

## **Structuring Healthcare Management Arrangements: Corporate Practice of Medicine, Regulatory Compliance**

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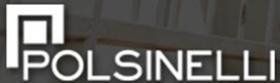
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# Structuring Healthcare Management Arrangements: Corporate Practice of Medicine, Regulatory Compliance

Ashley Osak & Khaled Klele

January 5, 2022

# Session Outline

- Structure and purposes of healthcare management arrangements
- Regulatory compliance
  - Corporate practice of medicine
  - Anti-Kickback Statute
  - State laws
  - Stark law
  - Anti-assignment laws
- Compensation and FMV considerations

# Management Agreements Common Across Healthcare Subsectors

- Physician Practices
- Whole Hospitals
- Individual Service Lines
- Skilled Nursing Facilities
- Ambulatory Surgery
- Home Health & Hospice
- Renal Dialysis
- Ancillaries

# Definition & Types of Management Arrangements

## Non-Physician Services

- *Business* management
  - Day-to-day management of a group of administrative services:
    - Human resources
    - Payor contracting
    - Business development
    - Benchmarking
    - Supply chain
    - Accounting
    - GPO

## Physician Services

- *Clinical Co-Management* Services are provided by groups of physicians to manage the quality of hospital service lines.
  - For example, 10 cardiologists enter into a contract with a hospital to continuously improve clinical outcomes.
  - Think performance-based medical directorships.

# Common Service Combinations

- Separate, distinct services commonly offered in conjunction with business management services
- Business management often combined with:

Staff leasing or professional employer services (PEO)	Revenue cycle management or partial billing services
Equipment leasing	Facility timeshare
Technology, software (EHR Donation)	Credentialing (PHO)
Management company sometimes acts as a Group Purchasing Organization	Intellectual property via franchise or licensing

# Key Legal Issues Impacting Management Agreements

- Corporate Practice of Medicine Doctrines
- Anti-Kickback Statute
- State fee splitting laws and anti-kickback laws
- Stark law
- Anti-assignment laws
- Other management fee considerations

# Corporate Practice of Medicine

- A number of states prohibit the “corporate practice of medicine” (CPOM) to varying degrees
- The CPOM is generally defined as a prohibition on the operation of a medical practice, or the employment of physicians or other licensed professionals, by entities that are not themselves licensed to practice medicine

# Corporate Practice of Medicine

- Rationale for CPOM:
  - Protects independent judgment of physicians
  - Limits commercialization of the profession
  - Unlicensed corporate entities are not subject to the same professional standards and regulatory control
- Most states have some form of the CPOM doctrine, but key states include CA, TX, SC, NJ, NY, TN, WA, IL

# Corporate Practice of Medicine

Sources of the CPOM doctrine include:

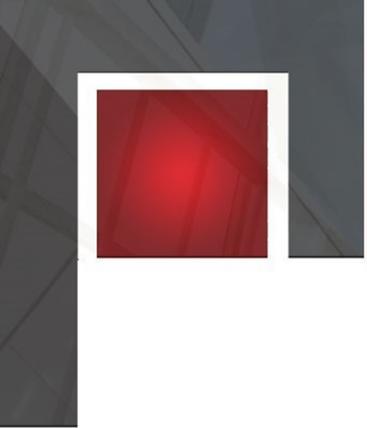
- State statutes and regulations
  - Example: Cal. Bus. & Prof. Code § 2400: “Corporations and other artificial legal entities shall have no professional rights, privileges, or powers....”
    - Cal. Bus. & Prof. Code § 2052: "Any person who practices or attempts to practice, or who holds himself or herself out as practicing...[medicine] without having at the time of so doing a valid, unrevoked, or unsuspended certificate...is guilty of a public offense.”

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- Example: N.J.A.C. 13:35-16.6: “such entity shall be composed solely of health care professionals, each of whom is duly licensed or otherwise authorized to render the same or closely allied professional service within this State”
    - Can be partners with allied professional
    - Limitations on ownership between plenary licensee vs. non-plenary licensee

# Corporate Practice of Medicine

- Case law

- Example: *State Farm Mutual Automobile Insurance Co. v. Mallela*, 175 F. Supp. 2d 401, 414 (E.D. N.Y. 2001): “[W]hen a professional health services corporation is owned by an unlicensed individual, ‘there is a danger that the doctor, knowing that he or she had to split his or her fees with one who did not render medical services, might be hesitant to provide proper services to a patient.’” (internal citation omitted)

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- Example: *Allstate Ins. Co. v. Northfield*, 228 N.J. 596, 629 (2017): Holding that New Jersey’s regulatory scheme is intended to deprive “anyone or any corporate entity of the opportunity to control or attempt to exert control over the exercise of professional discretion by a plenary licensee.”

# Corporate Practice of Medicine

- Medical Board guidance
  - Example: The Medical Board of California
    - The CA Medical Board views the following as health care decisions that should be made by a physician:
      - Responsibility for the ultimate overall care of the patient, including treatment options available to the patient, and referrals to other providers
      - Determining how many patients a physician must see in a given period of time or how many hours a physician must work available to the patient

# Corporate Practice of Medicine

- Medical Board guidance (continued)
  - Example: The Medical Board of California
    - The following “business” or “management” decisions should be made by a licensed physician:
      - Ownership is an indicator of control of a patient's medical records, including determining the contents thereof, and should be retained by a California-licensed physician
      - Selection, hiring/firing (as it relates to clinical competency or proficiency) of physicians, allied health staff and medical assistants
      - Setting the parameters under which the physician will enter into contractual relationships with third-party payers.
      - Decisions regarding coding and billing procedures for patient care services
      - Approving of the selection of medical equipment and medical supplies for the medical practice

# Corporate Practice of Medicine

- Medical Board guidance (continued)
  - Example: The Medical Board of California
    - The following structures are prohibited:
      - Non-physicians owning or operating a business that offers patient evaluation, diagnosis, care and/or treatment
      - Physician(s) operating a medical practice as a limited liability company, a limited liability partnership, or a general corporation
      - MSOs arranging for, advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice
      - A physician acting as "medical director" when the physician does not own the practice

[http://www.mbc.ca.gov/Licensees/Corporate\\_Practice.aspx](http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx)



## ■ Medical Board Guidance

### -- Example: NJ Board of Medical Examiners

- Very Similar to California although there are some differences
- Corporate structures allowed
- Ownership with allied professionals
- MSO structures. N.J.A.C. 13:35-16.6(f)(5)

# Corporate Practice of Medicine

- Common sources of CPOM guidance:
  - Medical Practice Acts
  - Fee splitting/kickback statutes
  - Court cases
  - Attorney General opinions
  - Medical Board guidance and enforcement actions
  - Secondary sources (treatises, articles, etc.)

# Corporate Practice of Medicine

- Common CPOM exceptions (state specific):
  - Professional corporations
  - HMOs
  - Public hospitals
  - Certain other licensed health care facilities
- Penalties for violating the CPOM doctrine include:
  - Enforcement action by state AG
  - Enforcement action by applicable professional board
  - Debarment of the professional
  - Civil, criminal penalties, injunctive relief
  - Recoupment of monies by payors

# Corporate Practice of Medicine

- Key management agreement provisions to review:
  - Compensation
  - Medical records
  - Hours/schedules
  - Employment of licensed professionals
  - Selection of equipment and supplies
  - Third-party payor contracting
  - Proprietary information
  - Clinical care

# Anti-Kickback Law

- Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
- Federal criminal statute, also civil penalties
- Intent-based statute
- Covers all types of arrangements & individuals
- Safe harbors (provide immunity for certain arrangements; not required)
- OIG Advisory Opinions

# Anti-Kickback Laws

- A violation requires three elements:
  - “Remuneration,” which means anything of value, in cash or in kind
  - The remuneration must be made “knowingly and willfully”
  - The remuneration must be made with intent to induce referrals or business; according to certain federal courts, a violation may be found if only **one purpose** of the remuneration is to induce referrals, even if there are also legitimate reasons for the payment

# Anti-Kickback Laws

- Potential penalties for Anti-Kickback Statute violations include:
  - Up to \$25,000 per offense
  - Up to five years imprisonment per offense
  - Mandatory exclusion from federal health programs
  - Civil monetary penalties
  - Liability under the False Claims Act

# Anti-Kickback Laws

- Common safe harbors for management agreement arrangements
  - Personal services and management contracts
  - Space rental
  - Equipment rental
  - Employees
  - EHR donations
  - Small entity investments

# Anti-Kickback Laws

- **OIG Advisory Opinions involving management arrangements:**
  - **OIG Adv. Op. 98-4 (physician practice)**
  - **OIG Adv. Op. 03-08 (rehabilitation unit)**
  - **OIG Adv. Op. 04-17 (pathology laboratory)**
  - **OIG Adv. Op. 11-15 (pathology laboratory)**
- **Advisory opinions provide certainty for parties, but:**
  - **All material facts must be presented**
  - **Usually only apply to parties who submitted the opinion request**
  - **Time consuming process**

# Anti-Kickback Laws

- Watch out for state anti-kickback statutes and fee splitting prohibitions!
- Some form of state anti-kickback law and/or fee splitting prohibition exists in most states
- Types of state anti-kickback laws:
  - All payor
  - Insurance
  - Medicaid

# Anti-Kickback Laws

- Example: Cal. Bus.& Prof. Code § 650:
  - “... the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.”
  - Important exception: “The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer”

# Anti-Kickback Laws

- Example: N.J.A.C. 13:35-6.17(c)
  - “A licensee shall not, directly or indirectly, give to or receive from any licensed or unlicensed source a gift of more than nominal (negligible) value, or any fee, commission, rebate or bonus or other compensation however denominated, which a reasonable person would recognize as having been given or received in appreciation for or to promote conduct by a licensee including . . . making or receiving a referral”
  - Numerous exceptions including the provision of “non-clinical services”

# Anti-Kickback Laws

- Example: Epic Medical Management v. Paquette, 244 Cal.App.4<sup>th</sup> 504 (2015)
  - Dispute over MSO compensation and services
  - Services provided by MSO:
    - Lease office space to physician
    - Lease all equipment to physician
    - Provide support services
    - Provide non-physician personnel
    - Establish and implement a marketing plan
    - Conduct billing and collections
    - Perform accounting services

# Anti-Kickback Laws

- MSO compensation
  - 50% of office medical services
  - 25% of surgical services
  - 75% of pharmaceutical expenses
- Physician argued that because some of the fees were for marketing services, the payments were illegal kickbacks for referred patients (and the MSO did refer patients to the practice)

# Anti-Kickback Laws

- Holdings
  - No state anti-kickback statute violation: No evidence that the amount the MSO received was for referrals
  - No CPOM violation: the Court found a strict delineation between non-medical services provided by the MSO and medical services provided by the practice



## ■ Examples

- *Allstate Ins. Co. v. Northfield*, 228 N.J. 596, 629 (2017): Inter-related Agreements designed to circumvent regulations
- *Galkin, et al. v. SmileDirectClub, LLC, et al.*, Docket No. A-2867-19 (App. Div. 2021): Succession Agreements
- *In the Matter of Aspen Dental Management, Inc.* (June 2015): Financial and Marketing Control
- *Andrew Carothers, M.D., P.C. v. Progressive Insurance Company*, Docket No. APL-2017-00225 (NY Court of Appeals 2019): Equipment leases and limited involvement by licensee

# Anti-Kickback Laws

- Key management agreement provisions to review:
  - Compensation provisions
  - Marketing provisions
  - Other requirements of applicable safe harbors

# Physician Self-Referral Law (Stark)

- Covers only physician relationships
- Intent is generally irrelevant
- Civil statute, prohibits payments, and (for knowing violations) provides for civil monetary penalties
- Exceptions are required (if a financial relationship exists with a physician referring designated health services (DHS))
- CMS Advisory Opinions

# Physician Self-Referral Law (cont.)

- Basic Prohibition:
  - Absent an exception, a physician may not refer a Medicare patient for DHS to an entity with which the physician or an immediate family member has a “financial relationship”
  - An entity may not present a claim for payment for such services
- A financial relationship means (i) an ownership or investment interest, or (ii) a “compensation arrangement” between the referring physician and the provider

# Physician Self-Referral Law (cont.)

## Designated Health Services

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services (also nuclear medicine)
- Radiation therapy services and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Durable medical equipment and supplies

# Physician Self-Referral Law (cont.)

- Examples of Stark Exceptions
  - In-office ancillary services
  - Rental of office space
  - Rental of equipment
  - Personal service arrangements
  - Non-monetary compensation
  - Fair market value compensation
  - Indirect compensation arrangements
  - (And there are many other exceptions)

# Physician Self-Referral Law (cont.)

- Penalties for Stark violations:
  - Payment denial/recoupment by Medicare and Medicaid
  - Civil monetary penalties up to \$15,000 per prohibited service/billing (inflation adjusted)
  - Circumvention schemes face civil monetary penalties of up to \$100,000 per incident (inflation adjusted)
  - Exclusion from Medicare/Medicaid participation
  - Liability under the FCA

# Physician Self-Referral Law (cont.)

- Key aspects of management agreement arrangements to review:
  - Who owns the management company (hospital, physicians, etc.)?
  - Compensation terms
  - Be aware of indirect financial relationships

# Medicare and Medicaid Anti-Assignment Rules

- Federal law generally prohibits the payment of Medicare and Medicaid funds to anyone other than the provider or supplier
- Exceptions generally include:
  - Court orders
  - Agency agreements
  - Employers of physicians
  - Certain entities that contract with physicians
  - Government entities
- Use of lock box/sweep accounts

# Medicare and Medicaid Anti-Assignment Rules

- Key management agreement provisions to review:
  - Billing services
  - Bank account control and ownership

# Role of Fair Market Value

- Management service deliverables are intangible and susceptible to abuse
- Recognized standard of value for related party transactions
  - *The price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.*
- Third-party opinions provide independence

# Example #1: Health System Physician Practice Management

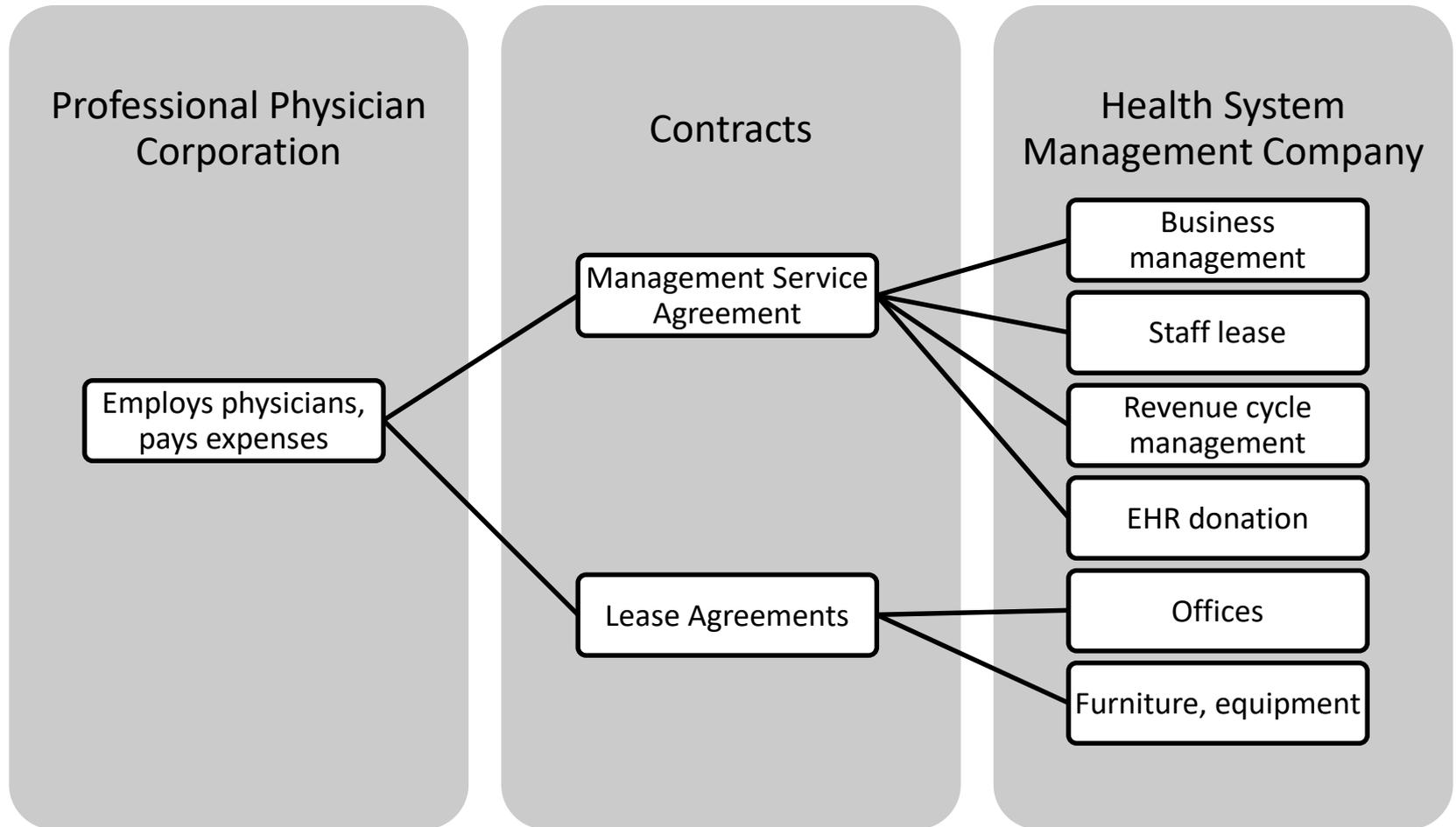
- Health systems develop for-profit management company subsidiaries to provide services to community physicians who are not employed by the system

- Physicians choose from a menu of services:

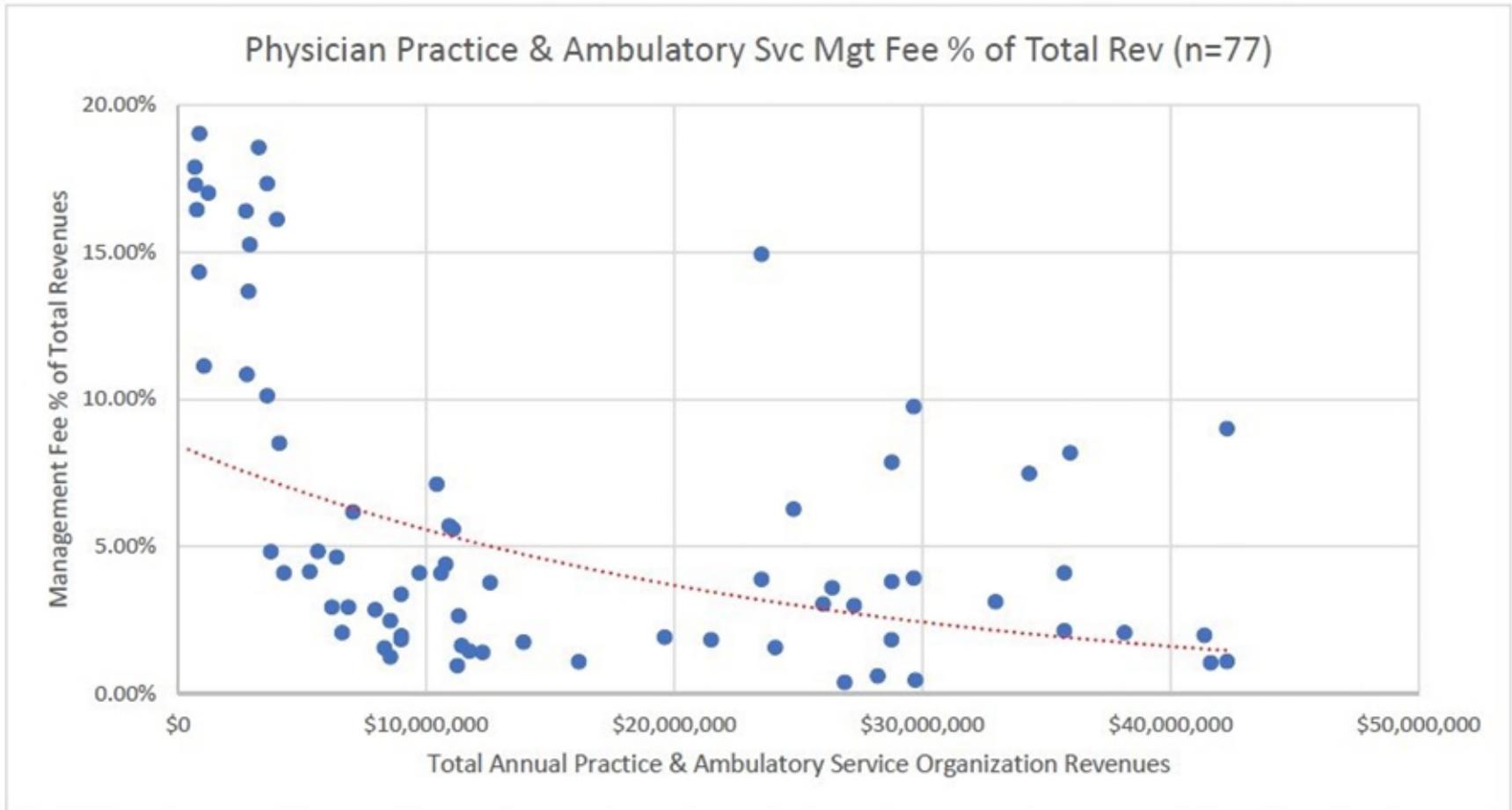
Staff leasing of non-physician staff: Salaries, benefits, taxes +1%-3% markup	Revenue cycle management: 4% to 6% collections
Technology, software (EHR Donation): ≥85% costs under safe harbors, exceptions	Credentialing (PHO): Fixed fee per provider

- Some practices also lease space and equipment so group's legal entity only employs physicians

# Example #1: Health System Physician Practice Management



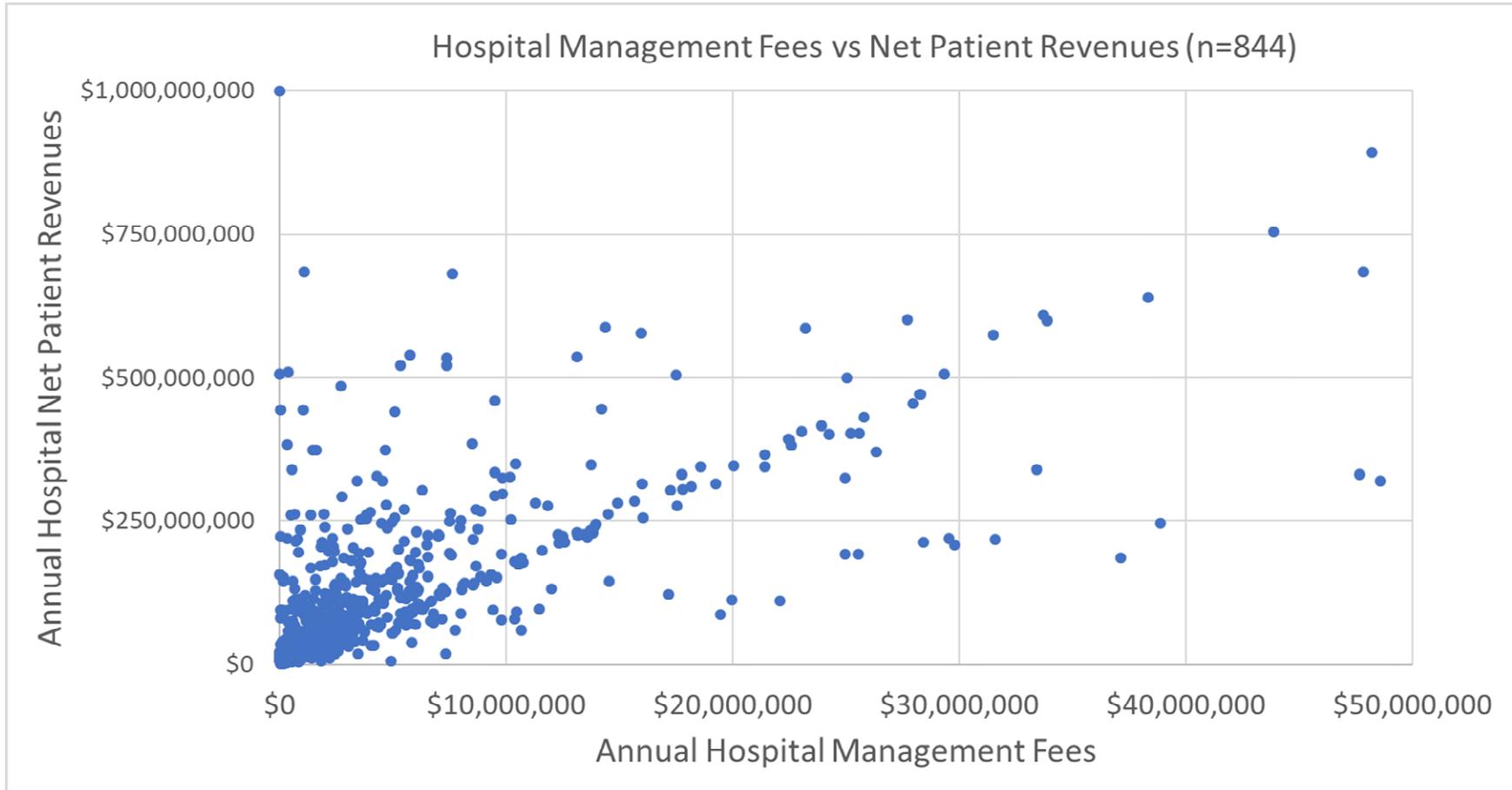
# Example #1: Health System Physician Practice Management



## Example #2: Health Systems Manage Critical Access Hospitals

- Over 1,300 rural hospitals are now Critical Access
- When health system acquires or takes over management, millions of dollars of system overhead may be allocated to these hospitals with cost-based reimbursement
- Market management fees are key factor
- Highly dependent upon scope of services

# Example #2: Health Systems Manage Critical Access Hospitals

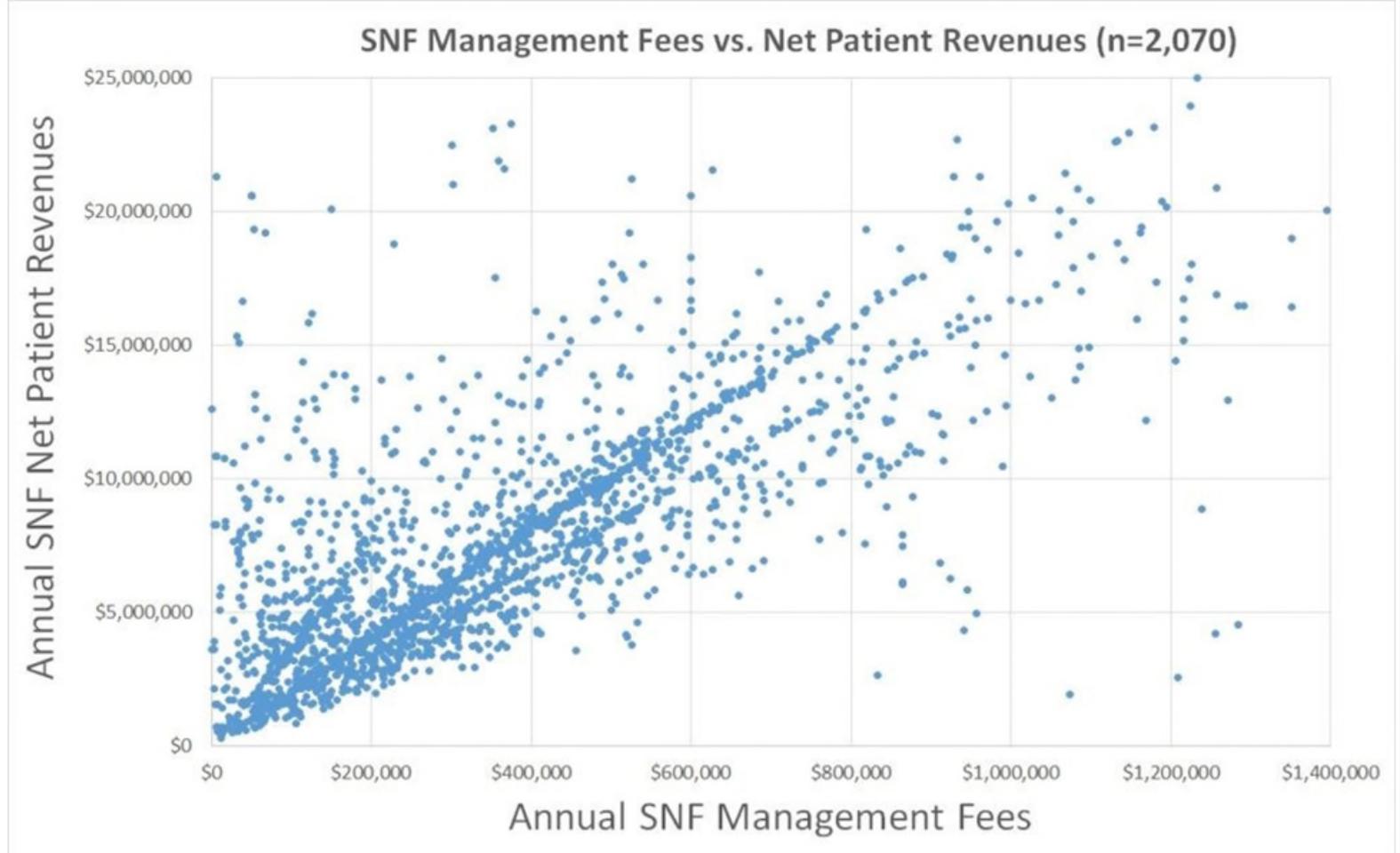


## Example #3:

# Nursing Facility Leaseback-Management

- Skilled nursing facilities in many states participating in enhanced Medicaid payment programs that brings Medicaid rate (~\$100/day) up to Medicare rate (~\$300/day)
- Involves leasing nursing facilities to district or county hospitals to access federal funds through inter-governmental transfer
- Both facility lease and management arrangement subject to FMV

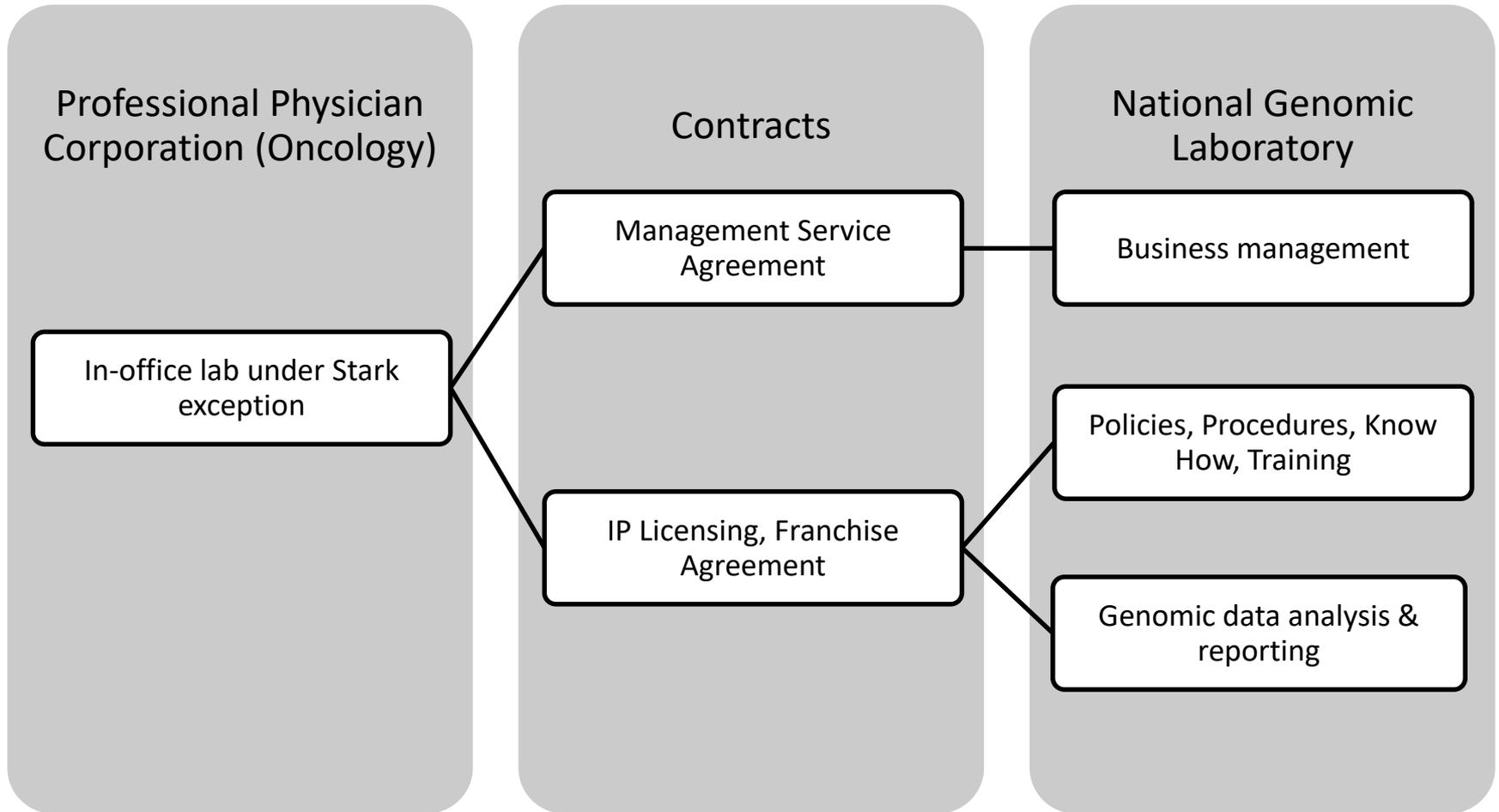
# Example #3: Nursing Facility Leaseback-Management



# Example #4: Genomic Laboratory Management

- Next Generation Sequencing technology costs have declined
- Some oncology groups and hospitals can afford sequencers
- The scientific *know how* to prepare samples and interpret genomic data still esoteric to most
- Management services, franchising, licensing, and professional services used to shift genomic laboratories to local markets with local ownership
  - Data analysis performed by third-party

# Example #4: Genomic Laboratory Management





# Example #5: Revenue Cycle Management

- A pain management physician turns his business office into a Central Business Office (CBO) that provides services to community physicians
- Some of the CBO's clients are primary care physicians and surgeons in a position to refer patients to the CBO owner
- Underpricing the CBO's services could be construed as a kickback to referral sources
- The CBO owner desires to fulfill the Safe Harbor requirements of the Anti-Kickback Statute





# Practical Considerations

## What's To Come



# Speaker Information

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