2024 HEALTHCARE PRIVATE EQUITY OUTLOOK & TRENDS

Look ahead with our take on private equity M&A trends in strategic & private equity investing.

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With various headwinds resulting in down volume in 2023, buyers and sellers alike find themselves asking whether 2024 will see a rebound in deal activity. As we begin 2024, we have highlighted the issues and trends that private equity (PE) investors should consider when evaluating transactions in the healthcare sector.

1. Healthcare Continuation Funds: Strategic Considerations

BY BRYAN BYLICA

With a sluggish 2023 for platform exits, an increasing number of PE funds looked to continuation funds to offer liquidity to their limited partners (LPs). With the outlook for the first half of 2024 still uncertain, PE funds should continue to evaluate continuation funds as a viable option. A continuation fund is a general partner-led secondary transaction that is designed to offer LPs liquidity with respect to their interests in one or more mature portfolio companies within an existing PE fund. Continuation funds offer LPs in a PE fund the option to either cash out their investments before the underlying portfolio investments generate liquidity on their own or to retain their investment and "roll" into the continuation fund (and often make an additional incremental commitment to support the mature portfolio company(ies) in the continuation fund). Continuation funds are often formed to extend the life of a successful fund, enabling the fund manager to retain and manage mature, high-performing assets for an extended period rather than selling them prematurely. This strategy can be beneficial for both fund managers and investors, allowing for increased flexibility and potentially higher returns. It also offers the opportunity for institutional secondary investors to invest in high-performing portfolio investments managed by experienced sponsors. A typical continuation fund transaction will be led by a single institutional investor experienced in secondary transactions or a small group of experienced secondary investors that will negotiate the terms of the continuation fund transaction and the continuation fund structure.

Continuation funds in the context of healthcare investments operate similarly to those in general PE. These funds are particularly relevant in the healthcare sector, where the development of innovative therapies and technologies may require longer investment horizons. The continuation fund model offers fund managers the flexibility to extend the life of a healthcare fund nearing the end of its term to allow high-performing portfolio companies the time they need to reach their full potential while providing additional capital to support the continued growth and development of these portfolio companies, while at the same time offering liquidity to LPs that wish to exit the investment.

Considerations when utilizing continuation funds include:

- **Alignment.** Ensure that the interests of the existing and new investors align in terms of investment horizon, risk appetite, and return expectations. New investors will also seek alignment with the general partner through the reinvestment of crystallized carried interest and often an investment of fresh capital.
- **Valuation and Pricing.** Carefully assess the valuation of the portfolio investments being transferred to the continuation fund to ensure a fair and transparent pricing mechanism. The existing fund's advisory board often plays a role in approving the valuation of the portfolio investments, given the inherent conflicts of interest in continuation fund transactions.
- **Transaction and Fund Structure.** Design a continuation fund transaction and fund structure that is tax efficient for selling, rolling and new investors and accommodates the specific needs and preferences of both rolling and new investors.
- **Due Diligence.** The lead investors will conduct thorough due diligence on the portfolio companies being transferred to the continuation fund to identify any potential risks, challenges, or opportunities that may impact the continued performance of these investments. Representation and warranty insurance is generally available for continuation fund transactions where the existing investors desire a "walk away" deal.

- **Legal and Regulatory Compliance.** Ensure that the continuation fund adheres to all relevant legal and regulatory requirements. Given the highly regulated nature of the healthcare industry, it is crucial to navigate and comply with healthcare-specific regulations, including understanding and addressing any changes in healthcare laws that may impact the portfolio companies. Compliance with patient data security and privacy laws, FDA regulations, and other industry-specific standards is paramount. Potential risks and challenges associated with regulatory approvals, clinical trials, and market access, among others, can significantly impact the success of healthcare investments.
- **Reimbursement Landscape.** Assess the reimbursement landscape for the healthcare products or services offered by the portfolio companies. Changes in reimbursement policies and healthcare payment models can influence the financial viability of healthcare investments.
- **Technological Innovation.** Stay attuned to evolving healthcare technologies and innovations. Continuation funds in healthcare often involve companies at the forefront of medical advancements, and it is crucial to understand the competitive landscape and potential disruptions.
- **Long-Term Commitment.** Recognize the longer time frames typically associated with healthcare investments. The continuation fund structure should align with the extended development timelines often required for healthcare companies to bring products to market and provide sufficient capital to support these ongoing development needs.
- **Communication and Transparency.** Maintain open and transparent communication with existing and incoming investors throughout the process. Clearly articulate the rationale behind the continuation fund and make comprehensive disclosures about the process, mechanics, risks and obligations of each of the interested parties.
- **Exit Strategy.** Develop a well-defined exit strategy for the continuation fund, taking into account the optimal timing and method of realizing returns for investors, along with the unique market dynamics of the healthcare sector. This may involve an eventual sale, public offering, or other strategic options for the portfolio companies.

By incorporating these considerations, stakeholders in a healthcare continuation fund can navigate the complexities of the industry and maximize the potential for successful, long-term investments.

2. Diversity of Offerings and Agility is Key for Pharma Services Companies

BY SHANNON WILEY

Drug commercialization, distribution, and reimbursement are among the most complex and highly regulated industries. With the effects of the Inflation Reduction Act's Drug Price Negotiation Program on the horizon for 2026, a heavily vertically consolidated drug commercialization channel, continued compressed margins for healthcare providers, and macro-economic trends constraining drug utilization, we expect biopharma and investor focus in 2024 to be on pharma services companies that offer dynamic solutions to clear the pathway for patient access and extend the vitality of a product throughout its life cycle. Post-launch drug and biologic strategies will likely take into consideration the following industry trends:

- **Distribution and Reimbursement Challenges.** Pharmacies and pharma services companies that have the agility to successfully navigate distribution and reimbursement challenges are key elements of a successful channel strategy. Cell and gene therapies are perhaps the most complicated use case, but drugs that have both medical and pharmacy benefit coverage or are not self-administered also present challenges. This flexibility should extend to managing logistics and cold chain, navigating board of pharmacy regulations, clearing complex reimbursement challenges under both medical and pharmacy benefits, coordinating with prescribers and administration sites, and often, ensuring Risk Evaluation and Mitigation Strategies compliance.

- **Hub and Patient Services Companies.** Having the dexterity to navigate the labyrinth of reimbursement challenges facing brand products is table stakes for hub and patient services companies. Varied benefit design, ever-changing payor requirements for how prior authorizations can be processed, and data privacy laws, among others, are obstacles to providing a streamlined, transparent, and tech-reliant solution. Hub and patient services companies with a broad range of offerings spanning enrollment, reimbursement support, manufacturer-free drug program management, and adherence monitoring are likely to win out over companies offering biopharma one part of a piecemeal solution.
- **Data-Driven Insights.** Across all pharma services companies, the ability to generate data-driven insights is key. Beginning as early as pre-commercialization and extending to the end of a product's life cycle, clean and actionable data drives market access. Whether it be supporting expanded payor coverage criteria, understanding prescribing and utilization patterns, or targeting reimbursement challenges, crisp and actionable data is invaluable for biopharma companies.
- **Geographical Access to Care.** Geography is also a factor in access to care. Whether it be due to a rural location, socio-economic considerations that limit access to sites of care, or even our "on demand" culture, drug manufacturers look to pharma services companies to bridge the gaps. Consumer-driven prescribing with integrated dispensing, alternative sites of care for non-self-administered drugs, technology applications to reduce steps and redundancies are just some of the solutions upon which biopharma companies rely.

3. Continued Market Response to 340B Program Court Decision

BY JEFF DAVIS

In 2024, we will continue to see healthcare providers who participate in the federal 340B drug pricing program consider opportunities to expand their use of discounted drugs purchased through the 340B program and increase access to program savings. This comes on the heels of a recent federal district court decision ruling against the government's narrow interpretation of a 340B-eligible "patient." Under the 340B statute, safety net providers can purchase outpatient drugs at discounted prices and use them for their "patients." The more individuals who qualify as eligible patients, the more 340B drugs a provider can use and the more program savings a provider can generate.

On November 3, 2023, a judge in the U.S. District Court for the District of South Carolina overturned part of the government's interpretation of what a 340B-eligible patient entails. In *Genesis Healthcare Inc. v. Becerra*, the court ruled in favor of a 340B provider (Genesis) that challenged an audit finding issued by the Health Resources and Services Administration (HRSA). HRSA took the position that Genesis committed diversion in violation of the 340B statute by using 340B drugs for individuals who were not the provider's patients because the prescriptions were not written at the provider's locations and did not originate with Genesis. The court found that a prescription does not need to originate with the provider to be 340B-eligible, although the patient must still have had an initial provider encounter, and the provider must still have an ongoing relationship with the patient.

As we begin the new year, 340B providers and their pharmacy partners will continue to consider the impact of the *Genesis* decision on their 340B programs, including whether there are opportunities to update their policies on patient eligibility to qualify additional prescriptions as 340B-eligible. 340B providers also will continue to consider whether opportunities to update 340B policies may help mitigate the impact of drug manufacturer restrictions on the use of 340B drugs through contracted pharmacies, which have diminished the ability of 340B providers to generate program savings in recent years. These developments are also likely to impact deal activity in and around this space on a go-forward basis.

4. Value-Based Care in 2024

BY DANIELLE SLOANE & JULIA TAMULIS

Tensions created by an aging population, provider shortages and the increasing number of Medicare beneficiaries aligning with an accountable care organization (ACO) or choosing Medicare Advantage (MA) coverage (that is expected to exceed 50% of Medicare beneficiaries in 2024) are likely to encourage continued focus on value-based care in 2024, including through new entrants, consolidation and joint ventures. The industry - payors, providers and investors alike – has gained confidence and experience with negotiating and implementing value-based care models and sharing risk on patient populations throughout 2022 and 2023. Much of this growth has been facilitated by companies providing technology, data analysis and care management resources to coordinate care and address social determinants of health. Primary care continues to play an important role in this space, but there is momentum in other specialty areas, including behavioral health, palliative care, oncology and cardiology.

We anticipate value-based care companies will increasingly leverage innovative technology that can help streamline operations, improve the patient experience and facilitate the business of healthcare in order to both reduce costs and allow caregivers to focus on patients. The accuracy and agility of that technology and the data inputs will be important in order to keep up with regulatory changes in 2024. For example, in 2024, CMS will begin implementing a number of changes to its Hierarchical Condition Categories (HCC) risk adjustment model as part of the shift to Version 28. Accurate coding remains critical, particularly as risk adjustment data validation audits could result in extrapolated overpayment determinations under MA for payment years 2018 and later, which could have a significant financial impact on MA plans and their downstream contractors.

Moreover, with the recent growth in value-based care, we anticipate increased competition for attracting and engaging patients. The patient is central to effectuating a value-based care model, including obtaining, maintaining and motivating patients to take steps to improve their health. Those in the value-based care space will need to be careful that greater competition does not result in aggressive or misleading marketing tactics, which would be likely to garner the attention of enforcement agencies given the regulatory limitations surrounding marketing, including recent changes and proposals to strengthen those limitations.

Given the above factors, we anticipate continued market consolidation in 2024 as value-based providers and investors aim to improve economies of scale by increasing the size of their risk-based populations.

5. CRO Investment: Key Due Diligence Questions

BY CLINT HERMES

The already enormous global clinical trial market is continuing to grow, and site management organizations (SMOs), contract research organizations (CROs), formal and informal study site networks, and other clinical research businesses are stepping up to meet this demand. As noted in our Healthcare Trends & Transactions: 2023 Year in Review, the U.S. clinical trial site market, at approximately $16 billion, is estimated to grow at a cumulative annual growth rate of 6.8% through 2025. Although investors navigating challenges in other healthcare sectors may see investment in the research space as an attractive alternative, it has its own unique considerations.

When exploring a potential investment in the research space, questions PE investors should ask include:

- **Clinical Trial Agreements.** Does the company enter into clinical trial agreements (CTAs) with research sponsors to perform studies as a research site would, or does the company agree to perform some or all of the research sponsor's own responsibilities?

- If the former, how does the company engage investigators and study sites, and how do important CTA terms get passed on to them? How much of the site payments does the company retain, and what contractual risks does the company assume for these studies?
- If the latter, the company is a true CRO and will be regulated by the Food and Drug Administration (FDA) as if it is the study sponsor. More extensive FDA-related due diligence should be performed if an investment in a CRO is considered.

- **Federally-Funded Studies.** Does the company agree to conduct federally-funded studies? Many companies in this space began conducting federally-funded studies during the COVID-19 pandemic without realizing the extent of the compliance obligations that accompany federal funding.
- **Investigator-Initiated Research.** Does the company support any investigator-initiated research? This research carries more prestige and the possibility of developing important intellectual property, and supporting it is often necessary to attract star investigators, but this also involves more regulatory and contracting challenges.
- **Third-Party Payors.** Does the company bill any third-party payors for study-related services, or does it advise study sites about what study costs can be billed to third-party payors? SMOs will often perform payor coverage analyses for clinical trials because the financial viability of some trials depends on permissible claims submission. Doing this incorrectly, however, creates risk under the False Claims Act.
- **Quality Study Concerns.** Does the company have a history of study quality concerns? These might have been raised by the FDA through an FDA Form 483 or by a study sponsor audit.

6. Mitigating Privacy Risks in Data- and AI-Driven Healthcare Companies

BY EMILY BURROWS & ROY WYMAN

Investment in innovative healthcare technology companies is sure to continue in 2024. Investors are increasingly attracted to the potential of artificial intelligence (AI) and other data-driven technologies as a way to transform and enhance existing service offerings and offer new diagnostic and treatment solutions. As attractive as these new technologies (and investments in them) may be, PE investors should proceed with astute awareness, given the persistent risk of loss or misuse of sensitive personal health information. In fact, the integration of AI and large data processing amplifies the already existing concerns around data security, patient confidentiality, and regulatory compliance in healthcare technology.

Any company subject to the Federal Trade Commission (FTC) Act, global privacy or AI-related regulations, or the growing number of state privacy statutes, and those interested in investing in such companies should be aware of the ever-evolving regulatory landscape. Further, many legal requirements are currently being drafted or are already signed but not yet effective, which will continue to inform the enforcement environment. Companies subject to these regulations should be nimble and resilient to protect value and avoid regulatory penalties, mass litigation, and other risks.

To mitigate risk when investing in healthcare technology companies, particularly those with an AI/data integration focus, PE firms should consider the following:

- **Existing Data Laws.** Diligence each target's compliance with data protection laws such as HIPAA, the FTC Act and state privacy laws in the United States, GDPR in Europe and the UK and various other international regulations.
- **New and Proposed Data Laws.** Work to understand targets' actions taken in preparation for new and proposed laws relating to these technologies, including reviewing any data impact assessments and otherwise determining the relative risk of use cases and products involving sensitive data or the use of new technologies. This risk review should consider security risks and, just as importantly, any material impact their technologies may have on individuals.

- **Data Encryption Protocols.** Ensure that targets have strong protocols for data encryption, anonymization and secure storage.
- **AI Training.** Review how AI training materials and other data are developed (e.g., scraping of websites) and individuals' consent for the use of data, including in AI databases.
- **AI Transparency.** Assess the target's AI systems' transparency and accountability mechanisms, ensuring they are designed with privacy and security in mind.
- **AI Bias.** Understand processes that are in place to protect against inherent bias in training materials and the potential for "hallucinations" in AI output.

Once an investment is made, PE sponsors should encourage management teams to embrace a culture of data privacy and security within portfolio companies, emphasizing regular audits, assessments prior to rolling out new use cases, employee training and a proactive approach to identifying and addressing potential vulnerabilities (e.g., via regular penetration and vulnerability tests).

These steps should help investors mitigate risks post-transaction and demonstrate responsible and impactful investment in what will be a radically transformed future of healthcare.

7. The Federal Corporate Transparency Act: Impact on PE

BY CHRIS CLIMO, RINEY GREEN & RYAN THOMAS

The Corporate Transparency Act (CTA) became effective January 1, 2024. It requires corporations, limited liability companies and limited partnerships operating in the United States to provide certain identifying information about any individuals who are an entity's major owners and senior officers to the U.S. Treasury's Financial Crimes Enforcement Network (FinCEN). These new reporting requirements will add administrative burden and may require reporting companies to invest additional dollars in human capital to comply with such requirements in 2024.

Under the CTA, a business (called a "reporting company") that does not qualify for one of 23 specific statutory exemptions must submit a confidential online report to FinCEN disclosing certain unique identification details (name, date of birth, residential address and driver's license or passport image and number) regarding each individual who is defined as a reporting company's "beneficial owner." The CTA classifies a beneficial owner as any individual who either owns or controls, directly or indirectly, at least 25% of a company's ownership interests or exercises "substantial control" over a company. By FinCEN regulation, a reporting company's "senior officers" are deemed to be "beneficial owners." The "substantial control" test of beneficial ownership will present challenging interpretive issues and administrative hurdles as companies strive to comply with the CTA's new reporting obligations.

Willful non-compliance with the CTA reporting obligations can lead to civil and criminal monetary fines (up to $10,000) and imprisonment (up to two years) for individuals and companies. FinCEN has recently announced that companies should "consider putting in place mechanisms" to ensure compliance with the CTA disclosure obligations.

PE organizations and sponsors that currently file an annual Form ADV with the Securities and Exchange Commission (SEC) (typically PE groups with aggregate portfolio company investments valued in excess of $150 million) will be entitled to CTA exemptions (available to SEC-registered investment advisers and certain "pooled investment vehicles") for many of their affiliated investment funds, general partner and management entities listed on their Form ADV. It's less likely, however, that the investment fund, general partner and management entities affiliated with smaller-sized PE organizations that don't qualify for "venture capital" treatment under SEC regulations will be eligible for an exemption from the CTA disclosure obligations unless any of those entities separately meets the criteria for the "large operating company" exemption.

Each portfolio company affiliated with a PE sponsor group will be subject to the CTA disclosure regime unless it falls under one of the statutory exemption categories. The most commonly available exemptions for an operating business will be those for a publicly-traded company and a "large operating company."

A business entity must satisfy the following three conditions to be exempt as a large operating company:

1. Employ more than 20 persons in the United States on a "full time" or equivalent basis.
2. Generate more than $5 million of annual revenues from U.S. operations.
3. Have a physical location in the United States.

Wholly-owned subsidiaries, regardless of size, of large operating companies, publicly traded companies and certain other CTA-exempted categories of entities are not subject to the FinCEN reporting obligations.

All reporting companies formed prior to January 1, 2024, are required to submit their initial CTA ownership report to FinCEN no later than January 1, 2025 (and no earlier than January 1, 2024). The filing deadline for a reporting company formed during the 2024 calendar year is the 90th day following its formation date. Any reporting companies formed after December 31, 2024, are subject to a reporting deadline of 30 days after the date of organization. A reporting company is subject to a continuous obligation to update its information report within 30 days of any changes in information, including any individual who becomes a newly reportable "beneficial owner" and whenever any previously reported beneficial owner's identifying information changes.

Join Bass, Berry & Sims attorneys for a webinar on January 18, 2024, as they provide an overview of the CTA and discuss key areas of focus for private equity sponsors and their investment funds and portfolio companies, including compliance challenges, reporting exceptions and other related considerations.

Click here to register for this complimentary webinar.

8. Voluntary Self-Disclosures in Mergers & Acquisitions under DOJ Safe Harbor Policy; New OIG Guidance

BY KRISTIN BOHL, MEREDITH COLLINS & ANGELA HUMPHREYS

On October 4, 2023, Deputy Attorney General Lisa Monaco announced in a speech that the Department of Justice (DOJ) had adopted a new Mergers & Acquisitions Safe Harbor Policy (Safe Harbor) focused on encouraging self-disclosure of criminal misconduct discovered during the M&A process. The new DOJ-wide Safe Harbor builds on DOJ's other efforts this past year to encourage voluntary self-disclosure, such as its Corporate Voluntary Self-Disclosure Policy. The Safe Harbor applies to criminal conduct discovered in bona fide, arms-length M&A transactions, not to misconduct that was otherwise required to be disclosed or already public or known to DOJ.

DOJ highlights the benefit of disclosure under the Safe Harbor, focusing on a presumption of a declination of prosecution for acquiring entities who self-disclose. In order to benefit from the Safe Harbor, entities must be aware of certain timelines. The misconduct must be reported to DOJ within six months of the transaction closing date, regardless of whether the conduct at issue was identified pre- or post-closing. Once disclosed, DOJ provides an acquiring company one year from the closing date to cooperate with the investigation and engage in appropriate remediation, restitution and possible disgorgement. Although these timelines form the applicable baseline for the Safe Harbor, DOJ will apply a reasonable analysis based on the circumstances to adjust the timeline as it deems appropriate. The general parameters of the Safe Harbor are established throughout DOJ, and the policy allows each part of the DOJ to tailor its application of the policy to fit its specific enforcement regime. This results in uncertainty for those who may choose to disclose under the Safe Harbor regarding how this policy will actually be implemented in practice.

Monaco's speech focused on compliance issues in non-healthcare transactions, but it has garnered attention from healthcare companies and their advisors. While we await written guidance on the policy, perhaps the biggest takeaway from Monaco's speech was the signaling of DOJ's future enforcement efforts to companies who do not adequately invest in compliance, whether in legal diligence or otherwise: "Invest in compliance now or your company may pay the price – a significant price – later." In fact, following DOJ's announcement, on November 6, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) released new General Compliance Program Guidance, which is the most up-to-date, comprehensive and practical general compliance guidance in decades.

The practical implications of the DOJ's announcement to healthcare M&A transactions include the following:

- **Buyer Due Diligence.** For buyers, this means not only performing thorough legal due diligence (particularly around compliance) but also budgeting for and accelerating operational integration in order to identify and remediate potential issues that may not have surfaced during diligence.
- **Buyer Indemnification.** For buyers, ensuring clear and adequate indemnification protections for conduct that may have begun pre-closing and continued post-closing, but in some cases, may not have been identified until post-closing.
- **Seller Disclosures.** For sellers, ensuring the right to actively participate in any post-closing disclosures by buyers.
- **Seller Cut-Off Period.** For sellers, ensuring an appropriate cut-off period for exposure for any post-closing conduct.

9. Proposed Changes to Antitrust Review of Mergers Raise Significant Issues for PE Deals in Healthcare

BY MICHAEL DASHEFSKY, LUKE SMITH & PATRICK ZINCK

The FTC and DOJ ("the Antitrust Agencies" or "the Agencies") have outlined two sets of major changes relating to antitrust review of mergers that may significantly increase the burden and antitrust risk associated with healthcare transactions beginning in 2024.

Change One: New and More Stringent Merger Guidelines

The Antitrust Agencies recently finalized their new Merger Guidelines, which replace the Agencies' previous Guidelines establishing the framework used to evaluate the competitive effects of potential transactions. The new Merger Guidelines greatly expand the types of mergers that are deemed harmful to competition. Some of the changes that are likely to have the greatest impact on PE include:

- **Market Share.** Any deal creating a company with a market share of 30% or more will be viewed as presumptively anticompetitive, even if one of the parties to the transaction contributes as little as 1-2% of the share. This change will significantly increase the antitrust risks of transactions in markets where a healthcare provider is already present.
- **Scrutiny of Total Impact.** The Agencies will now consider the total impact of a series of prior acquisitions when examining a merger, whereas previously, the Agencies evaluated only the deal before them. Roll-up strategies will face increased scrutiny, and parties may now be required to answer questions about prior transactions that are unrelated to the transaction being investigated.
- **Vertical Integration.** Transactions involving vertical integration will be deemed presumptively anticompetitive if one of the parties has a 50% or more share in its market, even if the other party is only a small player in its respective market. This increases the antitrust risk of complementary/add-on transactions that may have received little or no scrutiny under the old Guidelines.

- **Potential for Lengthy Investigations.** In sum, the new Merger Guidelines may result in lengthy investigations of, and challenges to, transactions that would not have been investigated or challenged under the Agencies' previous Guidelines.

Change Two: Significantly More Extensive HSR Filings (Proposed)

The FTC has proposed changes to the Hart-Scott-Rodino (HSR) premerger notification rules, which would significantly increase the time, effort and expense associated with an HSR filing. Here are a few key takeaways from the proposed changes:

- **Increased Time and Expenses.** The FTC estimates that the new rules would increase by 4x-7x the time and expenses associated with an HSR filing. We believe this estimate is low. Filing within 5-10 business days of signing, which transaction agreements typically require, will not be possible without significant pre-signing preparation.
- **Submission of Narratives.** The new rules would require the submission of narratives related to the transaction rationale and the competitive impact of the transaction, requiring the parties to take an affirmative position on the proper antitrust analysis of all filed transactions and expend significant resources on the antitrust analysis that may involve engaging economists and consultants.
- **Required Documentation.** Documents required to be produced for a filing would be vastly expanded to include draft documents and various ordinary course business documents unrelated to the deal, significantly increasing the burden of identifying, maintaining and producing documents for the HSR filing.
- **Mandatory Disclosures.** HSR filings would require mandatory disclosure of prior transactions for the past ten years, regardless of size, which could result in investigations of long-closed transactions, including transactions that were previously non-HSR reportable. In addition, HSR filings would require intrusive disclosures for PE funds regarding their structure and the identity of their limited partners, financing sources and creditors.

The proposed changes to the HSR premerger notification rules will significantly increase the burden associated with HSR filings and could delay many deals and even deter some deals at the margins. The proposed HSR rules are not yet final but could go into effect as early as Q1 of 2024.

10. Emerging State Healthcare Notification Laws: Pre-Closing Notice Requirements for Certain Healthcare Transactions

BY DELANEY DURST & LARA FLATAU

A growing number of states have proposed or enacted legislation requiring pre-closing notice and/or approval of certain healthcare transactions. Although states have historically limited regulatory review of healthcare transactions to licensed providers, such as hospitals, many of the newly enacted statutory requirements have expanded review requirements to include transactions involving physician groups and management service organizations, among others. These laws highlight increased state government focus on healthcare mergers and acquisitions, joint ventures and other strategic transactions and transactions involving PE firms, which appear to be some of the primary intended targets. Lawmakers enacting this legislation are acutely focused on the impact of continued consolidation in the healthcare industry on patient care, healthcare costs and access to services.

Generally, the applicable state notification requirements allow the relevant state agency (commonly the state attorney general or health department) to review healthcare transactions that meet the statutory criteria or that involve certain healthcare entities. The state laws vary considerably in the types and sizes of transactions to which they apply, the filing requirements and the timing considerations. However, the laws all share a common goal of allowing state regulators to assess the impact of certain healthcare transactions on local market competition and restrictions on patients' access to care.

Although a number of the applicable laws require that notice to be provided include the parties, impacted locations, the effective date of the transaction and a description of the transaction, certain states with more robust requirements require disclosure of more detailed information about the parties (including, in some states with respect to PE transactions, information regarding the sponsor and other portfolio companies), the transaction structure, material terms and the proposed market impact of the transaction. In these states, the applicable regulatory body has the authority to enjoin transactions and levy other penalties if it determines that the transaction has the effect of being anti-competitive or proper notice was not given. Parties to healthcare transactions should become familiar with these laws in the early stages of their transaction process to determine their applicability and consider associated impacts on transaction timing.

As of January 1, 2024, thirteen states have enacted transaction notification requirements – California (goes into effect April 1, 2024), Colorado, Connecticut, Hawaii, Illinois, Massachusetts, Minnesota, Nevada, New York, Oregon, Rhode Island, Vermont and Washington. Several of these states, including California, New York, Minnesota and Illinois, enacted legislation in 2023, making this an emerging trend among states that we expect will likely continue in 2024.

11. Restrictive Covenant Developments: Non-Competes and Non-Disparagement

BY LYMARI CROMWELL & BOB HORTON

PE investors looking to protect their investment in human capital as part of their transactions continue to take a wait-and-see approach heading into 2024 while awaiting the final resolution of some wide-sweeping proposed changes from 2023. Below, we analyze the current state of play in both non-compete and non-disparagement provisions.

Non-Compete Developments

After receiving over 25,000 comments regarding its January 2023 proposed rule significantly limiting non-compete agreements, the FTC has yet to release the status of the proposed rule. In the meantime, covenants not to compete and other restrictive covenants have continued to come under attack by the National Labor Relations Board as well as state legislatures and courts. Notably:

- **Section 7 Rights of Employees.** In May 2023, the General Counsel of the National Labor Relations Board (NLRB) issued a memo indicating that the proffer, maintenance and enforcement of non-compete agreements in employment contracts and severance agreements with non-supervisory employees infringes upon the Section 7 rights of employees. Section 7 rights under the National Labor Relations Act include the right to self-organization, to form, join or assist labor organizations, to bargain collectively through representatives of their own choosing and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection. The General Counsel takes the position that non-compete agreements infringe on Section 7 rights in a number of ways, including by interfering with employees' ability to concertedly threaten to resign (and to carry out such threats) in an effort to obtain better working conditions.
- **Recent Delaware Non-Compete Rulings.** The state courts of Delaware, once considered a non-compete friendly state, have issued several rulings in the past 18 months in which the courts have refused to reform or blue pencil non-compete restrictions that the courts deemed overly broad, instead striking the restrictions as unenforceable, including in connection with the sale of a business. As a "reasonable alteration" state in which the courts have discretion to reform an overly broad non-compete or strike it as unenforceable, businesses have historically relied upon the willingness of the courts in Delaware to blue pencil or reform an overly broad restriction. These recent rulings create a very clear and alarming precedent, which is causing investors to rethink whether they should default to Delaware's choice of law in their restrictive covenant agreements, whether in the employment or investment context.

- **State Ban on Non-Competes.** Effective July 1, 2023, Minnesota became the fourth state in the United States (following California, Oklahoma and North Dakota) to ban employment-related non-competes. The law specifically states that employers cannot avoid application of the law by choosing non-Minnesota law or venue in the agreement.
- **California Civil Actions.** Effective January 1, 2024, California employees will be able to bring civil actions against any employer who subjects the employee to a post-employment non-compete. Aside from invalidating the non-compete, prevailing employees will be entitled to damages, attorneys' fees and costs. Moreover, as of February 14, 2024, employers will be required to notify current and former employees subject to an unlawful non-compete that such non-compete is void. The notice must be in a written, individualized communication to any employee or former employee employed after January 1, 2022. Failure to comply may result in civil penalties under California law.
- **Pending New York Legislation.** In June 2023, the New York State legislature approved a bill that would ban employment-related non-competes. On December 22, 2023, Governor Kathy Hochul vetoed the bill and recommended that non-competes be banned in the state for any employee earning under $250,000 per year. Revised legislation is expected in the future.

Non-compete law varies drastically from state to state and continues to change rapidly. PE investors should continue to monitor these laws as they apply to the current operations of their portfolio companies and new states where they are looking to expand.

Non-Disparagement Clauses in the Wake of McLaren

The NLRB has taken the position that broad non-disparagement clauses for non-supervisors violate the National Labor Relations Act (the Act) because the clauses restrict the rights of non-supervisors to freely discuss (and criticize) the terms and conditions of their employment (commonly referred to as employees' Section 7 rights where such rights for non-supervisory employees are found in the Act). In McLaren Macomb, 372 NLRB No. 58 (2023), the NLRB took the position that broad non-disparagement clauses in severance agreements unlawfully infringe on Section 7 rights of non-supervisory employees. The NLRB's general counsel issued a memo thereafter stating that these non-disparagement clauses in employment agreements also would be considered a violation of an employee's Section 7 rights. The NLRB also found that confidentiality clauses in severance agreements prohibiting the disclosure of the terms of a severance agreement infringe on Section 7 rights as well.

The NLRB's general counsel has stated that "a narrowly-tailored, justified, non-disparagement provision that is limited to employee statements about the employer that meet the definition of defamation as being maliciously untrue, such that they are made with knowledge of their falsity or with reckless disregard for their truth or falsity, may be found lawful." This is obviously just a statement that employees may not defame their employer by stating something "maliciously untrue," which employees are already prohibited from doing under common law. However, absent having agreed to a non-disparagement clause, employees may openly criticize their employer as long as such criticism does not include any false factual statements. Hence, there is a need for non-disparagement clauses.

One particular challenge regarding healthcare services of which PE investors should be aware is the question of whether physicians and advanced practice providers (APPs) are "supervisors" for purposes of the Act. The Act defines "supervisor" as "any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibly to direct them, or to adjust their grievances, or effectively to recommend such action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment."

Employers in the healthcare field often wish to take the position that physicians and APPs are supervisors under the Act because physicians and APPs "responsibly direct" other providers such as nurses or medical assistants while caring for patients. The current NLRB appears to be reluctant to accept that kind of direction as indicia of supervisory status and looks further for evidence of whether the physician or APP assigns the time and place of work or whether the record demonstrates that a nurse or medical assistant was actually hired, promoted, disciplined or fired solely based upon the recommendation of the physician or APP. If an argument for supervisory status relies on the fact that the

physician or APP "responsibly directs" others in the course of providing care, the employer should consider the extent of such direction (does it occur throughout the day, once a day, less?), whether the activity which the physician or APP is directing to be performed would have been performed even in the absence of such direction and whether the physician or APP is held accountable for the provision of such care that was directed to be performed.

In order to ensure that restrictive covenants in employment agreements, purchase agreements, equity agreements and other corporate organizational agreements are enforceable, it is imperative that investors stay apprised of changes to these laws as they are being challenged more frequently and continue to evolve.

12. What Do "Market" Terms for M&A Deals Look Like? New 2023 ABA Deal Points Study Provides Answers

BY TATJANA PATERNO

Bass, Berry & Sims is pleased to provide its valued clients with key highlights from the 2023 American Bar Association (ABA) Private Target Mergers & Acquisitions Deal Points Study that was published in December 2023. The Study examines the prevalence of certain contract provisions in M&A transactions and is considered the preeminent study of M&A transaction terms. It is widely utilized by attorneys, investment bankers, corporate development teams, and other advisors to determine "what's market" for various acquisition agreement terms.

The latest biannual Deal Points Study includes over 100 pages of detailed data on various negotiated deal points in acquisition agreements. It draws on data from middle market transactions executed or closed in 2022 or Q1 of 2023 involving privately-held targets. Transactions included in the Study range in size from $30 million to $750 million and represent a broad base of industries, with technology, healthcare and financial services representing approximately 20%, 16% and 10%, respectively, of the deals analyzed.

Here are a few highlights from the Study:

1. ***Use of Representation and Warranties Insurance (RWI) Contracted.*** 55% of deals in the 2023 Study referenced RWI, as compared to 65% of the deals in the 2021 Study. This decline could be attributable to higher costs and limited availability of RWI during the period covered by the 2023 Study, could indicate market participants' growing preference for a traditional indemnity structure, or the increasing difficulty in recovering under RWI as some RWI customers have experienced.
2. ***Prevalence of Earnouts.*** Use of earnouts increased significantly – by 30% (i.e., from 20% during the period covered by the 2021 Study to 26% during the period covered by the 2023 Study). This likely reflects the growing valuation gap that we have observed in the market during the period covered by the 2023 Study. Further, 25% of all deals with an earnout included an express disclaimer of fiduciary relationship with respect to the earnout, an increase of over 300% from the period analyzed by the 2021 Study. This could reflect a swing to more buyer-friendly terms as the M&A market changed during the more recent period. As a reminder, earnouts in healthcare transactions must be carefully structured to ensure compliance with applicable regulatory requirements.
3. ***#MeToo Representation Increased.*** 57% of all transactions analyzed in the 2023 Study included a stand-alone #MeToo representation, as compared to 37% of deals in the 2021 Study. This indicates increased focus on this issue as buyers diligence target companies.

Over 50 experienced M&A attorneys from prominent law firms across the globe contributed to the Study, including Bass, Berry & Sims member Tatjana Paterno, who co-chaired the Study, and associates David Venturella and Brad Yenter. To request a copy of the 2023 Study, or if you have questions regarding the Study, please contact Tatjana Paterno at tpaterno@bassberry.com.

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About the Bass, Berry & Sims Healthcare Private Equity Team:

The Healthcare Private Equity Team at Bass, Berry & Sims has advised in more than 200 private equity transactions in the healthcare industry over the past two years, including *The M&A Advisor's* 2023 M&A Deal of the Year (Between $1B-$5B) award for the acquisition of PANTHERx Rare from Centene Corporation by Vistria Group, General Atlantic, and Nautic Partners. The firm is ranked the #4 Most Active in Healthcare Private Equity Deals by PitchBook. As the fourth largest healthcare law firm in the U.S. (as ranked by American Health Law Association in 2023), with deep corporate and healthcare regulatory experience, Bass, Berry & Sims has long been recognized as the go-to law firm for private equity funds investing in healthcare. To learn more about our team, industry experience and value-add, click here.

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