



Fraud and Abuse (September 2021)

Private Equity in Physician Practices: Compliance Considerations

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Presented by | Annapoorani Bhat, Principal, PYA & Kelly Koeninger, Of Counsel, Robinson Bradshaw

Presenters



Annapoorani Bhat

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Annapoorani Bhat specializes in valuation and related consulting services for entities in the health sciences sector, including providers, payors, pharmaceutical companies and health care technology companies. Her primary area of expertise is in the valuation of businesses and assets for financial reporting, regulatory compliance and internal strategic planning purposes. She provides valuation consulting services to facilitate mergers, acquisitions, affiliations and financial reporting of acquired intangible assets.

Anna works primarily with health systems and other providers in valuing provider entities to facilitate transactions. She also supports fair market value compensation analyses for services in the context of arrangements that include physician employment agreements, professional services agreements and management agreements. Additionally, Annapoorani assists provider organizations, especially academic medical centers and teaching hospitals, with their brand valuation needs related to affiliations and joint venture arrangements.

Anna is a member of the American Society of Appraisers (ASA) and is an ASA-Accredited Senior Appraiser in the Business Valuation discipline. She is a member of AHLA and a frequent speaker at national conferences on valuation-related topics specific to health care.

Presenters



Kelly A. Koeninger
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Kelly Koeninger is a versatile corporate and regulatory attorney and trusted adviser. She focuses her practice on health care regulatory and transactional matters and also counsels clients on privacy and cybersecurity issues. When representing health care entities, Kelly understands the intersection between business, clinical and legal objectives in health care, and she brings a global approach to transaction structuring and compliance issues by incorporating an understanding of federal and state fraud and abuse laws (including Stark and the Anti-Kickback Statute), state corporate practice of medicine rules and privacy laws with an extensive background in corporate and commercial transactions.

On behalf of health care entities, Kelly's experience includes the negotiation of complex joint venture transactions between regulated entities and providers as well as mergers and acquisitions and professional services agreements. She advises health care clients on transaction structuring, licensing matters, surprise billing, and federal and private payor issues.

Kelly also regularly counsels clients on HIPAA and other privacy laws and breach matters.

INTRODUCTION



Private Equity in Health Care

- Private equity role in health care
- The laws and regulations governing PE's participation in health care
- Structures, arrangements and agreements relied upon compliant participation
- Focus on compliance

INTRODUCTION



Extent of Private Equity Transactions (Study Results)

- **2000 – 2018**
 - Health care deals grew more than 20-fold
 - Annual deal value > \$100 billion
- **2003 – 2017 Hospital Deals**
(Research Article – Health Affairs, May 2021)
 - 42 PE-led deals
 - 282 unique hospitals
 - 36 states
- **2013 – 2016 Physician Practice Deals**
(Research Letter – JAMA, Feb. 2020)
 - 355 physician practices acquired
 - 1,426 sites
 - 5,714 physicians

Types of Arrangements

Private Equity Involvement in Medical Services



Capital Intensive

- I. Imaging Centers
- II. Radiation Therapy Centers
- III. Surgery Centers

Ancillary/Technical Services

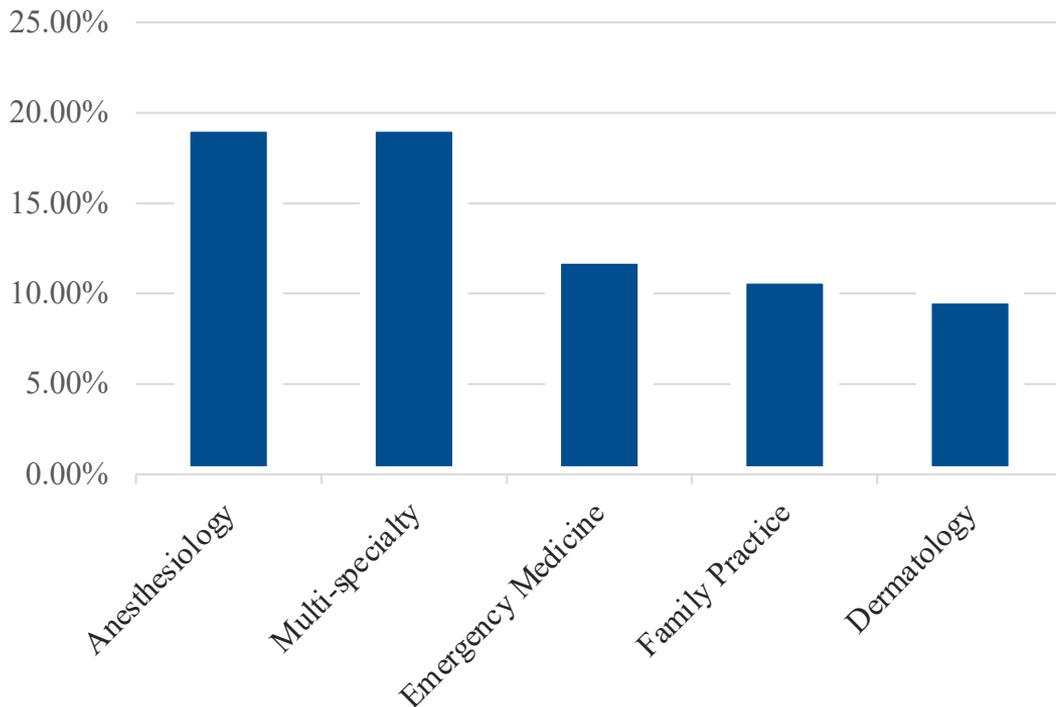
- I. Cardiology
- II. Laboratory
- III. Ophthalmology
- IV. Dermatology

Services Originating In Hospitals

- I. Anesthesiology
- II. Hospitalist/Emergency Medicine Services
- III. Radiology

INTRODUCTION

Private Equity Acquisition of Physician Practices



Specialties In Focus – 2013 to 2016

- Anesthesiology
 - Hospital-based services
 - Out-of-network billing
- Multi-specialty
 - Ancillary/technical revenue
 - Primary care to support specialties
 - Labs, imaging, tests
- Emergency Medicine
 - Hospital-based services
 - Out-of-network billing
- Dermatology
 - More recent
 - Fragmented providers
 - Leverage PE infrastructure

INTRODUCTION



Private equity involvement in health care is significant and growing

Newer and newer specialties are becoming targets

Physicians benefit from PE's role in non-clinical aspects of the practice

Arrangements operating within the boundaries of existing regulatory framework is key

Outline of Presentation



01

- Discuss select investigations and settlements involving private equity, identifying key focus areas for regulators

02

- Discuss various types of arrangements utilized by PE to participate in health care practices

03

- Present legal and regulatory considerations, including a discussion on fraud and abuse laws

04

- Discuss key valuation considerations

05

- Apply learnings to relevant case study

Illustrative Settlements



Illustrative Settlements



Diabetic Care RX

- PE firm directly responsible under settlement
- Payment of commissions based on % of billings

Illustrative Settlements



Diabetic Care RX

- PE firm directly responsible under settlement
- Payment of commissions outside of FMV

EMCARE

- Exclusive ED services contract as inducement for kickbacks

Illustrative Settlements



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EMCARE

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21st Century Oncology

- Stark law violations
- Meaningful use false attestations

Illustrative Settlements



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EMCARE

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21st Century Oncology

- Stark law violations
- Meaningful use false attestations

Surgery Partners

- Stark and AKS violations
- Billed for unnecessary laboratory tests

Illustrative Settlements



Diabetic Care RX

- 2019 – \$21,360,000 settlement
- Diabetic Care RX purchased by private equity firm.
 - Expanded to providing prescription pain cream through compounding pharmacy.
 - Compensated marketing firms based on percentage of referrals; targeted TRICARE beneficiaries.
- First time private equity company directly liable for settlement with DOJ under FCA.
- Case survived motion to dismiss, PE firm directly involved in decisions related to business practices.

Illustrative Settlements



EMCARE

- 2017 – \$29,600,000
- Part of broader DOJ investigation into Health Management Associates, LLC (HMA).
 - HMA increased inpatient admissions through required company-wide admission benchmarks for patients at ED.
 - Pressured ED physicians through threats of termination.
- EMCARE suit brought by whistleblowers.
- EMCARE granted exclusive ED staffing contracts at HMA hospitals.
- Alleged EMCARE retained and received new contracts with HMA through promises to increase ED admissions.
- Bonuses paid to EMCARE physicians for increased admissions.

Illustrative Settlements



21st Century Oncology

- 2017 – \$26,000,000
- 21st Century Oncology self-reported that it knowingly submitted false attestations to CMS related to meaningful use.
- Settlement also resolves allegations re: violations of Stark law.
 - Allegedly, employed physicians were compensated based on their referrals for DHS to other parts.
 - Stark law claim brought by whistleblower.

Illustrative Settlements



Surgery Partners

- 2020 – \$41 million
- Surgery Partners is a nationwide network of surgical facilities and ancillary services, including pain management.
- Bought by PE firm. After acquisition, PE firm formed wholly owned lab subsidiary (Logan Labs) that performed urine toxicology testing.
- Surgery Partners allegedly put into place policies to discourage cheaper, in-office testing and instead incentivized testing at Logan Labs that was more expensive.
- In addition, whistleblowers made allegations that Surgery Partners provided incentive compensation to employed physicians based on cash collections of ancillary services.
- OIG settled with Surgery Partners, but not the PE firm; after settlement, whistleblowers amended complaint to focus the pleading on the liability of the PE firm, including focus on the management and control PE firm exercised over Surgery Partners and Logan Labs.
- Complaint discussed on other grounds.

Lessons Learned from Enforcement



Enforcement Environment

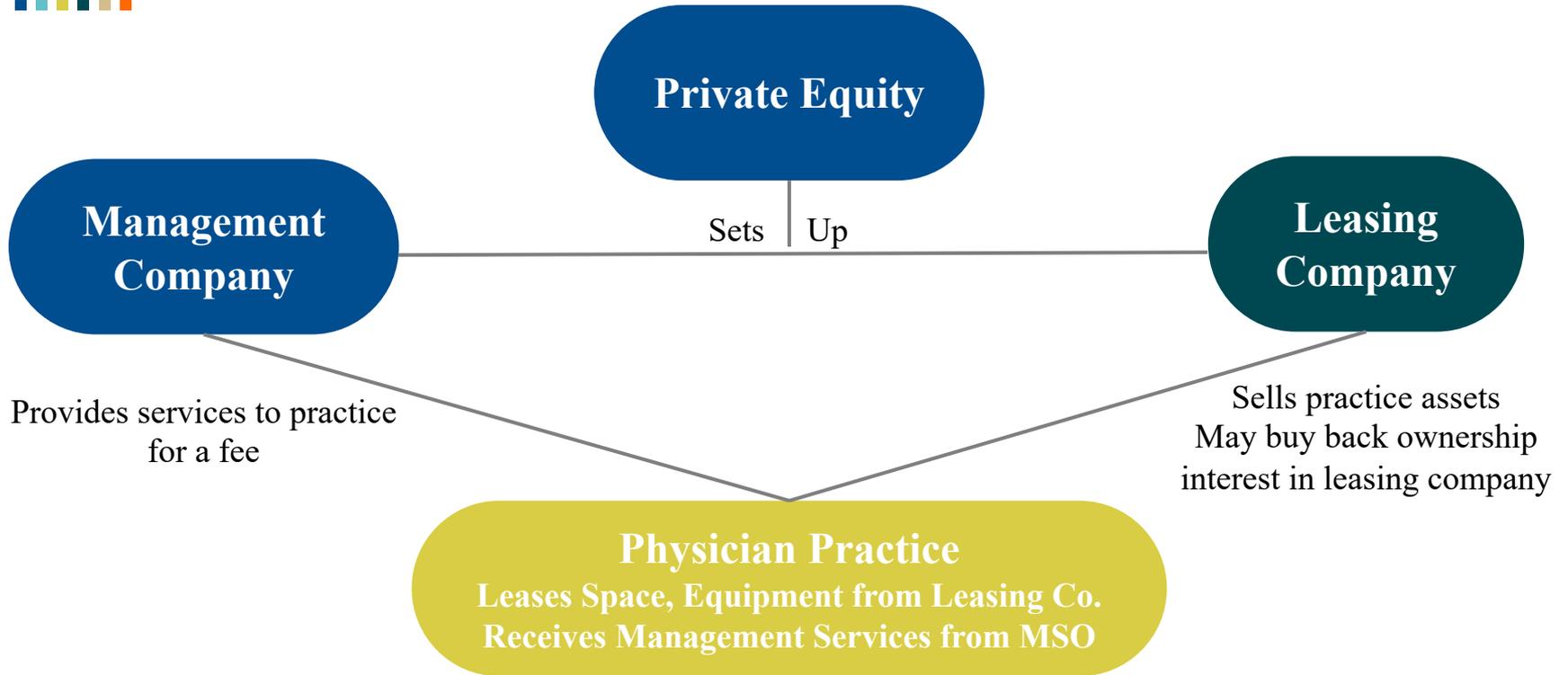
- Whistleblowers are active and incentivized.
- Potential PE direct liability is a further incentive for whistleblowers (and their counsel), given PE deep pockets.
- PE firms need to take action to ensure regulatory compliance of their portfolio companies, including:
 - Compliance policies;
 - Regulatory due diligence in acquisitions; and
 - Proper structuring of relationships with physicians, including compliance with Stark and AKS.
- Physicians to be attuned to regulatory compliance as well – direct liability for physicians participating in any kickback scheme (e.g., Glenn A. Kline, D.O. – 2019 – \$4.25 million settlement).

Types of Arrangements



Types of Arrangements

PE Acquires Assets and Establishes Arrangements

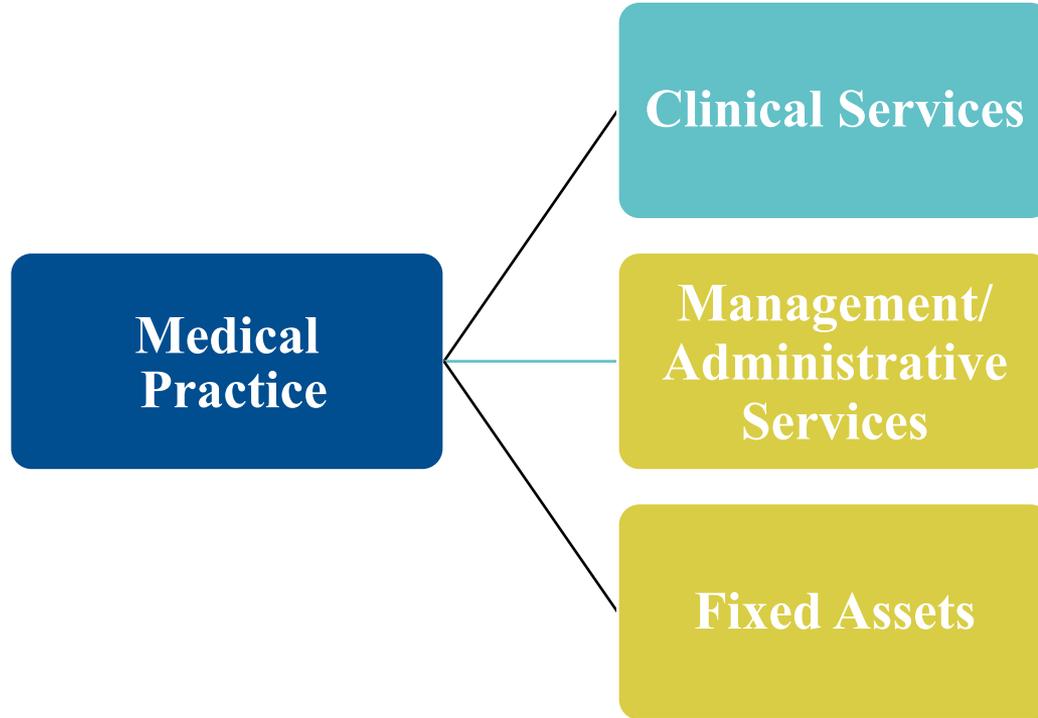


Types of Arrangements

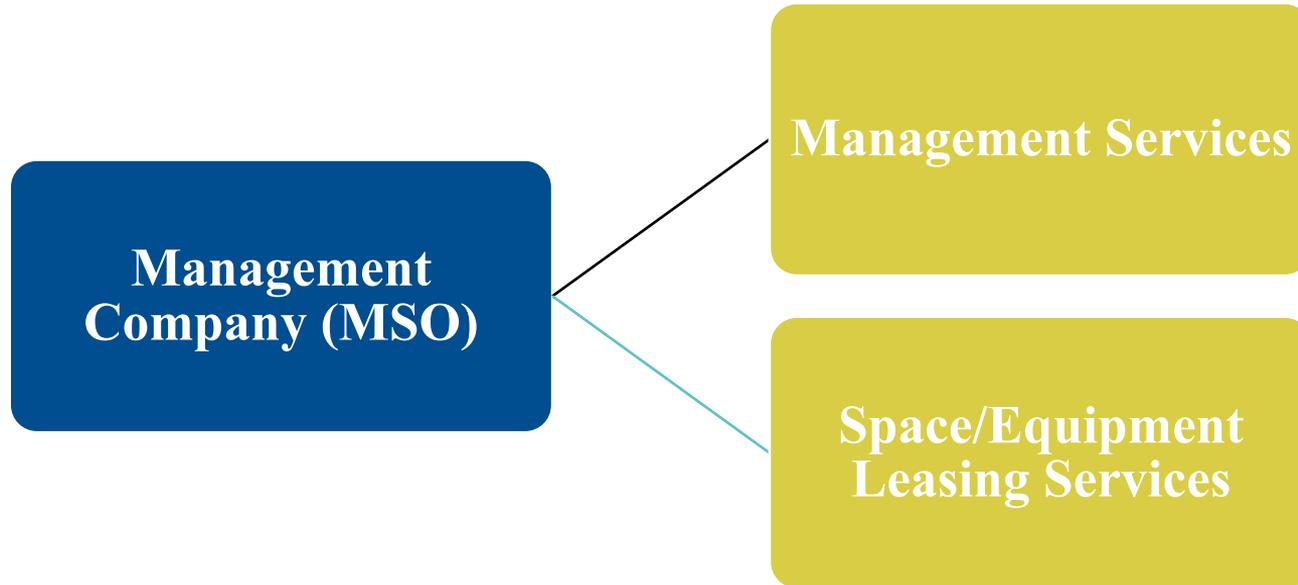


- MSO to provide Physician Practice with non-clinical services
- MSOs will seek compensation:
 - Payment for services rendered
 - A return for assuming the business risks

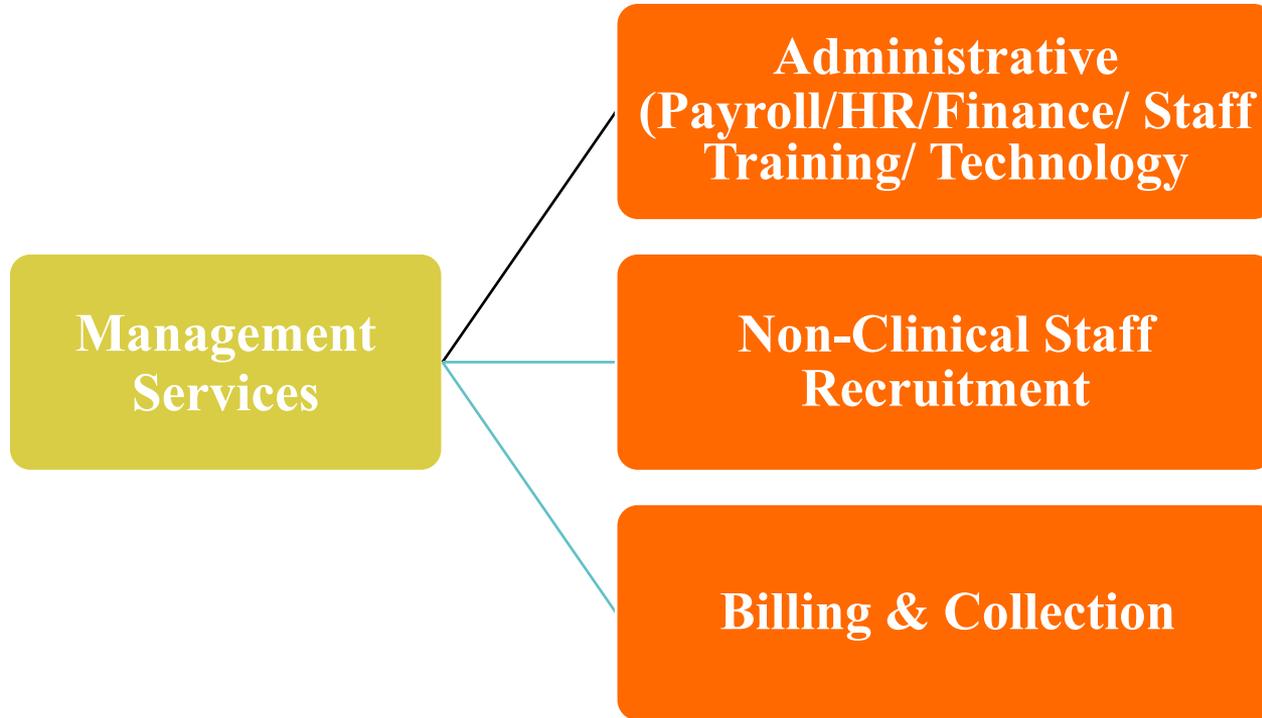
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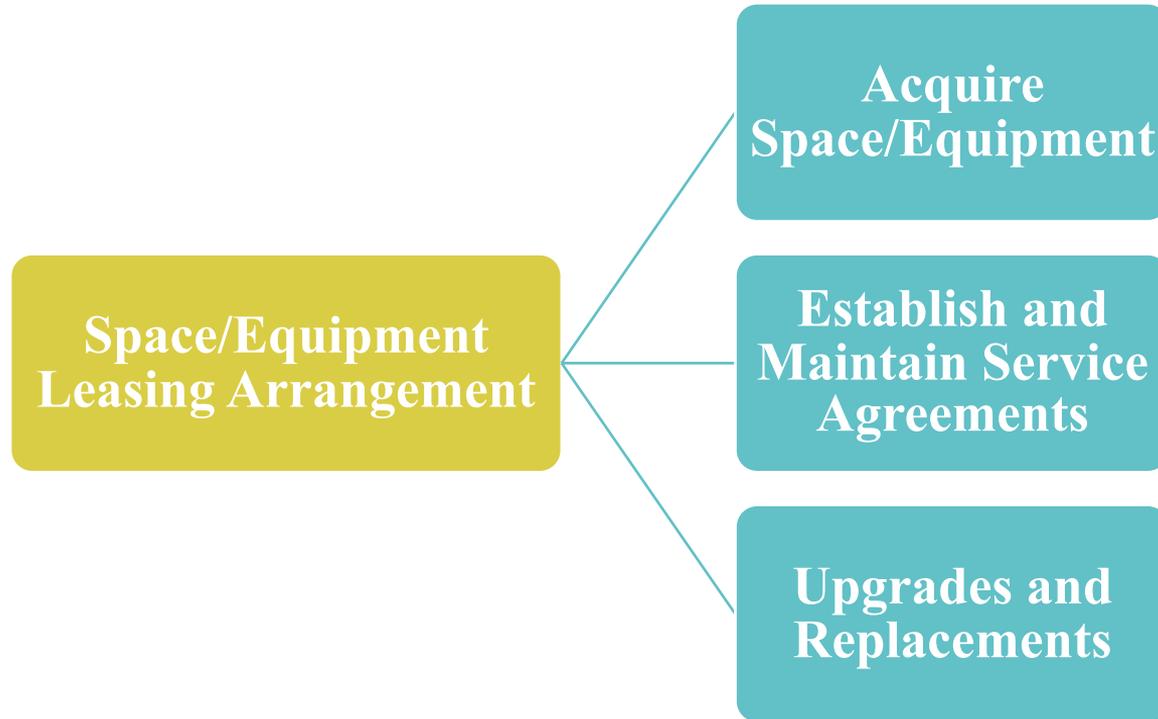
Types of Arrangements



Types of Arrangements



Types of Arrangements



Selected Legal Risk Areas for Private Equity Investments in Physician Practices



No Surprises Act



- Effective January 1, 2022
- Insurers to cover out-of-network services at in-network healthcare facilities (hospital, ambulatory surgical centers) at in-network rates for enrollees
- Prohibits balance billing for services provided in an in-network healthcare facility
- Insurers and providers to determine payment for out-of-network services based on IDR
- Applies to nearly all private and non-grandfathered marketplace plans
- Where stricter, state surprise billing laws preempt federal law

False Claims Act



- Knowingly submits false or fraudulent claim
- Treble damages & penalties
- Whistleblower provision allows private individuals to bring claims and recover percentage of recovery
- Claim can be considered “false” for a variety of reasons
 - Lack of medical necessity, failure to comply with regulations, upcoding, etc.
- \$1.8 billion recovered in the fiscal year ending Sept. 30, 2020

Stark Law



- Prohibits physicians from referring patients to an entity for the furnishing of certain designated health services (DHS) that are otherwise reimbursable by Medicare, if the physician or an immediate family member has a financial relationship with that entity, unless an exception applies
- Prohibits entities that provide DHS that are reimbursable by Medicare from billing the Medicare program for any items or services that result from a prohibited referral
- FMV particularly important: explicitly required in numerous exceptions
- Penalties: overpayment/refund obligation; FCA liability, CMPs and program exclusion for known violation; treble damages

Anti-Kickback Statute



- “Whoever knowingly and willfully offers or pays (or solicits or receives) any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made, in whole or in part, under a Federal healthcare program, shall be guilty of a felony..., shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.”
- Penalties:
 - Criminal: fines up to \$25,000 per violation/up to 5-year prison term per violation
 - Civil: FCA, CMP and program exclusion, treble damages

State Law



- State law analogues of Stark law and Anti-Kickback Statute
 - Many track federal laws, but there are several common differences:
 - Scope of services
 - Payors
 - Professionals
 - Disclosure
 - Penalties
- Corporate Practice of Medicine – state-level restrictions vary on who can own a medical practice – creates need for complicated management structures
- Fee-splitting restrictions

Commercial Reasonableness/Fair Market Value (FMV)



- Why they're important . . .
 - Aggressive enforcement
 - DOJ averaging more than \$2.5 billion in health care FCA judgments and settlements per year
 - Healthy return on investment – Total ROI of the Health Care Fraud and Abuse Control Program (HCFAC) over the last three years (2014 – 2016) is \$5.00 returned for every \$1.00 expended
 - FMV and CR are (by far) the most commonly litigated elements in AKS and Stark cases
- Amid ongoing, incremental adjustments to Stark and AKS, FMV and CR will remain at the core
 - Explicitly required in over 15 Stark exceptions and AKS safe harbors
 - Implicitly required for AKS compliance in the first place – presumption that inducement of referrals is intended, if financial arrangements are not FMV and CR

Valuation Considerations



Valuation Considerations



Physician-Owned P.C. without MSO

Net Revenue from Medical Services

Less Expenses:

- Salaries & Benefits – provider, other clinical, non-clinical
- Supplies – medical, non-medical
- Professional Liability/Other Insurance
- Occupancy Cost
- Medical equipment-related expenses
- Billing & Collections
- Other Administrative – payroll processing, HR, accounting

= Operating Income

Valuation Considerations



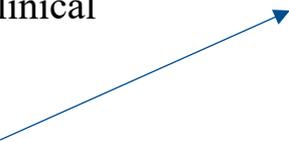
Physician-Owned P.C. with MSO

Net Revenue from Medical Services

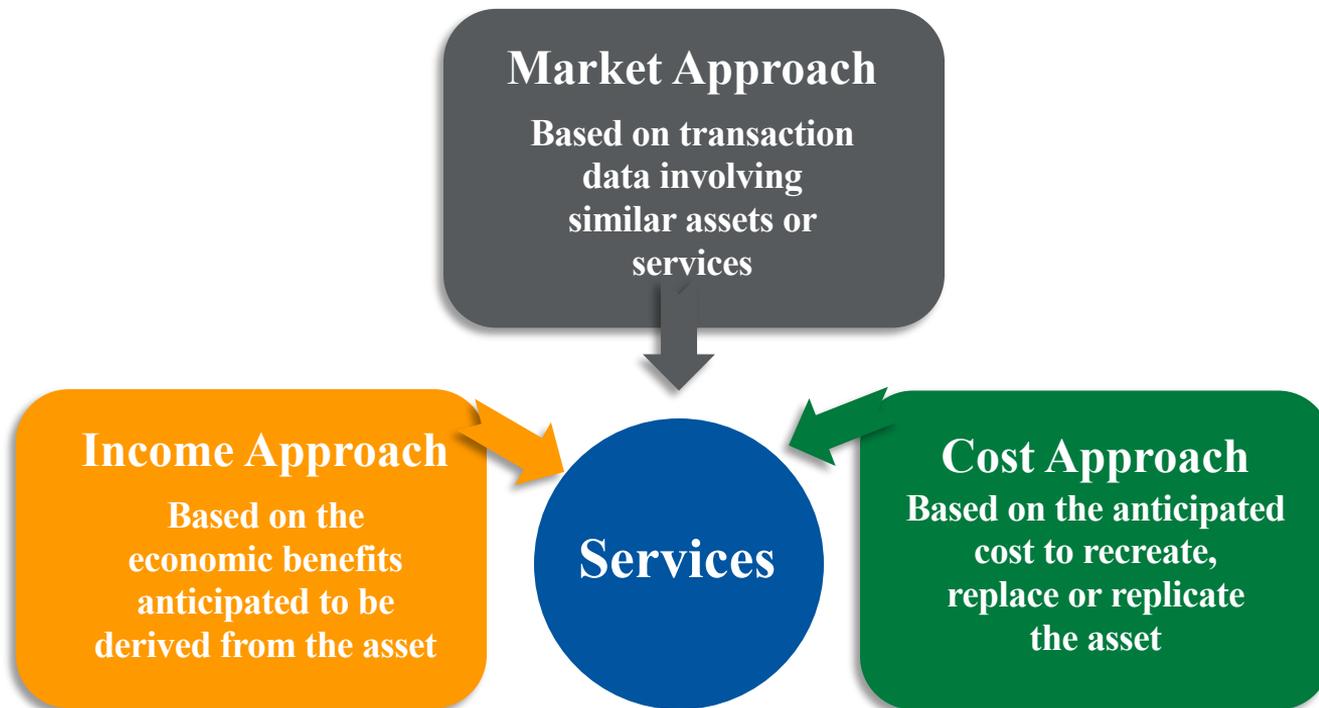
Less Expenses:

- Salaries & Benefits – provider, other clinical
- Professional Liability/Other Insurance
- Management Fee at Fair Market Value

= Operating Income

- 
- Support staff salary for staff handling administrative tasks
 - Equipment maintenance/depreciation
 - Space/facilities lease expense/depreciation
 - Billing & collections expenses
 - Overheads to run management company

Valuation Considerations



Valuation Considerations



Cost Approach – Avoided Cost Method

- Business costs to perform services
 - Staffing/FTE needs
 - Overheads incurred
 - Direct expenses such as supplies, travel expenses, professional services
 - Premium for a reasonable profit margin to cover business risks and cost of capital

Valuation Considerations



Market Approach – Comparable Transactions Method

- Look to comparable arrangements; e.g., Management fees commonly paid in the management of other specialty clinics (Urgent care, ASCs, dialysis clinics etc.)
- Review services to ensure an apples-to-apples comparison
- Make necessary adjustments

Valuation Considerations



Summary of Focus Elements

- Review agreement for all relevant facts:
 - Identify the components of an arrangement that require a valuation
 - Specific assets and/or services being provided
 - Non-clinical staff – leased or managed?
 - Is recruitment of staff responsibility of MSO?
 - Is equipment maintenance included in lease?
 - Who bears replacement of asset when it ages?

Valuation Considerations



Summary of Focus Elements

- Review agreement for all relevant facts:
 - Term of agreement, e.g., potential for lease renewal
 - Termination provisions
 - Compensation structure
 - fixed fee, percent of net revenue
 - monthly, one-time

Case Study



Case Study



EMCARE

- Primary areas of regulatory concern:
 - Compensating physicians for increasing admissions
 - Promise of new contracts to EMCare if admissions were increased
 - EMCARE granted exclusive ED staffing contracts at HMA hospitals
- Need to ensure compensation is at FMV and for appropriate services
- Commercial Reasonableness Assessments may be helpful in determining if exclusive provider arrangements are in patient's best interest.



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