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2024 Healthcare Private Equity Outlook and Considerations

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Healthcare Transactions in 2024

The healthcare sector is anticipated to remain an attractive investment for private equity and healthcare companies in 2024. Media reports 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 device and pharmaceutical manufacturers. Based on recent activity in the space, we also expect an increased interest in platforms providing value-based care as well as health IT platforms utilizing artificial intelligence to streamline and improve the provision of healthcare, as well as back-office functions for healthcare companies.

State-Level Healthcare Transaction Notification and Filing Obligations

At least 10 U.S. states have recently adopted healthcare transaction review laws (often also referred to as “mini-HSR” laws) focused on consolidation in the healthcare industry. Similar legislation is pending in additional states, and we expect to see more movement in 2024.

These state transaction notification laws generally require parties to submit filings to state regulators, including attorneys general, of “material transactions,” which may include, but are not limited to, majority or minority changes of ownership and joint and collaboration agreements involving entities providing healthcare services in the state. Some states have passed laws specifically targeting certain types of transactions (e.g.,

California and retail drug firms), while other states' laws (e.g., Oregon) broadly capture transactions involving a variety of different entities in the healthcare space, including but not limited to physician practice management organizations and dental services organizations. Most of the transaction review laws require pre-closing filings and, in some cases, approval, which may lengthen the time between signing and closing by up to six months. The filings can require detailed information, including transaction financing, anticipated impacts on the company's operations, commitment to quality of care and impacts on overall market competition.

FTC in Healthcare Transactions

The Federal Trade Commission ("FTC") may exercise increased oversight of healthcare transactions, and, in particular, those that involve, directly or indirectly, private equity players in 2024. This year, the FTC withdrew and replaced long-standing policies on healthcare merger enforcement, in conjunction with the Department of Justice, which are aimed at the commonly employed "rollup" strategy, stating, "[a] firm that engages in an anticompetitive pattern or strategy of multiple small acquisitions in the same or related business lines may violate Section 7, even if no single acquisition on its own would risk substantially lessening competition or tending to create a monopoly." In addition to the new policy changes, the FTC also initiated multiple challenges echoing similar policy rhetoric; however, the outcome of these challenges is yet to be determined.

Increased Ownership Transparency of PE in Healthcare

2023 saw several changes to provider's reporting obligations regarding private equity management and control that we expect to continue into 2024 both at the federal and state level.

The Centers for Medicare and Medicaid Services ("CMS") finalized new ownership disclosure requirements for Medicare institutional providers, including but not limited to hospitals, home health agencies, skilled nursing facilities ("SNF") and Medicaid nursing facilities. The final rule requires such institutional providers to disclose whether any entities with 5% or more ownership interest in, or which exert managerial control over, the provider are a private equity company or a REIT. In connection with the final rule, the Office of Management and Budget approved a revised Form CMS-855A, requiring all enrolling and currently enrolled institutional providers to disclose

information relating to private equity company or REIT ownership or control as part of any initial enrollment or change of ownership.

Artificial Intelligence Considerations in the Healthcare Industry

- **Fraud, Waste and Abuse.** We expect fraud, waste and abuse prevention to remain a top priority for CMS in 2024. As artificial intelligence technology ("AI") becomes more prevalent in clinical settings, AI developers and providers must consider both the advantages of AI and the potential risks for increasing fraud waste and abuse in healthcare delivery. Some considerations that providers should be mindful of may include:
  - The occurrence of false positives or faulty programming that may lead to unnecessary treatments; and
  - The possibility of increased fraudulent billing by algorithm-driven upcoding may increase the risk of overpayment obligations.

    Developers and providers should evaluate how to mitigate risks to avoid regulatory scrutiny and compromising care by patients.

- **FDA and Clinical Decision Support.** We expect the FDA will continue to evaluate its approach to, and understanding of, the use of AI. We expect that the FDA, along with several other federal agencies including the Department of Homeland Security will work together in response to President Biden's recent October 2023 executive order regarding AI and machine learning ("ML"), which directs these federal agencies to take action to address AI-related privacy and safety concerns. Refer to Kirkland & Ellis' key takeaways from President Biden's executive order.

    There may also be congressional action to enable these agencies to promulgate further rules and guidance on AI and ML safety, while still promoting innovation. FDA has already made strides in this arena, but device manufacturers and users should be prepared to adjust processes and programs in response to the additional rules and guidance documents that are to come. Refer to Kirkland & Ellis' overview of the impact of AI on healthcare, including specifically clinical decision making and FDA regulation.

Patient Privacy Laws and Enforcement Trends

Health data privacy and security remains of critical importance in 2024 as patient health information continues to be the target of security breaches and a growing concern of regulators. We anticipate further development of laws and enforcement of health data privacy and security at both the federal and state levels.

In addition to the numerous states that have implemented general privacy laws over the past few years, in 2023 Washington, Nevada, Connecticut and New York passed health data-specific privacy legislation that healthcare organizations should have on their radar. These laws generally institute requirements on the collection, sharing and selling of health information (not already covered by HIPAA and other laws) and prohibitions on geofencing around health facilities. Refer to Kirkland & Ellis' key takeaways from Washington's My Health My Data Act.

We can expect the federal government to also remain active in this space in 2024. The Office for Civil Rights ("OCR"), the Substance Abuse and Mental Health Services Administration ("SAMHSA") and the FTC are expected to have their proposed rules on HIPAA, Part 2, and the Health Breach Notification Rule ("HBNR") (respectively) finalized by 2024, requiring applicable organizations to update health data use, disclosure and protection practices accordingly.

Additionally, we can expect continued enforcement and litigation around the use of pixel tracking technology on the websites and apps of healthcare organizations to not only continue but increase in 2024. The FTC has been active in enforcement on the use of tracking pixels under the HBNR and issued statements with OCR warning against their use without proper guardrails. OCR has yet to commence enforcement action against covered entities for the use of pixels that potentially violate HIPAA, but many expect OCR to do so in 2024.

HHS OIG Updated General Compliance Program Guidelines

On November 6, 2023, the Department of Health and Human Services Office of Inspector General ("OIG") published updated General Compliance Program Guidance ("GCPG"). Initially announced in April 2023, the publication marks the GCPG's first substantial update in more than 15 years and offers several modifications and modernizations. Key takeaways from the GCPG include:

- Starting in 2024, the OIG will publish both broad, general healthcare industry compliance program guidance, as well as industry-specific guidance that will be

published separately.

- OIG notes that new entrants have entered the healthcare sector in increasing numbers, including technology companies, investors and organizations providing nontraditional services that should also be mindful to review the GCPG and other OIG published guidance.
- Similarly, OIG warns that investors, including private equity funds, should scrutinize operations, incentive structures and payment methodologies to ensure compliance with federal fraud and abuse laws.
- The GCPG provides an overall update to its *Seven Elements of a Successful Compliance Program*, placing heavy emphasis on the roles of the Compliance Officer and the Compliance Committee. Notably, OIG stressed the importance of the Compliance Officer maintaining independence from the entity's legal or financial functions.
- In keeping with findings that incentivization, rather than punishment alone, encourages compliance, OIG recommends that organizations begin incorporating both consequences and incentives into compliance training, programs and procedures.

Increased Enforcement in the Dietary Supplement Industry

The FTC and FDA, which share jurisdiction and enforcement over the marketing of dietary supplement products, have both taken recent actions aimed at scrutinizing dietary supplement claims in advertising and marketing materials. In December 2022, the FTC issued updated guidance addressing the requirements for dietary supplements to adequately support product claims including the rigor of clinical studies in advertising materials (e.g., studies should be statistically meaningful, randomized, controlled, truthful and not misleading). On the heels of this guidance, in April 2023 the FTC sent approximately 670 notices of potential penalty offenses to companies involved in the marketing of over-the-counter drugs, homeopathic products, dietary supplements and functional foods, stating they may incur significant civil penalties if they fail to adequately substantiate their product claims.

FDA regulations permit dietary supplements to make permitted "structure function" claims, however, these products may not make disease claims. In 2023, FDA sent numerous warning letters to companies advertising supplement products with claims to cure, treat or mitigate diseases (e.g., assist in insulin resistance or lower cholesterol levels), among others. To further promote the FDA's oversight and enforcement of these products, FDA's 2024 legislative proposals include a plan to reform certain

standards of dietary supplement and food regulation, which could require dietary supplements to be listed with the FDA.

Medicare Advantage

Participation in Medicare Advantage Plans ("MA Plans") continued to grow in 2023, with more than half (51%) of the eligible Medicare population currently participating in an MA Plan. The OIG has increased enforcement activity of these plans in recent years, and we expect that MA Plans will continue to face considerable enforcement into 2024 and beyond.

CMS requires MA Plans to submit data, including diagnosis codes, which are used to determine the healthcare needs/projected cost of an MA Plan's patient population, which in turn correlates to the capitated payment that the MA Plans receive. Enforcement actions against MA plans have primarily involved allegations by the DOJ or U.S. state authorities that MA Plans improperly manipulated or submitted diagnosis codes. In October 2023, the DOJ announced a settlement with Cigna for $172 million to resolve claims that it manipulated diagnosis codes and risk adjustment data. This type of enforcement within the Medicare Advantage space is expected to continue.

Additionally, MA Plans have been scrutinized for marketing efforts and alleged high rates of denials for services. The U.S. Senate and state and federal regulators have taken note of these concerns and noted them as areas of focus.

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Related Services

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- Healthcare & Life Sciences Transactions
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Suggested Reading

- 10 January 2024 Press Release Kirkland Advises New Catalyst Strategic Partners on Strategic Minority Investment from Apollo
- 10 January 2024 Press Release Kirkland Counsels MEI Rigging & Crating on Able Machinery Movers Acquisition
- 09 January 2024 Press Release Kirkland Advises Energos Infrastructure on Acquisition of Transformative Marine LNG Asset with Long-Term Charter Contracts in Germany