilities become asset/liabilities of new Integrated Practice divisions



Divisional Structure

- Each division operates as its own profit center
- Physician agreements
- Benefits
- Indemnification



Governance

- Board of Directors
 - Each division represented
 - Manages and maintains control over matters affecting corporation as a whole
- Divisional Boards/Advisory Committees
 - Membership determined by the division
 - Manages division's day-to-day operations and makes recommendations to the Board of Directors regarding significant matters



Regulatory Considerations

- Stark
 - Ancillaries
 - Group Practice
 - Compensation Methodologies
- State law/Cross-border implications
- Antitrust



Management Service Organizations ("MSOs")



What is an MSO?

- Management Services Organization
- Provides various administrative services to physician practices, surgery centers, and other providers
 - Billing and Collection
 - Accounts Payable
 - Revenue Cycle Management
 - Payer Negotiations and Credentialing
 - Employment of Non-Clinical Staff
 - IT Services
 - Human Resources
 - Marketing
 - Real Estate and Equipment Rental
 - Compliance



Pros:

- Alternative to PE
- Allows Outside Investment
- Equity Opportunity for Non-Physician Staff
- Market Expansion
- Estate Planning
- Consolidating Admin Functions of Multiple Practices

Cons:

- Cultural Challenges
- Failure to Launch
 - costs of unwinding



Regulatory Issues

- Corporate Practice of Medicine ("CPM") Prohibition
- Fee-Splitting
- Anti-Kickback
- Stark
- Antitrust
- Benefits



Regulatory Issues

- Corporate Practice of Medicine ("CPM") Prohibition
 - Prohibits corporations from employing professionals or owning professional practices
 - Prohibits corporations from controlling clinical decision-making



Regulatory Issues

- Potential Ramifications for Violating the CPM Prohibition
 - Injunction against continued operation
 - Criminal prosecution
 - Arrangement voided
 - Refusal to pay claims
 - Loss of "private practice", "physician office" and similar exceptions from state licensing requirements







Anti-Kickback Statute

- Prohibits payment of remuneration in exchange for referrals of persons for the furnishing of items or services paid for by a federal health care program
- Requires intent
 - Courts and the Office of Inspector General ("OIG") have said that if <u>one purpose of</u> a payment is to induce or pay for referrals, then the law is violated
- Number of "safe harbors"
 - You are not required to meet a safe harbor



Stark Self-Referral Prohibition

- A <u>physician</u> may not make a <u>referral</u> to an entity for the furnishing of <u>designated health services</u> if the physician (or an immediate family member) has a <u>financial relationship</u> with the entity
- An entity may not bill for designated health services furnished under a prohibited referral



State Laws

- Fee splitting can't "divide fees" "solely for referring a patient."
- Self-Referral/Anti-Kickback Laws
 - Ex. Minnesota Statutes, Section 62J.23



Miscellaneous Issues

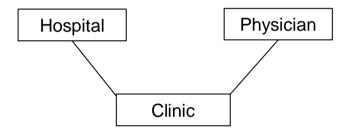
- Antitrust
 - need for firewalls
- Benefits
 - Affiliated Service Groups
- Privacy and Security Rules



Physician Hospital JVs and Hospital Investments in Physician Practices



Hospital Investment In Clinic





Stark Law

- The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:
- (b) In-office ancillary services



Billing

- (3) They are billed by one of the following:
- (i) The physician performing or supervising the service
- (ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice
- (iii) The group practice if the supervising physician is a "physician in the group practice" (as defined at § 411.351) under a billing number assigned to the group practice



Group Practice

- Single legal entity. For purposes of this subpart, a group practice is a physician practice that meets the following conditions:
- The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations....



Group Practice, Cont.

 A group practice that is otherwise a single legal entity may itself own subsidiary entities



What About Antikickback?

- Likely will not meet small entity safe harbor
- Meet as many requirements as possible no sweetheart deal
- Intent key to analysis



Corporate Practice Doctrine

- State laws differ
- Hospital authority
- No lay governance
- Associated PC
- Nonprofit exception



Class B Shares

- Rights and preferences set forth in resolution
- Profit and loss in JV operations
- Preferred? Convertible? Withdrawal?
- Governance



Partnership

- Partnership is both an entity and the aggregation of the partners' activities
- Must bill in name of practice
- Some complication re single entity test
- Careful of corporate practice rules



Examples

- Hospital wants to work with clinic to establish a new clinic location
- Hospital wants to bring clinic into system, but clinic wants to retain independence



Lessons Learned

- Investment in clinic is an underused strategy
- Many forms and approaches
- Don't do this at home



Value Based Enterprises (VBEs)



Value-Based Care

Arrangements

- Broad umbrella of arrangements between medical providers, manufacturers, and payors shifting from fee-for-service payment toward quality and cost accountability
- Incentivizing quality in health care is not new
- Historically, CMS attempted to incentivize the shift to value-based care through CMS-supported programs with corresponding regulatory waivers (e.g., MSSP, BPCI, etc.)
- Terminology has varied greatly (and continues to vary), but has recently focused on definitions within the applicable exceptions and safe harbors under Stark and the Anti-Kickback Statute



Regulatory Amendments

- CMS and OIG issued value-based care exceptions (for Stark) and safe harbors (for the Anti-Kickback Statute) to help incentivize the shift on a broader scale.
 - Certain arrangements may otherwise have been prohibited under Stark and/or suspect under the Anti-Kickback Statute
 - Exceptions and safe harbors are definition heavy
 - Differentiates based on the level of risk: (1) low risk "value-based arrangements" or care coordination arrangements; (2) meaningful or substantial downside financial risk; and (3) full financial risk
 - Must be a "value-based participant" in a "value-based enterprise"



VBE (Defined For Stark & AKS)

- Value-based enterprise. Two or more VBE participants:
 - Collaborating to achieve at least one value-based purpose;
 - Each of which is a party to a value-based arrangement with the other or at least one other VBE participant;
 - That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and
 - That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its valuebased purpose(s).
- 42 CFR § 411.351



Other Key Definitions

- Value-based arrangement. An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:
 - The value-based enterprise and one or more of its VBE participants; or
 - VBE participants in the same value-based enterprise.
- Value-based purpose. Any one of the following:
 - Coordinating and managing the care of a target patient population;
 - Improving the quality of care for a target patient population;
 - Appropriately reducing the costs to or growth in expenditures of payers without reducing the quality of care for a target patient population; or
 - Transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.
- Value-based activity. Any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
 - The provision of an item or service;
 - The taking of an action; or
 - The refraining from taking an action.



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VBE – In Practice

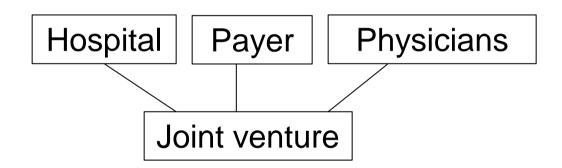
- VBEs do not need to be separate legal entities
- VBEs may take the form of a CIN (or other physician network), ACO, or separately established legal entity to manage and administer value-based care arrangements between parties
- Tied to specific and identified "target patient populations."
- Structure must conform to applicable Stark exception and should fit as closely with AKS safe harbor as possible



Hospital-Payer-Physician Arrangements



Hospital Payer Co-ownership





Motivations

- Aligning incentives beyond traditional payer arrangements
- Payers are increasingly competing with PE for opportunities



What Are "Aligned Incentives"

- Total Cost of Care Adjustments
- Payer's incentive is to reduce medical cost
- Provider's incentive is to reduce cost, but not cost of own services



"Aligned Incentives"

- Capitation
- Payer is incented to pay cap that is less than FFS pay structure
- Provider incented to reduce cost, especially of other providers in pool



Payer Responsibility for Provider's Economic Results

- Most alignment arrangements don't do this
- Payer ownership of part or all of provider
- Contract that approximates financial results of ownership



Ownership/Regulatory Issues

- Exemption—Redlands analysis
- Corporate Practice
- Conflict of Interest
- Choice of Entity
- Governance—preserving separate interests



Regulatory Issues, Cont.

- Antitrust
- Fee-Splitting
- Anti-Kickback
- Stark



Miscellaneous and Q&A

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Network Arrangements

- Insurance laws
- Antikickback and Stark issues
- Network distributions
- Participation of other providers



Presenters



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