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Kirkland Alert

2023 Healthcare Private Equity Outlook and Considerations

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Healthcare Private Equity Transactions in 2023

The healthcare sector is anticipated to remain an attractive investment for private equity in 2023, especially in high-demand categories such as behavioral health, health IT, and specialty physician platforms such as orthopedics. We also anticipate a strong investment market across the life sciences, including transactions involving specific drug compounds and patented molecules, as well as ancillary businesses such as clinical research organizations, pharmaceutical outsourcing and consulting services. These types of healthcare investments are viewed as relatively downward resilient, with recessionary factors countered by the base high-demand volume. We also anticipate liability management to remain active amidst a fairly tight credit market.

Continued Government Focus on Private Equity Investment in Healthcare

Federal and state regulators are expected to continue to concentrate on private equity investments in healthcare. On February 13, 2023, the Centers for Medicare & Medicaid Services ("CMS") announced a proposed rule that would require skilled nursing facilities and nursing homes to disclose more information about their ownership and management, including whether they are owned by private equity firms or real estate investment trusts (REITs). Under the proposed rule, a private equity company is defined as a publicly traded or non-publicly traded company that collects capital investments from individuals or entities (that is, investors) and purchases an ownership share of one or more businesses.

This proposed rule implements provisions of the 2010 Affordable Care Act that requires disclosure of information about nursing home ownership and oversight. CMS stated that this additional data would give a more complete background on the organizations and individuals that own, oversee and facilitate the operations of nursing homes. CMS also claims that this rule is part of an effort to increase the transparency of ownership and management and to empower families to make informed decisions about care.

The proposed rule is open for public comments until April 17, 2023.

Medicare Advantage Risk Adjustment Data Validation Final Rule

On January 30, 2023, CMS released its final rule regarding the Risk Adjustment Data Validation ("RADV") program utilized by CMS to recover improper risk adjustment payments made to Medicare Advantage Organizations ("MAOs"). The purpose of risk adjustment is to ensure that payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries, and that MAOs are paid appropriately for their plan enrollees. The final rule provides that CMS will only collect the non-extrapolated overpayments identified in the CMS RADV audits and OIG audits between PY 2011 and PY 2017. Extrapolation will begin with the PY 2018 RADV audit and be applied thereafter. CMS declined to adopt any specific sampling or extrapolation methodology, but noted that the methodology will identify and focus on the payors at the highest risk for improper payments. Such extrapolations will likely result in substantially larger recoveries from MAOs, because they magnify any recoupment amount resulting from distinctly observed coding variances. For the new methodology plan contracts dating back to 2018, CMS will not apply an adjustment factor, known as a Fee-for-Service Adjuster, in RADV audits. CMS stated that the adjuster is no longer needed and found it had a negligible effect of less than 1% on average in favor of the MAOs.

FTC Non-Compete Rule

Last month, the Federal Trade Commission ("FTC") announced a new proposed rule that would broadly prohibit non-compete clauses in agreements between employers and employees, including between healthcare businesses and physicians, registered nurses and other clinical personnel. We anticipate the rule to be challenged for its breadth of scope, but if finalized could have significant impact on private equity investments in the healthcare space. Without this security and "stickiness" of a non-compete, the value proposition of acquiring a practice is likely to decrease and aspects of the transaction, including purchase price, may need to be adjusted accordingly. Refer to Kirkland & Ellis' key takeaways of the proposed rule previously published here.

Restructuring and Liability Management Considerations for Healthcare Companies

Recent challenges facing healthcare providers (e.g., COVID-19, increased labor costs, labor shortages and financing difficulties) resulted in an uptick in restructurings and liability management exercises for healthcare companies in 2022 and is expected to continue into 2023.

As providers and other healthcare businesses contemplate potential restructuring and liability management options, specific considerations unique to the healthcare industry should remain top of mind, including:

- Patient record retention or disposal obligations and potential ongoing costs and liability associated with same;
- The appointment of a patient care ombudsman for facilities to monitor the quality of patient care and represent the interests of patients; and
- Continuity of care obligations and to maintain medical records.

Moreover, as part of any liability management involving healthcare entities, consideration must be given to the suite of licenses, permits and accreditations required to operate, as such licenses typically need to remain in effect while the company is in bankruptcy. Additionally, certain regulatory agencies require that a license holder or an enrolled entity provide notice when the entity or its parent company enters bankruptcy or are considering a restructuring, regardless of the need to transfer any such license.

Healthcare companies enrolled in Medicare and Medicaid also face unique challenges given that the government has routinely taken the position that Medicare and Medicaid provider agreements may not be sold or assigned without satisfaction and payment of liabilities associated with such enrollments (e.g., payment of any identified overpayments).

Protecting Patient Privacy: A Look Ahead at New Laws, Regulations and Enforcement Trends

Health data privacy and security remains of critical importance in 2023. The Office for Civil Rights plans to publish final rules on proposed changes to the HIPAA Privacy Rule in spring 2023, including allowing patients to inspect their medical records in person, reducing the maximum time for covered entities to respond to requests for records and permitting individuals to request the transfer of their records to a personal health application. The FTC is increasing its focus in how companies use and share sensitive health data. Several states, including New York and Washington, are currently weighing legislation that would increase privacy protections for health data processed by private entities as well as broader consumer data privacy bills.

Inflation Reduction Act Impact on Drug Investments

In August 2022 the U.S. government enacted the Inflation Reduction Act ("IRA"), which addressed, among other measures, the pricing of certain prescription drugs paid for by federal healthcare programs. Beginning in 2023, the IRA will allow the HHS to negotiate with drug companies and effectively set prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, with the first negotiated prices to be effective in 2026. Generally, these government prices will be capped at a statutory ceiling price (called a "maximum fair price" or "MFP") that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. It is too soon to tell how the U.S. government will set the prices during these negotiations.

The IRA may meaningfully influence pharmaceutical industry strategies and private equity investment by potentially reducing the attractiveness of investment in small molecule innovation and disincentivizing drug developers from funding expensive development processes and bringing new drugs to market. At the same time, the IRA incentivizes biosimilars by increasing the Medicare Part B add-on payments from six percent to eight percent of the reference product's average sale price.

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Suggested Reading

- 06 January 2023 Kirkland Alert Federal Trade Commission's Proposed Ban on Noncompete Agreements
- 21 June 2022 Kirkland Alert Proposed California Legislation Imposes Attorney General Approval Requirements
- 10 March 2022 Kirkland Alert Healthcare Developments to Watch in 2022