Navigating Regulatory Scrutiny in Private Equity Health Care Transactions

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The Role of "Friendly PC" and MSO Models

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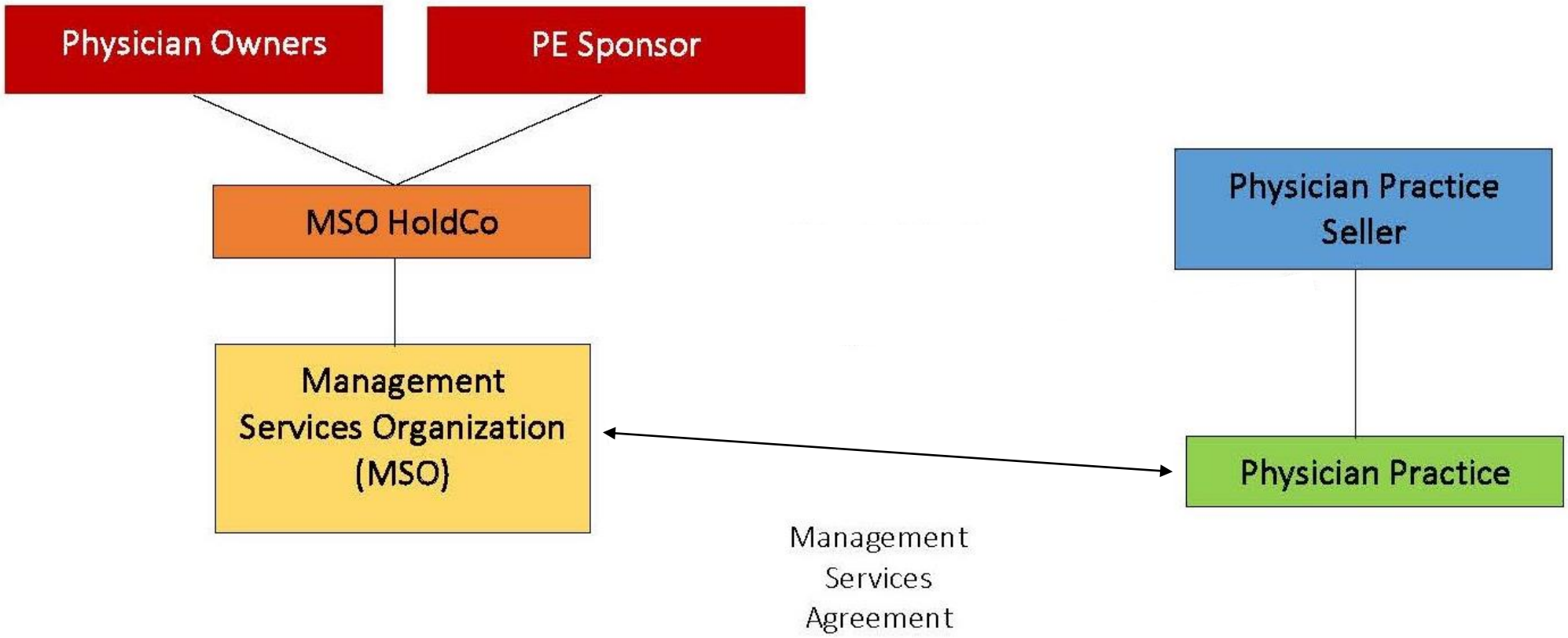
Corporate Practice of Medicine (CPOM)

- **All states limit the "practice of medicine" to certain licensed professionals.**
- **States that recognize the CPOM doctrine have statutes, regulations, case law, medical board guidance, etc. that effectively:**
  - Prohibit corporate entities (Inc., LLC) from employing physicians, or engaging physicians as independent contractors, to provide professional medical services;
  - Prohibit unlicensed individuals and entities from owning an interest in a medical practice entity; and
  - Require physicians to practice through certain professional entities (i.e., PC/PLLC).
  - Simply put: Employing physicians = practicing medicine.
- **Underlying Policy**
  - Protect physician's medical judgment from interference by unlicensed individuals and entities.
- **<u>Exceptions vary by state and include:</u>**
  - Professional entities (PC, PLLC, foreign PC/PLLC).
  - Hospitals and other state-licensed entities.

Friendly PC/MSO Model Sample



FTC and State Oversight for Roll-Up Models

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Increased State Legislative Activity

Driving Factors:

1. ***Private Equity***: Role of private equity and management/dental services organizations in the delivery of health care.
2. ***Consolidation***: Increased consolidation is fueling concerns about anti-competitive behavior.
3. ***Healthcare Outcomes***: Impact on access, quality, costs, and competition.

Enacted State Legislation

The following states have enacted healthcare transaction review laws:

1. **California** - California Health Care Quality and Affordability Act: 22 CCR 97431 *et seq.*
2. **Colorado** - Colorado Hospital Transfer Act: C.R.S. § 6-19-101 *et seq.*
3. **Connecticut** - Public Act No. 14-168 (Conn. Gen. Stat. § 19a-486(i))
4. **Illinois** - Illinois Antitrust Act: 740 ILCS 10/7.2a
5. **Indiana** – Notice of Health Care Entity mergers: Senate 9 (IC 25-1-8.5)
6. **Massachusetts** – Notices of Material Change and Cost and Market Impact Reviews (958 CMR 7.00 (M.G.L. c. 6D, § 13)
7. **Minnesota** – Requirements for Certain Health Care Entity Transactions (Minn. Stat. §145D.01) and Data Reporting of Certain Health Care Transactions (Minn. Stat. §145D.02)
8. **Nevada** – Notification of Certain Transactions Involving Health Care (Nev. Rev. Stat. 598A.370)
9. **New Mexico** – Health Care Consolidation Oversight Act (Senate Bill 15)
10. **New York** – Disclosure of Material Transactions (PBH § § 4550-52)
11. **Oregon** – Oregon Healthcare Market Oversight Program (OR Rev. Stat. §415.500 *et seq.*)
12. **Rhode Island** – The Hospital Conversions Act (R.I. Gen. Laws § 23-17.14 *et seq.*)
13. **Vermont** – Notice of Acquisition (18 V.S.A. § 9405)
14. **Washington** – Health Care Market Participants, Material Changes Notice (RCW 19.390 *et seq.*)

Examples of State Legislation

California:

- **Effective Date** – April 1, 2024
- **Covered Transactions** – "Material change transactions"
- **Covered Entities** – Health facilities, ASCs, imaging facilities, specialty clinics, hospitals, health systems, physician organizations, and non-profit clinics.
- **Size Threshold** – Health care entities
    a) With annual revenue of at least $25 million or that owns or controls California assets of at least $25 million,
    b) With annual revenue of at least $10 million or that owns or controls California assets of at least $10 million and is a party to a transaction with any health care entity satisfying subclause (a)
    c) Located in in a designated primary care health professional shortage area
- **Notice** – Notice to the Office of Health Care Affordability ("OHCA") of proposed material change transactions at least ninety (90) days before closing
- **Approval** – Not explicitly required
- **Confidentiality** – Public record, unless OCHA approves otherwise

Examples of State Legislation

Indiana:

- **Effective Date** – July 1, 2024
- **Covered Transactions** – Any agreements, arrangement, or activity resulting in a change of ownership
- **Covered Entities** – Health care entities, including but not limited to medical and dental providers, insurers, administrators, and private equity partnerships entering into transactions with health care companies
- **Size Threshold** – at least one health care entity with assets of at least $10 million
- **Notice** – Notice to the Office of the Attorney General ninety (90) days before closing
- **Approval** – Not explicitly required
- **Confidentiality** – Indiana Attorney General keeps confidential all nonpublic information

Summary of Key Elements:

- **<u>Who Must File</u>**:
  - ***Nevada*** – All parties to a reportable health care, health carrier or group practice transaction.
  - ***New York*** – Health care entities (including, physician practices, physician groups, management services organizations or similar entities, and health insurance plans).
- **<u>Transactions Covered:</u>**
  - ***Illinois:***
    - (1) Any merger, acquisition or contracting affiliation between two or more health care facilities or provider organizations not previously under common ownership or contracting affiliation, and
    - (2) (a) The transaction is between an Illinois health care entity and an out-of-state health care entity where the out-of-state health care entity generates $10,000,000 or more in annual revenue from patients residing in Illinois; or (b) the transaction is between Illinois health care entities.
  - ***Washington*** – The transaction would result in a "material change" to a hospital, hospital system or provider organization.

Summary of Key Elements:

- **<u>Notice Contents</u>**:
  - ***Colorado*** – Transactions between Nonprofit and For-Profit Entities – In addition to providing public notice seven days after notifying the AG, the transacting parties must submit all proposed agreements, financial and economic reports the nonprofit entity relied on in negotiating, and an explanation that the transaction will comply with Colorado's requirement that the transaction be in the public interest.
  - ***New York*** – Parties, agreement copies, details regarding what locations may be impacted, any plans to eliminate services or plan participation, and detailed description of the transaction.

Summary of Key Elements:

- **Notice Period**:
  - ***California*** **–** 90 days before closing
  - ***Colorado*** **–** 60 days before closing or effective date
  - ***New York*** **–** 30 days before closing
  - ***Oregon*** **–** 180 days before closing
- **Review Period**:
  - ***California*** **–** 60 days following receipt of notice
  - ***Colorado*** **–** No prescribed timeline
  - ***New York*** **–** No approval, but public disclosures required
  - ***Oregon*** **–** Preliminary review within 30 days of notice. If OHA elects to conduct a comprehensive review, it must be completed within 180 days following receipt of notice.

Pending Legislation

Minnesota: Minnesota previously passed HF 402 largely focused on hospital transactions on May 21, 2023. Subsequently, the Minnesota state legislature introduced House Bill 4206 directly targeting private equity companies and real estate investment trusts. If enacted, the bill would prohibit private equity-backed companies from acquiring or increasing any ownership (direct or indirect) in, or operational or financial control over, certain health care providers. The bill has been referred to the Committee on Commerce Finance and Policy.

Pennsylvania: The Pennsylvania legislature has three proposed bills sitting in both the House of Representatives (H.B. 2012 and H.B. 2344) and Senate (S.B. 548) with the purpose of mandating that health care facilities, systems or providers engaging in certain health care transactions provide the notice to the Pennsylvania Attorney General's office 90 to 120 days prior to the effective date of the agreement. The legislature is on break and will not reconvene until September 16, 2024.

Failed Proposed Legislation

California: The California State Legislature's AB 1091 aimed at requiring certain health care entities entering transactions resulting in a material change with a value of least $15,000,000 to submit pre-closing notice and obtain approval from the California Attorney General's office failed in 2024.

Florida: The Florida State Legislature's H.B. 711 and S.B. 1064 aimed at requiring health care entities to submit pre-closing notice to the Florida Attorney General's office with respect to certain transactions failed in 2020 and 2021.

Maine: The Maine State Legislature's H.B. 894 aimed at requiring health care entities to submit pre-closing notice of certain health transactions and obtain approval from the Maine Attorney General's office failed in 2023.

FTC/DOJ/HHS Joint RFI

- Launched public inquiry into “private-equity and other corporations’ increasing control over health care.”
- The agencies raised concerns that private equity firms and other corporate owners are increasingly involved in health care transactions and that their involvement may threaten patient health, worker safety, quality of care, and affordability of care.
- Tri-agency commitment to pursue action in this space.
- Responses to inform agencies’ enforcement priorities and drafting new regulations

Heightened Congressional Attention

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Federal State of Play

- Congress is increasing oversight and legislative activity related to the role of private equity in health care.
- Bipartisan effort has been focused on transparency efforts – particularly in ownership structures and debt.
- Ownership Transparency Left out of *Lower Costs, More Transparency Act* (passed House December 2023).
- Congressional Research Service (CRS) Report – August 8.

Federal Legislative Activity

- Several Senate Information Requests on Private-Equity Backed Health Care – Reports to be Issued
  - Senate Budget Committee Chairman Sheldon Whitehouse and Ranking Member Chuck Grassley; Senate Homeland Security Committee Chair Gary Peters
- Two Pieces of Federal Legislation Introduced to Curb Private Equity Investment in Health Care:
  - The Health Over Wealth Act
  - The Corporate Crimes Against Health Care Act

The Health Over Wealth Act –

Sen. Ed Markey (D-MA) and Rep. Pramila Jayapal (D-WA)

- The legislation would:
  - Require private equity-owned health care entities to publicly report on their debt, executive pay, lobbying and political spending, health care costs for patients, and any reductions in services to patients or wages and benefits for staff.
  - Require private equity-owned firms set up escrow accounts for health care entities they own to cover five years of operation and capital expenses to ensure that essential health care is still being provided in the event of financial disruptions that could risk hospital closure or service reduction.
  - Require private equity firms to obtain a license from the Department of Health and Human Services (HHS) to invest in health care entities
  - Require that, prior to hospital closures or service reductions, hospitals notify the public, receive public comment, and create a plan to preserve health care access.
  - Prohibit private equity firms from stripping assets from health care entities.
  - Would “close tax loopholes for health care real estate investors”.

The Corporate Crimes Against Health Care Act – Sen. Elizabeth Warren (D-MA) and Sen. Ed Markey (D-MA)

- Proposes new criminal and civil penalties to punish executives (including executives of financial investors) that "contribute to a triggering event."
- "Triggering Event" – legislation names five specific actions:
  - Failure to pay salaries and wages of 25% or more of the workforce for 90 days.
  - Closure.
  - Failure to pay rent for more than 90 days.
  - Default on a loan payment for more than 90 days.
  - Bankruptcy.
- Imposes felony criminal penalties (PRISON!), civil penalties and compensation clawbacks that extend to investors and executives in certain cases where patient injury occurs.

The Corporate Crimes Against Health Care Act – Sen. Elizabeth Warren (D-MA) and Sen. Ed Markey (D-MA)

- Excludes participation in federal health care programs for entities that sell assets to or use assets as collateral for a loan made to a real estate investment trust.
- Revokes favorable tax treatment for REITs for all investors in health care properties, as well as current provisions allowing influence on facility operations.
- Creates new disclosure and transparency requirements.

Legislative Outlook?

Current Transaction Trends for PE-Backed Providers

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Headwinds

- Increased regulatory scrutiny and enforcement activity at the state and federal level
- Pending ban on non-competes
- Rising interest rates

Tailwinds

- Shrinking reimbursement
- Continued market fragmentation
- Consumer demand
- Wage inflation
- Rising operational costs (*e.g.*, costs of drug and medical supplies)
- Record high committed but not yet deployed capital (*i.e.*, dry powder)

Health Care Private Equity Activity

- According to Bloomberg data, private equity firms have raised $78 billion in new health care buyout funds, and closed buyout funds retained $123 billion in dry powder.
- The average size of health care-focused investment vehicles increased from $215.4 million in 2022 to $410 million in 2023.
- Bloomberg expects that at least 10 health care buyout funds of at least $1 billion will begin fundraising in 2024, with many smaller funds to do so as well.
- According to a survey conducted by Adams Street Partners, nearly 40% of LP respondents identified health care and technology among the top three investment opportunities for 2024, second only to ESG and Impact themes.

Health Care Retailers

- Walmart announced that it will be closing Walmart Health and selling Walmart Virtual Care.
- Walgreens is downsizing Village MD Clinic.
- Optum closed its virtual care business.
- Amazon laid off hundreds of employees at its primary care subsidiary, One Medical.

Advances in Artificial Intelligence

- Advances in AI are expected to have a major impact on the health care industry (*e.g.*, drug discovery and patient engagement).
- Private equity funds are looking to harness technology in business services adjacent to health care (*i.e.*, revenue cycle management).
- Investors looking to disrupt or enhance operations, products, and business models of healthcare targets during sourcing and diligence.

Secondary Transactions

- Uncertainty in the marketplace may lead some private equity investors to consider whether the typical 7 to 10-year investment cycle is an optimal time for an exits.
- GPs of health care-focused funds are increasing assessing whether a portfolio company can generate higher value beyond the typical fund’s lifespan.
- Continuation funds allow GPs to continue holding assets for an extended period until these assets reach their full potential while eliminating the need to sell the assets to another private equity fund.

Healthcare M&A Activity Generally

- **Physician Practices**:
  - Ability to transition specialist to outpatient settings as a cost saving measure
- **Health Care Information Technology**:
  - Ability to drive revenue generation and cost efficiencies through innovation
- **Biopharma**:
  - Increased demand for manufacturing capacity
- **Home Health Care**:
  - Interesting reimbursement landscape and anticipated increase in costs
- **Behavioral Health**:
  - Increased demand for mental health, counseling and substance abuse services, and improved insurance coverage and reimbursement rates

Potential Impacts and Key Considerations When Transacting

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The hurdles are real…

Practical Impacts

- State-Level Health Care Transaction Regimes – the microscope just got bigger – and there are more hurdles to clear
- Due diligence is paramount
  - Need to understand direct and indirect ownership
  - Role of managers and operators
  - Assess for appropriate aims
  - Culture of compliance?
  - Increased transparency and public disclosures of financing sources, operational matters, and anticipated operational changes
- Careful planning and timing
- Post-closing considerations

Practical Impacts (cont.)

- Longer Timelines
  - Notice versus approval processes
  - Seeing some states with 90-day timelines
  - FTC and increased scrutiny; pull/refile; second requests
- Increased Costs
  - Increased involvement of anti-trust counsel for smaller transactions
  - Restructuring of transaction models and related compliance programs to align with state-level regimes
  - Allocation of costs in definitive agreements

Definitive Agreement Considerations

- Exit Options
  - Reasonable efforts? Hell or high water?
  - SRDP and other disclosure requirements?
  - Pre-closing remediation?
- Notice/Filing Requirements
  - Who holds the obligation?
  - Approval by all transacting before submission?
- Cost allocation
- Indemnification
  - Caps; baskets; duration
  - RWI

Post-Closing Considerations

- Operationalizing the Asset
  - Management and compliance with CPOM, etc.
  - Compliance environment – is it where it needs to be?
- Clean-up needed?
- Tactical growth strategies moving forward
  - Bolt-ons – is the “juice worth the squeeze”
  - Organic v. strategic growth

Risk Profile and Tolerance

- Appetite to be a test case?
  - Where new rules/regs unclear
  - Potential to chill activity
- Pulling back the curtain
  - Sharing additional information (i.e., owners upstream) – could require restructuring considerations
  - Consumer advocates and role in lobbying
  - Opportunity for public comment
- AG Oversight Authority in certain circumstances
  - What level of comfort do you have as an operator?
  - Is your house in order?

Impact on Growth Strategies

- Resetting the playing field
  - One competitor's strength is another's weakness…until it isn't.
  - At its core – impact to health care providers when assessing career paths.
- Investors, operating partners and senior management teams are focusing on organic growth and optimization.
- Growth by add-on deals more limited due to macro-economic and political factors.
- Investors shifting focus to ancillary health care subsectors
  - An alternative route - access the economics of the health care ecosystems + mitigate risk.
  - Often lower infrastructure cost; less regulatory scrutiny; accretive to the overall business.

Questions?

For more information on these topics visit hallrender.com.

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