Health Law Basics

Part Two

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Agenda

- Intro to Deals
- Basic Corporate Structure
- Intro to HIPAA
- Intro to Provider Contracting
- What is a PSA?
- Pricing/Transparency/NSA

Intro To Deals

Process

- Confidentiality Agreement.
- Letter of Intent.
- Due Diligence.
- Negotiate and work on terms of legal agreements.
- Approvals.
- Execute transaction documents.
- Satisfy closing conditions.
- Closing of transaction.

Forms Of Practice Sale Transactions

- Equity Purchase
  - Purchase equity of target.
  - Capital gain to sellers.
  - Rarely used; Buyer takes on all liabilities of Seller (e.g. malpractice claims, bank debt, False Claims Act).
- Asset Purchase
  - Parties select which assets are purchased/sold and what will be left behind (e.g., accounts receivable).
  - Buyer only assumes certain agreed upon liabilities.
  - Ordinary income / some capital gain.
    - Consider personal goodwill.
  - Seller will need to pay obligations from proceeds of sale (e.g., bank debt).

Asset Purchase

- Types of assets that might be purchased:
  - Tangible.
    - Equipment.
    - Supplies.
    - Fixtures.
  - Intangible.
    - Goodwill.
    - Covenants Not to Compete.
    - Patient Lists.

Regulatory Issues

- Antikickback.
- Stark.
- Antitrust.
- Corporate Practice of Medicine.
- Tax Exemption (for tax-exempt organizations).
- Many other state and federal laws and regulations.

Antikickback

- It is illegal to offer, solicit, make or receive any payment intended to influence referrals under a federal health care program.
  - The government applies the “one purpose” test. If one purpose of the payment is to influence referrals, the payment is illegal.
  - Use of earn-outs?
- “Sale of Practice” Safe Harbor
  - Applies to physicians retiring or leaving the practice area (no referrals to buyer post-closing).
- Not required to meet a safe harbor.

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:
  - Isolated Transaction Exception

Covenants, Representations And Warranties

- Seller makes certain promises about its business in the purchase agreement (e.g., compliance with all laws, no amounts due others).
- If after closing, a representation is not true, Buyer may seek recovery against Seller.
- Purchase Agreement may describe limits to liability of Seller and its physician owners.

Covenants, Representations And Due Diligence – What Is This Process About?

Approval Requirements To Sell

- Shareholder/Board approval.
- Execution of new employment agreements.

Other Key Considerations

- If it is not in writing, the promise doesn’t exist from a legal perspective.
- People change.
- The health care environment is changing rapidly; no one is sure of the future.

Basic Corporate Structure

Choice of Entity

- Sole Proprietorship.
- Business Corporation.
- Nonprofit Corporation.
- Limited Liability Company.
- Partnership (LP, LLP, LLLP).
- Professional Corporation.

Why “Incorporate?”

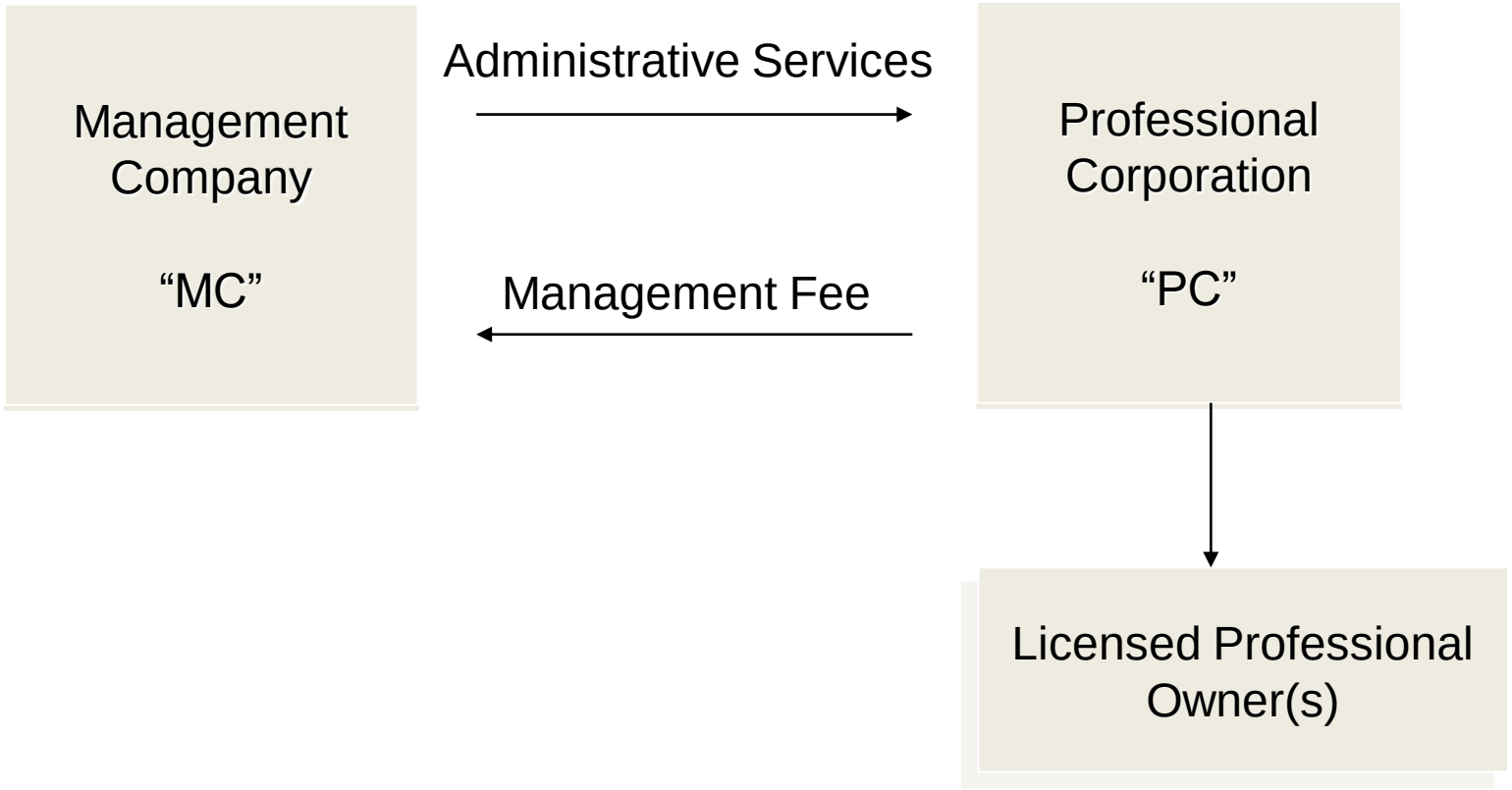
- Liability Protection for Owners.
  - Veil piercing.
- Centralized Management.
- Continuity of Life.
- Transferability of Ownership.
- Accommodate Financing – Debt/Equity.
- Potential Tax Benefits.

Regulatory Issues

- Corporate Practice of Medicine (“CPM”) Prohibition.
  - Prohibits corporations from employing professionals or owning professional practices.
  - Applies to many disciplines (e.g., dentistry, nursing, veterinary).
- Need to consider when partnering with PE.

Regulatory Issues (CPM Cont.)

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



Friendly PC Arrangement

- Common Aspects of Management Agreement.
  - Long-term.
  - Restrictions on termination.
  - Restrictive covenant.
  - Management fee.
- Other Agreements re: Continuity of Ownership.

Intro To HIPAA

What Is HIPAA?

- Health Insurance Portability and Accountability Act.
- Protects “protected health information” or PHI.
- Gives individuals certain rights with regard to PHI.
- Privacy, security and breach notification components.
- Sets a floor for the protection of health information.
  - Don’t forget about state law and special protections for certain types of health information.

HIPAA Compliance

- Risks:
  - Potential legal liability.
  - Reputational concerns.
- Rewards:
  - Clarity for workforce.
  - Patient trust.

Core Compliance Items

- ✓ Privacy Rule Policies and Procedures (PHI)
- ✓ Security Rule Policies and Procedures (ePHI)
- ✓ Security Rule Risk Assessments
- ✓ Business Associate Agreements
- ✓ Notice of Privacy Practices
- ✓ Breach Reporting
- ✓ Workforce Training

Privacy Rule Basics

- HIPAA permits these Uses and Disclosures:
  - Disclosure to the individual/personal representative.
  - Treatment, payment and health care operations.
  - Required by law.
  - Business associates.
  - As authorized by the patient.
  - Other.

Minimum Necessary

- Use and disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure.
  - Internal uses: use/disclosure should be consistent with job responsibilities.

Business Associates

- CE must have a Business Associate Agreement with every Business Associate.
- A Business Associate is a person or entity that creates, receives, maintains or transmits PHI on behalf of the CE (e.g., document storage companies, IT vendors, shredding companies, lawyers, outside coders).

Patient Rights

- Right to access.
- Right to request restrictions.
- Right to amend.
- Right to an accounting of disclosures.
- Right to confidential communications.

Patient Rights: Access

- A CE has 30 days to provide access.
  - One-time 30-day extension.
  - If person requests an electronic copy of PHI maintained in a designated record set, must provide access in electronic form/format requested by person, if readily producible, or (if not) in readable electronic format as agreed by CE and individual.
    - If the EHR has links to images or other data, the images/data must also be included in the electronic copy provided to the individual.

Patient Rights: Access

- If requested by an individual, a CE must transmit the copy of PHI directly to another person designated by the individual.
- Request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the PHI.
- Different from an authorization.

Patient Rights: Access

- Charging patients – “reasonable, cost-based fee.”
- Permits charging only for the labor costs of copying PHI, supplies, postage and labor to prepare summary/explanation (if agreed to in advance).
- Not ok to charge a retrieval fee.
- Not supposed to be a revenue stream.
- Consider state laws – but keep in mind what is “reasonable.”

Security Rule

- Requires covered entities to protect the "confidentiality, integrity, and availability" of **electronic** PHI.
- Administrative, physical and technical safeguards.
- Security Rule risk assessment.
- Security awareness training.
- Access restrictions.

Breaches

- What is a breach?
  - An impermissible use or disclosure of “unsecured PHI” is presumed to be a breach unless CE (or BA) can demonstrate that there is a low probability that the PHI has been compromised.
- What is “unsecured PHI”?
  - PHI that has not been rendered unusable and unreadable, or encrypted.

Not A Breach!

- Unintentional acquisition or access or use of PHI by an employee if made in good faith and in scope of authority AND doesn't result in further use/disclosure in violation of the rule.
- Disclosure made to unauthorized individual who couldn't reasonably retain the information.

Breaches

- Factors to assess the probability that PHI has been compromised:
  - Nature and extent of PHI involved, including identifiers and likelihood of reidentification.
  - Unauthorized person who used the PHI or to whom the disclosure was made.
  - Whether PHI was actually acquired or viewed.
  - Extent to which the risk to the PHI has been mitigated.
  - Other factors may be considered “where necessary”.

What If There Is A Breach?

- CE must report:
  - To the individual.
  - To the government.
    - Annually, in the CE's breach notification log; and
    - Right away, if the breach involves more than 500 people.
  - To the media, if the breach involves more than 500 people.
  - May name individuals or BA in notification.

Intro To Provider Contracting

Contract Types

- Contracts with health care professionals:
  - Employment.
  - Independent contractors.
  - Time shares.
  - Leases of space, staff, equipment.
- Service contracts
- Payer contracts

Regulatory Compliance

- Beware of templates and regulatory clauses.
  - Compliance depends on contract + arrangement.
- Understand the applicable regulations:
  - Federal AKS, Stark, CMP, EKRA and tax exemption.
  - Potential Reporting:
    - Capital expenditure or Certificate of Need filings.
    - Notification of ownership/financial disclosures.
    - State or Federal open payment disclosures.

Which Arrangements?

- Any and all contracts with referring. providers and their family members.
- “Contracts” – oral and written arrangements.
- How do you catch these?
  - Conflict of interest disclosure forms.
  - Contract management systems.
  - Clear rules on who is authorized to sign.

Special Considerations

- Safe harbor or exception regulatory language.
- Compensation methodologies.
- Confidentiality/health privacy.
  - Business Associate Agreements.
  - HIPAA acknowledgement language.
- Exclusion checks.
- Government program language.
- Data rights and ownership.

Third Party Payer Contracting

- High level review:
  - Put it in context.
  - Goals, purpose, red flags.
  - Evaluate and re-evaluate.
  - Educate and advocate (for yourself or with help).
    - Understand your rights and obligations.
  - Confirm accuracy.

Payer Contracts: Key Terms

- Does the contract clearly identify the parties, plans & products?
- Do you understand the key definitions?
- Compensation: How and how much you will be paid? How does it differ by product type?
  - Related terms: form of claims, timely filing limit, appeals, timeframes for claim adjustments, procedural requirements for billing patients when services are noncovered, etc.
- Quality and value-based programs, bonus and other payment opportunities?
- How and when you can get out of the Agreement?
- What administrative obligations and limitations apply? How can they be changed?
- How can the agreement be amended?
- How are disputes resolved?
- How can new providers, locations or services be added to the Agreement?
- Restrictive covenants? Exclusivity? Non-solicitation? Communication with patients?
- Assignment/Change of Control?
- Indemnification? (If so, is it mutual?)

What Can You Negotiate?

- It depends on your bargaining power.
- Some items are non-negotiable:
  - state insurance requirements.
  - government program requirements.
  - ACA requirements.
- Some items are “non-negotiable”:
  - Payer administration limitations.
  - Desire for uniformity.
  - Contractual obligations.
  - Business preference.

Negotiating Payer Contracts

- Ask questions.
- Request changes that meet your needs.
- Advocate for your position.
- Differentiate push back due to regulatory requirements versus business standards.
- Be prepared: It’s a time-consuming process.

What Is A PSA?

Professional Service Agreements

- What are they?
- Why do we use them?
- What are the critical terms?
- Which laws are relevant?

What is a Professional Service Agreement?

- Agreement between two health care providers for the provision of medical services
- Examples:
  - Hospital/specialists
  - Primary care group/specialists
  - Hospital/physician group

Why do we use Professional Service Agreements?

- Streamline the billing process
- Expand services to patients
- Greater flexibility and potentially lower costs

Critical Terms

- Term
- Termination Rights
- Exclusivity
- Payment
- Noncompetition
- Nonsolicitation/No-hire Clauses
- Performance Standards

Regulatory Issues

- **Federal Laws**
  1. Medicare Reassignment Rule
  2. Tax Exemption Laws
  3. Antikickback Statute
  4. Antitrust
  5. Stark
- **State Laws**

Medicare Reassignment

- Non-employee physician can reassign right to receive payment, as long as:
  - Joint and several liability
  - Access to billing records

Tax Exemption

- Tax-exempt hospitals (or clinics) must operate exclusively for charitable purposes.
- IRS intermediate sanction rules create penalties for excess benefit transactions (overpayments) which apply to recipient and responsible persons.

AKS Safe Harbor for Personal Services Agreements

- To fall within the safe harbor, the agreement must meet the following 7 requirements:
  1. In writing
  2. Covers all services to be provided
  3. If the services will be provided on a periodic, sporadic, or part-time basis, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals
  4. Term is at least one year
  5. Compensation is set in advance, consistent with FMV, and does not take into account referrals between the parties
  6. Agreement does not involve the promotion of illegal activity
  7. Services cannot exceed those reasonably necessary to accomplish legitimate business purpose

Stark Exception for Personal Service Arrangements

- Very similar to AKS Safe Harbor
- Must meet the following conditions:
  1. In writing
  2. Specifies and covers all services to be provided
  3. Term must be for at least one year
  4. Services cannot exceed those reasonable and necessary to achieve legitimate business purpose
  5. Compensation must be set in advance, not exceed FMV, and not take into account referrals between the parties
  6. Services cannot involve illegal activity

Group Practice Definition

- In Office Ancillary Exception
- Must be a “group practice” – one requirement is that “substantially all of the patient care services of the physicians who are members of the group (that is, at least 75% of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. . . .” 42 CFR 411.352(d).

Group Practice Definition

- “If the group’s business includes providing professional services to another entity, which, in turn, pays the group for those services, it is our view that these are services that should count as services a physician provides through the group. We are, therefore, interpreting the requirement that substantially all of a physician’s services be provided through the group and be billed ‘‘under a billing number assigned to the group’’ and amounts so received treated as receipts of the group to include any physicians’ professional services billed by a group under any group billing number regardless of the payer of the services, provided the receipts are treated as receipts of the group. In other words, the phrase ‘‘billed under a billing number assigned to the group’’ . . .does not refer exclusively to Medicare or Medicaid billing numbers.” 66 FR 905 (Jan. 4, 2001).

State Laws

- Antikickback Laws
- Anti-Referral Laws
- Fee-Splitting Laws

Pricing, Transparency And The No Surprises Act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Pricing

- Major Enforcement Priority.
- Not the Industry's Proudest Moment.
- Federal, State and Common Law Issues.

What Is Your Charge?

- The amount on the bill?
- The amount you have agreed to accept as payment in full?
- Your usual and customary charge?

Implied Contracts

- Absent express agreement, contractual terms can be imposed by a judge using what is reasonable / industry norms.
- If an uninsured patient gets a discount, why isn’t an insurer, or insured patient, entitled to the same break?

Medicare Is Not Entitled To Your Lowest Price

- Unlike most government contracts, no “most favored” pricing for Medicare.
- Medicare pays the lower of:
  - The fee schedule
  - The actual charge
  - Usual and customary charge. (U&C is defined as your median charge.)

Price Transparency

- 45 CFR Part 180, 84 Fed. Reg. 65524, Nov. 27, 2019 requires hospitals to disclose pricing.
- Shoppable services must be publicly disclosed.
- Provide machine readable data.
- Initial CMP of $300 a day increased to up to $5,500 for hospitals with more than 550 beds.

No Surprises Act

- View as two rules. First applies to services in hospitals, freestanding EDs, ASCs, and air ambulances.
  - Some impact on clinics because doctors often utilize hospitals or ASCs.
  - Requires notice, limits or requires consent for balance billing.
- The second requires Good Faith Estimate of charges. Currently, only for patients not using insurance, but ultimately industry-wide.

NSA: Emergency Services

- Generally treated as if they were in-network.
- Patient cost sharing capped at in-network rate.
- Insurers may not deny coverage based on the final diagnosis.

NSA: Non-Emergency Services

- Some balance billing is permitted, but there are major limitations.
- No balance billing for “ancillary services”

NSA: Ancillary Services

- Items and services “related to” emergency medicine, anesthesiology, pathology, radiology and neonatology. (Mentions physicians and non-physician practitioners).
- Items and services “provided by” assistants at surgery, hospitalists and intensivists.
- “Diagnostic services” such as radiology and laboratory.
- Any item or service provided by a non-participating professional if there is no participating professional who could provide the service.

NSA: Independent Dispute Resolution

- Baseball arbitration.
- Large fight about the “qualified payment amount.”

NSA: Disclosures and Good Faith Estimates

- CMS has model forms.
- You may, but need not, use them.
- Detailed requirements for what must appear, including the patient's birthdate, the provider tax ID number and NPI.

When Is The GFE Required?

- Estimate required if appt. is scheduled for 3 or more business days in advance:
  - 3-9 business days, provide within 1 business day after scheduling.
  - 10 or more business days, within 3 business days after scheduling.
- Patient can request without scheduling an appointment. Provide within 3 business days.

During Sto

NSA: Language Requirements

- For a GFE to be effective, the patient must be able to understand it.
- Notice and consent to balance balance bill must be translated into the 15 most common languages.

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