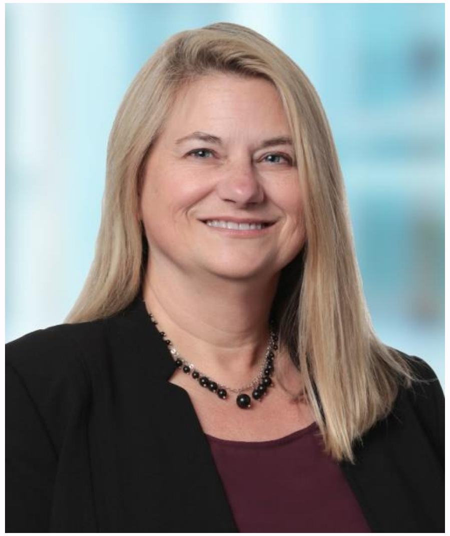
Relationship Building: Use of Brand in Teaching, Research and Clinical Care Arrangements

Speakers:



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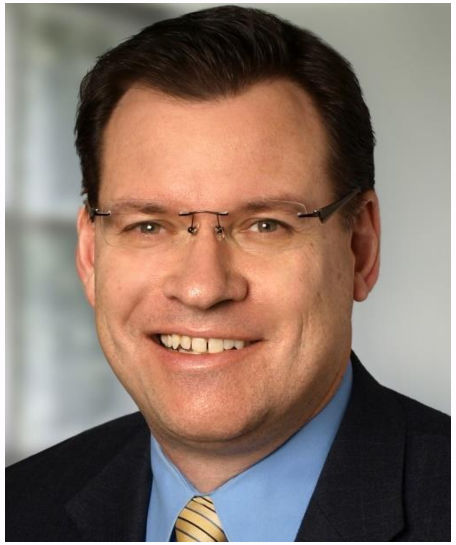

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Agenda

- Brand Strategies in the Health Care Industry
- Legal Framework
- Brand Valuation 101: Overview of Methodologies for Lawyers
- Protecting the Brand and Common Deal Points

BRAND STRATEGIES IN THE HEALTH CARE INDUSTRY

Brand Use in HealthCare

Hartford HealthCare
Cancer Institute

Memorial Sloan Kettering
Cancer Alliance
MEMBER

Banner
MD Anderson
~~Cancer~~ Center
Making Cancer History®

Seattle
Cancer Care
Alliance
Fred Hutch · Seattle Children's · UW Medicine
NETWORK MEMBER

CHRISTUS®
ST. VINCENT

MAYO CLINIC
CARE NETWORK
Member

Brand Use in Health Care

- Co-Branding is a common strategy in health care.
- Signals collaboration, excellence and high-quality service offerings.

- Brand may be leveraged in:
  - Teaching relationships
  - Affiliations
  - Clinically integrated networks
  - Services lines
  - Research activity
  - Joint ventures

Common Structures

Types of Relationships and Corresponding Brand Strategies

Increasing Degree of Integration →

Legal Structure	Teaching and Research	ACO/ Clinically Integrated Network	Affiliations	Service Lines	JV-Management, Provider/Payor	Merger/ Acquisition
Services Provided	Education and Training/Access Coordination		Service/Program Coordination	Shared Services Organizations	Shared Operating Board	Full Integration
Brand Strategy	Limited Use of Brand		Co-Branding (Service Line or Facility)		Full Use of Brand (Joint Venture/Ownership)	

LEGAL FRAMEWORK

Legal Framework - AKS

Federal Anti-Kickback Statute (42 U.S.C. § 1320 A-7B(B))

- The Anti-Kickback Statute (AKS) provides criminal and civil penalties for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce or in return for:
  - Referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable in whole or in part under federal or state health programs or
  - Purchasing, leasing, ordering or arranging for, or recommending, purchasing, leasing or ordering any good, facility or item payable under a federal or state healthcare program

Legal Framework - AKS

- Anti-Kickback Statute
  - Prohibition on “taking into account” volume or value of referrals
  - Valuations
- AKS Safe Harbor Regulations (42 C.F.R. 1001.952)
  - Compliance with safe harbors is recommended when feasible
  - Arrangement can be legal even if it does not fit within a safe harbor

Legal Framework - AKS

- Anti-Kickback Statute – Safe Harbors
  - Large entity investment interest safe harbor
    - Protects distributions to owners of entity with ≥ $50M in underappreciated net tangible assets if meet requirements
  - Small entity safe harbor 60/40 tests
    - No more than 40% of investment interests are held by investors in a position to generate business to the entity
    - No more than 40% gross revenues for the venture may come from investors
  - For both safe harbors, the investment offer must be on the same terms for referrers and nonreferrers

Legal Framework - AKS

- Anti-Kickback Statute – other considerations
  - Facts and circumstances analysis
  - OIG Advisory Opinions and Fraud Alerts
  - "Suspect" joint ventures
    - Selection of partners is based on their ability to generate referrals
    - Tracking of referrals occurs and is reported to the partners
    - Financial terms benefit referral sources (e.g., only offering interests to high referral sources, requiring divestiture if an owner cannot generate referrals, etc.)
    - Financial terms allow partners to earn returns disproportionate to their investment, without taking on significant business risk
    - Investment capital is loaned by one partner to another partner
  - Differential Pricing

Legal Framework – Stark Law

Stark Law (42 U.S.C. § 1395nn)

- A physician may not refer Medicare or Medicaid patients for designated health services ("DHS") to an entity with which the physician (or immediate family member) has a financial relationship unless an exception applies
- In addition, an entity may not present, or cause to be presented, a claim for payment for services provided as a result of prohibited referral
- DHS includes inpatient and outpatient hospital services, clinical laboratory services, radiology and certain other imaging services
- Financial relationship includes an ownership interest in such entity

Legal Framework – Stark

- Stark Law
  - For DHS Entity, Physicians
  - Every financial relationship must meet an exception
  - Isolated transactions exception
    - Remuneration is FMV and not determined in a manner taking into account volume/value referrals or other business generated between the parties
    - Arrangement is commercially reasonable even in the absence of referrals by physician to the entity
    - No other transactions for 6 months unless meet other Stark exceptions except for commercially reasonable post-closing adjustments that do not take into account volume/value or other business

Legal Framework

- Stark Law
  - Indirect compensation exception
    - Indirect financial relationship exists when there are one or more persons or entities in an unbroken chain between the physician (or family member) and the DHS entity
    - Remuneration is FMV and not determined in a manner taking into account volume/value referrals or other business generated between the parties
    - Does not violate the AKS or any other Federal or State law governing billing or claims submission

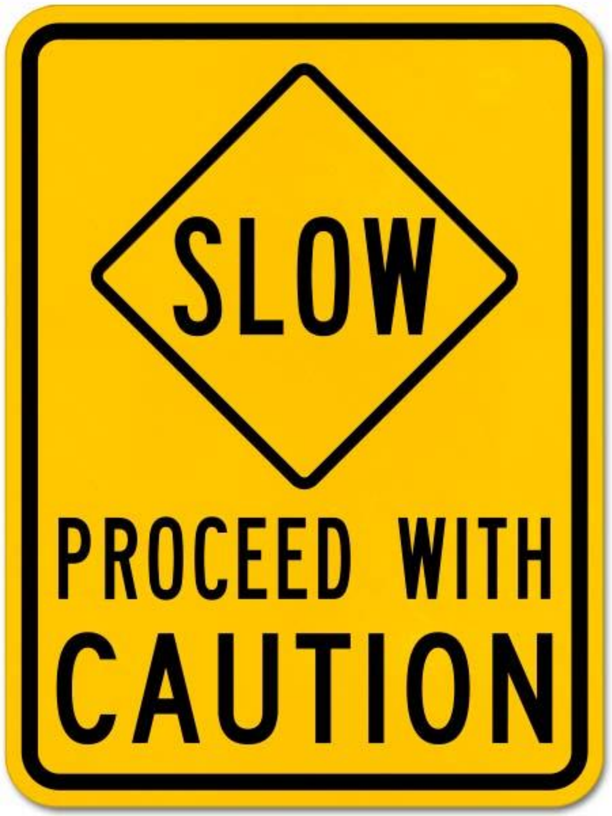
Legal Framework - Tax

- Tax Laws
  - Private Inurement
    - transaction between a tax-exempt organization and an “insider”—*i.e.*, someone with a close relationship with, or an ability to exert substantial influence over, the tax-exempt organization—results in a benefit to the insider that is greater than **fair market value**
  - Excess Private Benefit
    - 501(c)(3) organizations are prohibited from entering into transactions that result in more-than-incidental “private benefit” to another party, including unrelated third parties
  - If brand is owned by an exempt organization and licensed for less than FMV, it could result in private inurement/excess benefit and, if material, could jeopardize exempt status or result in excise taxes

Legal Framework - Tax

- Tax Laws
  - Unrelated Business Income Tax
    - Federal income tax imposed on tax-exempt organizations for income derived from a trade or business carried on regularly, but not substantially related to exempt purposes
    - Royalties are generally excluded from unrelated business taxable income (UBTI), however, if licensee is receiving more than use of name/logo in exchange for payment then the payment will be analyzed separately and may be UBTI
  - International transactions
    - Section 482 re-pricing – did the U.S. parent receive arms length consideration for license of the brand to a foreign corporation?
    - Review tax laws in licensee's domicile

Take Aways



- Risky Business
  - Global increase in payment rates
  - Minimal investment by licensor
  - Potentially duplicative payments
  - Not aligning the deal with FMV
- Important to ensure all arrangements are at fair market value
- Seeking a commercial reasonableness opinion

BRAND VALUATION 101: OVERVIEW of METHODOLOGIES FOR LAWYERS

A Note on the Role of Legal Advisors

- Lawyers can play a key role in prompting questions and soliciting key information from the business team
- Important to understand the nuances of the methodology for your regulatory analysis
- In-house counsel is often a key interface with the marketing team’s routine execution of the organization’s brand strategies and structure of transaction

Other Key Expertise

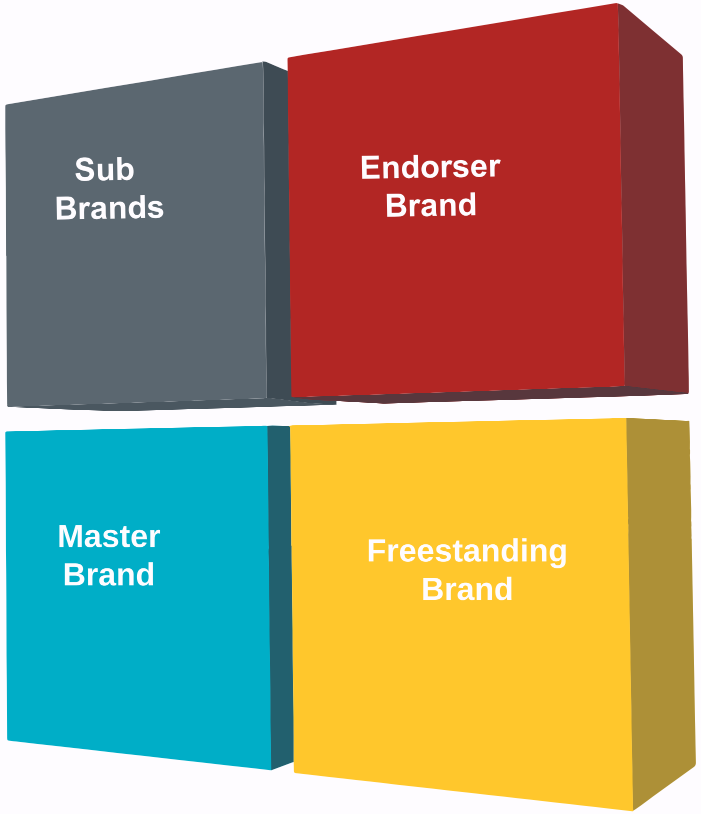
- Consultants
  - Advise on developing a brand framework in an evaluation
  - Perform FMV and Commercial Reasonableness assessments
- Financial Reporting
  - Intangible assets

Some Questions to Ask

- How does brand fit in the proposed relationship?
- What is your organizational brand strategy?
- Who is the other party in terms of perception in the market?
- What valuation methodology, or combination of methodologies, will work best?
- If not taking a brand valuation approach, could the use of the brand in a relationship be perceived as remuneration?

Brand Architecture

- What is the message you want to send to consumers?
  - Sub Brand: Corporate trademark with sub brand trademarks (e.g., Apple iPad)
  - Master Brand: One trademarked name and descriptive terminology (e.g., T-Mobile …)
  - Freestanding Brands: One unique brand (e.g., Pringles)
  - Endorser Brand: Product bands linked by an endorser brand (e.g., Oreos by Nabisco)



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Valuation of all Assets

Tangible Assets

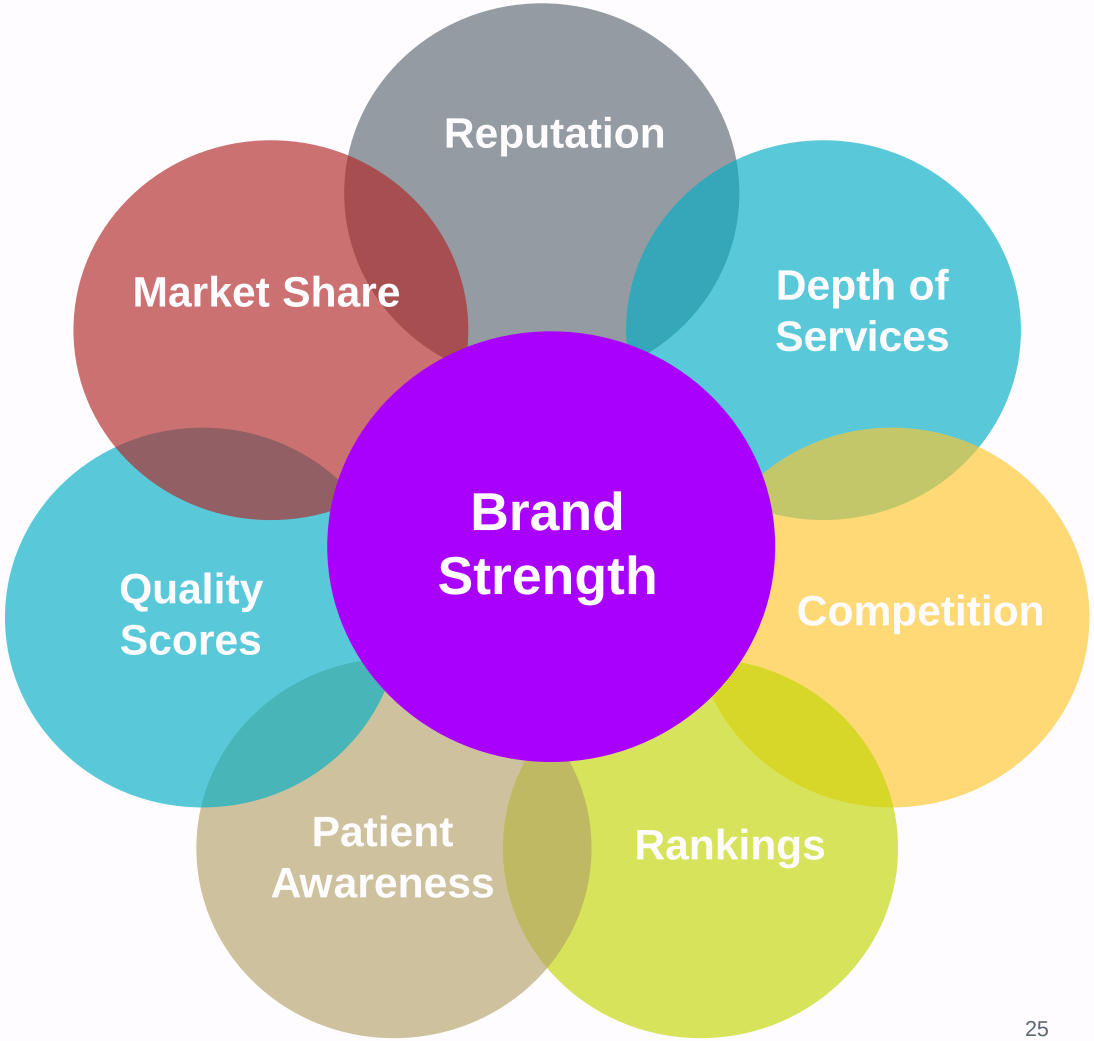
- Examples
  - Land
  - Buildings
  - Equipment

Intangible Assets

- Examples
  - Brand
  - Patents/Intellectual Property
  - Workforce

Assessing Brand Strength

- Multiple Factors
  - Qualitative
  - Quantitative
  - 360 view
  - Differentiation
  - Context



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Primary Brand Valuation Approaches

Income Approach

- Based on the economic benefits anticipated to be derived from the asset

Cost Approach

- Based on the anticipated cost to recreate, replace, or replicate the asset

Market Approach

- Based on transaction data involving similar assets or services

Cost Approach

- Based on the anticipated cost to recreate, replace, or replicate the asset
- Some constraints
  - Difficulty in estimating the investment over multiple years
  - Cost does not equal value
  - Economic benefits rarely captured

Market Approach

- Based on using transaction data involving similar assets or services
- Some constraints
  - Access to information
  - Similarity of transactions

Income Approach

- Based on the economic benefits anticipated to be derived from the brand asset
- Projects future economic benefits associated with the brand and determines the incremental benefit
- Premise is what a party is willing to pay is linked to the future economic benefit
- Multiple income approaches used

Common Approaches for Brand

- Relief from Royalty (RFR) – a combination of market and income approaches
  - Estimates the present value of a future royalty stream
  - Select a suitable royalty rate for the asset
  - Discount rate to net present value to incorporate risk
  - Allows the value consideration to fit various payment structures:
    - One-time up-front consideration for use of brand
    - Ongoing licensing fee for use of brand

Brand Valuation Approaches

- Incremental “Lift” – “With & Without” Method
  - Evaluate the net present value of future cash flows of the existing operations
  - Compare to the net present value of future cash flow after branding
  - Leads to the incremental benefit as a result of branding

Key Take Aways

- Methodology needs to fit the transaction framework
- Payments cannot vary based on referral volume or value
- Brand strategy needs to be complementary to the organization's brand architecture approach
- Key differences with other industries
  - Reimbursement constraints affect value
  - Level of regulation and emphasis on FMV

PROTECTING THE BRAND and COMMON DEAL POINTS

Common Transactions With Brand Considerations

- Collaboratives
  - Back-Office / Shared Services Collaborative
  - ACO/CINs
  - Population Health / Care Coordination Collaborative (e.g., Mayo Clinic Care Network, BJC Collaborative)
  - Service Line Coordination / Clinical Integration (e.g., MD Anderson Cancer Network)

Common Transactions With Brand Considerations

- Joint Ventures
  - Existing Business / Service Line Joint Venture
  - New Business / Service Line Joint Venture
  - Strategic Partner Joint Venture (e.g., Private Equity)
- Merger/Affiliations
  - Member Substitutions / Asset Purchase Transactions
  - Joint Operating Arrangements (“JOAs”)

Types of Agreements in Common Transactions

- Forms of Agreement(s) for Common Transactions include:
  - LLC Operating Agreement
  - Contribution Agreement
  - Professional Services Agreement
  - Management / Administrative Services Agreements
  - Joint Operating Agreement
  - Trademark Licensing Agreement
  - Affiliation / Purchase Agreement

Preliminary Questions To Ask

- What is being licensed?
  - Develop a clear understanding of the tradenames and trademarks being licensed, including whether there are particular versions (such as logos) that are to be included or excluded
- How is brand going to be used?
  - Develop a clear understanding of how the brand(s) may be used (e.g., in connection with the provision of services, marketing of services or both)
  - Where will the branding appear? Will it be co-branded?
- Define the territory that will be covered by the license

Preliminary Questions to Ask

- What is the consideration for use of the brand(s)?
  - Will the investment be in the form of an equity or membership interest (e.g., be treated as a capital contribution to a JV) or will there be a royalty payment?
  - How will the investor earn a return on investment?
- How (and importantly when) will the fair market value of the brand(s) be determined?
  - May not always be easily measurable
  - Must be evaluated considering all financial terms of proposed transaction
  - Based on contribution to overall affiliation

Preliminary Questions to Ask

- Will there be any performance criteria associated with the use of the brand(s)?
- Where will use of the brand(s) addressed?
  - In the definitive agreements (e.g., operating agreement, trademark license agreement, collaboration / affiliation agreement)?
  - In the ancillary agreements (e.g., professional services or management / administrative services agreements)?
  - Likely addressed in both the definitive and ancillary agreements
    - Tied to conditions cross-referenced in a license or other agreement?

Key Agreement Terms Impacting Use of Brand

- **Exclusivity**
  - Exclusive right to use the brand(s) vs. non-exclusive right to use the brand(s)
  - How far will the right to use the brand(s) be extended (e.g., will affiliates be allowed to use the brand(s) and, if so, how are they defined)?
  - Will there be any ROFR, ROFO or restrictive covenants related to services provided under the brand
- **Term and Territory**
  - Perpetual / Coterminous / Fixed Term
  - Territory should be closely aligned with anticipated service area (e.g., the parties can always mutually agree to expand the territory)
  - Exceptions / limitations for radio, TV and digital advertising that may extend beyond defined territory

Key Agreement Terms Impacting Use of Brand

- **Rights and Obligations of Licensor**
  - Ownership of marks and goodwill generated by use of the marks
  - Right to bring / enforce infringement actions
  - Approval Rights
    - Timing / Identity of persons providing approval
- **Rights and Obligations of Licensee**
  - No sublicensing or unauthorized users
  - Use marks consistent with branding and related requirements
  - Ensure compliance with any quality standards, professionalism or clinical excellence requirements
  - Ensure compliance with legal requirements

Key Agreement Terms Impacting Use of Brand

- **Protecting the Brand – Breach of Contract Triggers**
  - Loss of licensure and accreditation
  - Exclusion from a Federal Health Program
  - Fraud, conspiracy, corruption, criminal charges
  - Change of ownership or control
  - Failure to meet quality metrics
  - Financial distress (e.g., bankruptcy, insolvency)
  - Material breach of agreement
  - Reputational Harm
  - Others based on due diligence

Key Agreement Terms Impacting Use of Brand

- **Protecting the Brand – Remedies for breach of contract**
  - Dispute Resolution / Right to Cure
  - Termination of some or all agreements (but not dissolution)
  - Termination (e.g., cross default) of all agreements (including dissolution)
  - Self Help
    - In JV context, the right of licensor to act on behalf of the JV to unilaterally remedy any brand related issues that come up
  - Put / Call Rights
    - Can be difficult to structure given the negative impact on value of JV and inability to carry-on without use of brand
- **Transition steps and timeline for un-branding**

Key Agreement Terms Impacting Use of Brand

- **Financial Consideration for use of brand(s)**
  - Capital Contribution (in connection with JVs)
  - Royalty Payments
    - Earned Royalties (e.g., percentage of net revenue)
    - Minimum Royalties
    - Others (e.g., lump sum, annual fee)
  - Royalty Reporting
  - Audit Rights
  - Use restrictions (if any) for earned royalties (e.g., physician development)

Key Agreement Terms Impacting Use of Brand

- **Insurance and Indemnification**
  - Licensor’s indemnity obligations generally limited to infringement claims
  - Licensee’s indemnity obligations are generally broader and cover all losses related to the use of the marks or any act or omission by licensee in connection with the mark
  - Licensee usually required to maintain insurance at levels to cover any claims related to use of the marks
- **Assignment and Sublicenses**
  - Both are generally prohibited without the licensor’s consent

Take Aways

- **Start the valuation process early**
  - Valuation will determine relative contributions of the parties (and potentially establish the negotiation strength of the parties)
  - The process takes time and may impact governance rights and other terms of the agreements
- **Spend time up front on worst case scenarios**
  - Collaborations, by their nature, focus and build on the strength of the parties involved - but things can (and sometimes do) go wrong
  - Details matter; may not always want to rely on a general dispute resolution process as it may result in unintended consequences

Take Aways

- **Determine impact of default provisions across all agreements between the parties**
  - Termination of some or all agreements?
  - Put / Call?
  - Self Help Rights?
- **Ensure consistency across all documents**
  - This can be challenging when multiple parties are contributing / licensing their respective brands
  - Rights and obligations can vary based on the strength or dominance of the respective brands

Case Study

- **JV Between AMC and Community Hospital (CH)**
  - The CH will be co-branded with AMC's name.
  - AMC will provide clinical integration support via its clinically integrated network and the JV will provide administrative support services to the CH under separate agreements.
  - AMC will provide access to its clinical protocols (i.e., "know-how") related to clinical best practices, etc.

Case Study

- CH’s motivation for partnering with AMC include:
  - Improve quality of care via better access to clinical expertise and resources.
  - Increase footprint in region.
  - Improve recruiting and retention of physicians.
  - Potentially a first step towards a more expanded affiliation.

Case Study

- AMC's rationale for wanting to affiliate with CH include:
  - Fulfill mission to provide high quality health care to more people within its primary and secondary markets
  - Better utilization and leverage of key resources
  - Community outreach
  - Potential transfer of higher acuity patients to the AMC
  - Better positioning to compete within their primary and secondary markets (i.e., defensive marketing strategy)

Case Study

- Key financial issues related to the arrangement include:
  - AMC has a very valuable brand and desires to be compensated for using it.
  - AMC is also aware of the risk associated with the CH using its brand and desires to manage that risk via leadership oversight and by ensuring the CH and JV follow appropriate clinical protocols, etc.
  - AMC wants effective ways to manage the risk associated with its brand that are incremental (i.e., short of withdrawing all use)

Case Study

- Other key legal issues related to the arrangement include:
  - Due to regulatory/tax restrictions (e.g., the Federal Anti-kickback Statute, inurement) – the financial terms of the JV arrangement must be at "fair market value"
  - AMC ultimately was determined to receive very few referrals from CH
  - Royalty fee was evaluated and if included must be calculated without taking any referrals into account
  - Structure funds flow to avoid unrelated business income to AMC from licensing its brand (e.g., separate market rate license agreement)

Case Study

- Key provisions:
  - Quality metrics
  - Interaction between agreements – Operating Agreement, Contribution Agreement, Clinical Integration Agreement, Management Agreement, License Agreement
  - Termination triggers

Questions

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