

Top Legal Issues for Healthcare Investors and Business Development Teams

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Overview

- Introductions
- Health Care Investment Trends
 - Digital Health
 - Significant Growth in Health System “Venture” Activity
- Term Sheets
- Due Diligence

Health Care Investment Trends: Digital Health

- Digital Health
- Health System “Venture” Activity

Health Care Investment Trends: Health System “Venture” Capital

- Growing list of institutions have made investing in early stage healthcare startups part of their innovation strategy
- Many health system investors are not interested in a quick exit
- Health system and payor investment activity fueled in part by Affordable Care Act and its focus on value-based reimbursement
 - everyone needed to increase their innovation efforts
 - investment in start-ups provides opportunity to be first in line for new technologies, which can be deployed across systems

Confidentiality Agreements/NDAs

- Well-drafted NDAs protect intellectual property and confidential information.
- Companies often consider asking potential investors, venture capitalists and others to sign NDAs
- Many VCs and other investors will not sign NDAs for a variety of legal and non-legal reasons
- Companies can protect IP during pitches and initial discussions by limiting disclosure of technical, confidential information
 - companies should require signed NDAs in certain circumstances (for example, before disclosing highly confidential information)
- Always work with a lawyer to make sure the NDA is tailored to the situation.

Term Sheets

- Outlines the terms by which an investor will make a financial investment in a company.
- Generally have three key sections:
 - Funding
 - Corporate Governance
 - Liquidation

Term Sheets: Big Issues

- Valuation/Dilution
- Liquidation Preferences
- Governance/Board of Directors
- Protective Provisions
- Founder Vesting
- Antidilution Protection
- Exclusivity

Term Sheets: Valuation/Dilution

- Pre-Money vs. Post-Money
- Effect of Option Pools
- Other Considerations

Term Sheets: Liquidation Preferences

- Defines return an investor receives in sale of the company
 - can significantly impact founder's return
- Types of Preferences
 - Preferred (or straight-preferred)
 - Participating Preferred
 - Capped (or partially participating) Preferred
- Danger of “Precedent “ in Future Rounds

Term Sheets: Governance and Board of Directors

- Common Representation
- Investor Representation
- Independent Directors

Term Sheets: Protective Provisions

- Veto Rights
 - Sale of company
 - Amendment to Certificate of Incorporation
 - Financings
 - Other

Term Sheets: Founder Vesting

- Founder vesting is a must
 - avoids “free riding”
- Vesting Commencement Date
- Acceleration Upon Termination of Employment
- Acceleration Upon Change of Control (and termination of employment)
 - “double trigger”

Term Sheets: Antidilution

- **Broad Based**
 - adjustment depends on the number of shares sold relative to the company's existing stock as well as the difference in the price
- **Full Ratchet**
 - in event of a “down round,” adjusts number of common shares the preferred shares can be converted into based on the new share price (far less common than broad-based)

Term Sheets: Exclusivity

- Length of Exclusivity Period

Term Sheets: Pros and Cons

- Pros:
 - usually non-binding, meaning you can demonstrate commitment without being locked into the deal
 - can help identify points of dispute
 - although non-binding, create moral commitment
 - avoid misunderstandings
- Cons:
 - expense of engaging professionals to prepare and negotiate
 - accidentally creating binding obligations (duty to negotiate in good faith, for example)
 - getting bogged down in details

Convertible Notes

- Debt—priority over equity (stock)
- However, converts into equity upon occurrence of certain events
 - typically in connection with a “qualified financing”
- Often easier, cheaper, and faster than doing preferred stock financing

Convertible Notes: Pros and Cons

- From Company's Perspective
 - faster and cheaper, greater control, delays dilution, risks of being unable to pay, “insolvency”
- From Investor's Perspective
 - faster and cheaper, debt in insolvent entity, less control, problem of discounts vs risk

Convertible Notes

- Key Terms
 - Conversion Rate
 - Automatic Conversions
 - Optional Conversions
 - Interest
 - Maturity Date
 - Collateral
 - Amendment of Notes

Seed Preferred

- Series A “Lite”
- Equity without typical protections of a full Series A investment
- Investors usually get liquidation preference and preemptive rights

Due Diligence

Due Diligence

- Scope of Due Diligence
 - Depends on Type and Amount of Investment
 - Right Size Based Upon Risk

Due Diligence

- Standard due diligence
 - Legal/Litigation
 - Financial
 - Material Contracts
 - Employees/Operation
 - Intellectual Property

Due Diligence: Regulatory Issues

- Antikickback
- Stark
- Corporate practice
- Fee splitting
- Licensing
- HIPAA/Privacy laws

Antikickback

- It is illegal to offer, solicit, make or receive any payment intended to influence referrals under a federal health care program
- Prohibits the payment of anything of value to a referral source in return for the referral from/to a business reimbursable by a governmental program
 - The government applies the “one purpose” test. If one purpose of the payment is to influence referrals, the payment is illegal.
 - Safe harbors may offer protection, but you are not required to meet a safe harbor.
- State versions may apply more broadly

Antikickback

- Due Diligence
 - Understand payor sources and impact of state laws
 - Review agreements with referral sources
 - Internal policies

Stark

- Prohibits a physician from making a referral to a provider for “designated health services” if the physician has a financial relationship with the provider, unless an exception applies
 - Financial relationships include both compensation and ownership interests; direct and indirect
 - Failure to meet an exception = automatic violation
 - Civil, not criminal

Stark

- Due Diligence
 - Understand payor sources and impact of state laws
 - Review agreements with referral sources
 - Internal policies

Corporate Practice of Medicine (“CPM”) Prohibition

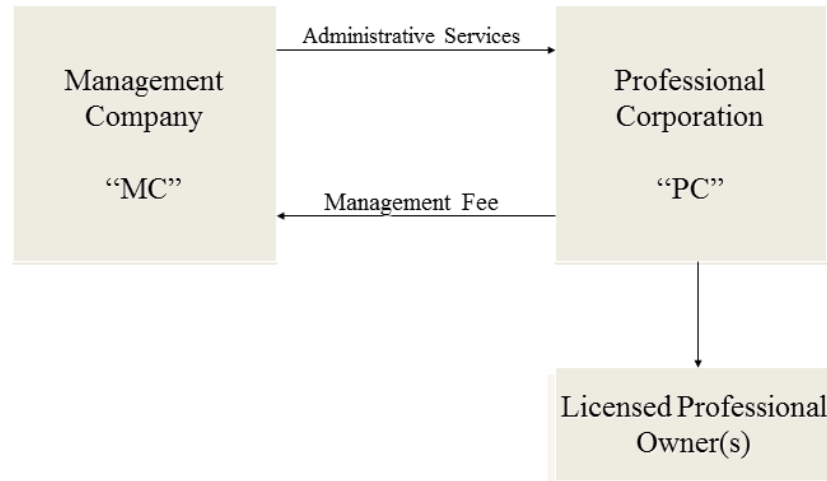
- CPM doctrine prohibits corporations from employing or controlling physicians or owning physician practices
 - Seeks to prevent lay control over medical judgment
- Medical practice acts generally do not explicitly prohibit the corporate practice of medicine
 - Acts prohibit the practice of medicine by a "person" without a valid license
 - Since adoption, the corporate practice doctrine has gone largely unenforced in all but a handful of states
- “Corporate practice” restrictions may apply to other professions (e.g., dental, physical therapy)

CPM Prohibition (cont.)

- Potential ramifications for violating the CPM prohibition include:
 - injunction against continued operation of practice
 - criminal prosecution for engaging in the unauthorized practice of medicine
 - entire arrangement could be declared void
 - refusal to pay claims
 - loss of “private practice”, “physician office” and similar exceptions from state licensing requirements (CON, lab license, etc.)

CPM (cont.)

- If state CPM prohibition applies to structure, the management company model may be an option



Fee-Splitting

- Most states prohibit fee-splitting
 - perceived danger of allowing professionals and non-professionals to share in income from professional services
 - the temptation for the physician and nonprofessional to maximize profit through medically unnecessary services
 - temptation for the physician and the non-professional to limit medically necessary services in order to maximize income

Due Diligence: Privacy and Security

- HIPAA
 - Core HIPAA documentation
 - Compliance with policies
 - Incidents or risks and the nature of those incidents/risks
 - Ability to address or mitigate gaps in compliance

Privacy and Security Issues

- Assess laws and regulations governing relevant data use (it's not just HIPAA...)
 - State laws
 - Substance use disorder records
 - Behavioral health
 - GDPR or other laws

Due Diligence: Security

- Security risk assessment
- Policies and procedures
- Comprehensive system security plan
- Awareness training
- Control of third-party risk

Due Diligence: Key Employees

- Leadership, sales, development
- Employees who are critical for the success of the business
 - Review employment agreements (contract duration, noncompete, incentives, etc.)

Due Diligence: Intellectual Property

- Key Developers
 - investor and IP legal counsel should talk to key developers
 - goal: determine sources of product design
 - working with or for a competitor?
- Consultants/Independent Contractors
 - assignment of invention provisions?
- License Agreements
- Other Issues (open source software, trademarks, etc.)

Presenters



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