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Healthcare M&A 2026

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USA: Law and Practice
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USA

Law and Practice

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Seyfarth Shaw LLP is a full-service law firm with approximately 1,000 attorneys across 17 offices in the USA, London, Hong Kong, Melbourne and Sydney. Its healthcare group is uniquely positioned to help clients develop and execute successful strategies for navigating and responding to industry-specific pressures. Seyfarth's transactional healthcare attorneys handle all aspects of a transaction – from the commencement of negotiations through closing and post-closing matters. In addition to the authors profiled, Seyfarth thanks attorneys Mark Coffin, Aaron Gillett, Tess Rabin and Karla Sanchez for their contributions.

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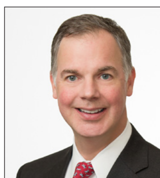

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1. Market Trends

1.1 Healthcare M&A Market

In 2024, the healthcare M&A market in the USA and Americas tracked the overall global decline in deal value – down 29% from 2023 – but saw a steeper decline in deal volume, which was down 24.5% from 2023 (versus a 20% drop globally). Although discouraging, this data suggests the US market is beating the global market on a value-per-deal basis. Much of this gain appears to be driven by deals worth less than USD5 billion, which saw a 19% increase in value. Continued high interest rates were a key factor slowing the pace of deal activity. Notable deals include AbbVie's USD10.1 billion buyout of Immunogen, as well as KKR & Co's acquisition of a 50% stake in healthcare analytics firm Cotiviti for approximately USD5 billion.

1.2 Key Trends

2024 saw a continuation of key M&A trends from both industry and regulatory perspectives. Pharmaceuticals (particularly specialised therapies), health care technology and digital health continued to be the most active sectors for healthcare M&A. From a regulatory perspective, antitrust concerns driven by private equity activity continue to dominate, with the Federal Trade Commission (FTC) finalising its new, increased pre-merger filing requirements in October 2024. Antitrust concerns were also reflected in the individual states, many of which implemented notice or notice-and-approval requirements for healthcare transactions.

2. Establishing a New Company

2.1 Establishing a New Company

New start-up companies, particularly those seeking institutional investment, often choose to incorporate in Delaware, thanks to its well-established legal framework, specialised courts and business-friendly laws. Although Delaware is the most common state for incorporation, businesses may incorporate in any state, regardless of the location of their owners, management or properties. The process of incorporating a new company typically takes a relatively short amount of time. Delaware offers expedited business formation services and in many cases, the incorporation process can be completed on the same day. Importantly, there is no fixed minimum capital requirement for incorporation in most states, including Delaware. However, parties should carefully consider the new company's financial needs, especially its operating expenses.

2.2 Type of Entity

The type of entity chosen depends on various factors, including business goals, intended organisational structure, funding, liability protection and tax implications. C corporations and limited liability companies (LLCs) are among the most common types of entities considered by entrepreneurs. Venture capital funds often prefer to invest in the stock of a C corporation, as corporate documentation and governance tend to be more straightforward compared to LLCs. Meanwhile, LLCs are favoured for their flexibility, cost-effective organisation and management and pass-through taxation.

2.3 Early-Stage Financing

The earliest stage of start-up funding is typically provided by friends and family, angel investors and sometimes the founders' own savings. These initial investments serve to kick-start the business, validate ideas and cover basic operational expenses. In seed-stage financings, the documentation often includes convertible notes, Simple Agreement for Future Equity (SAFE) instruments and other legal documents that outline investment terms and ownership details. These agreements establish the foundation for the start-up's future growth and development.

2.4 Venture Capital

In the USA, venture capital plays a critical role in funding early-stage companies with high growth potential. Typical sources of venture capital funding include:

- private venture capital firms that invest their own capital or funds raised from institutional investors;
- corporate venture capital (CVC), usually made by a large corporation through a related CVC arm;
- angel investors;
- crowdfunding platforms; and
- accelerators and incubators.

The USA benefits from a mature and active venture capital ecosystem, supported by an entrepreneurial culture and a deep bench of sophisticated investors. Although there are government programmes aimed at supporting small businesses, direct government-sponsored venture capital funds are less common than private alternatives. Additionally, foreign venture capital firms actively invest in US start-ups, particularly in technology hubs such as Silicon Valley, New York, Boston and Chicago.

2.5 Venture Capital Documentation

The National Venture Capital Association (NVCA) has developed a widely used set of model legal documents that serve as the industry-standard templates used in venture capital financings across the USA. These model documents aim to streamline the investment process and provide standardised terms and structures that are widely accepted by investors and entrepreneurs alike. The set of model legal documents includes templates for various key agreements, such as:

- term sheets;
- stock purchase agreements;
- investor rights agreements;
- voting agreements; and
- other ancillary documents.

Importantly, these model legal documents strike a balance between providing a standardised framework and allowing flexibility for customisation based on the specific needs of the parties involved. Start-ups and investors can use these templates as a starting point while tailoring them to their unique circumstances.

2.6 Change of Corporate Form or Migration

The decision of whether a start-up should maintain its existing corporate form and jurisdiction or make changes as it progresses in its development – particularly in the context of venture capital financing – can vary based on several factors. These factors include the company's growth trajectory, business requirements, legal and tax considerations and investor preferences. By way of example, venture capitalists often favour investing in Delaware C corporations, owing to advantages such as Delaware's well-established legal framework, investor-friendly legal protections and the flexibility C corporations offer for future financing rounds and exits. As a result, start-ups that initially structure as LLCs or other entity types may be advised to convert to a Delaware C corporation to align with venture capital financing requirements and maximise their growth potential.

3. IPO as a Liquidity Event

3.1 IPO v Sale

Investors in a start-up are more likely to pursue a sale process as the quickest path to liquidity. The healthcare sector follows this pattern, but in recent years, healthcare companies that have chosen the IPO route have been more successful than those in other industries in terms of funds raised. The choice is typically made at the outset and is highly dependent on the seller's existing circumstances and long-term goals. Recent developments, however, including the success of healthcare IPOs, have made a dual-track option more attractive. In addition, the SEC's March 2025 action to loosen certain restrictions on the avail-

ability of confidential initial registration review offers healthcare issuers, including non-US private issuers, more room to pursue an IPO while simultaneously evaluating a potential sale.

3.2 Choice of Listing
In the US, companies opting to do a listing have a strong preference for home exchanges. For health care issuers, this preference is likely driven by the expectation that a US listing will provide access to a deep pool of specialist investors with superior liquidity and valuation support.

3.3 Impact of the Choice of Listing on Future M&A Transactions
The choice of a foreign exchange for listing would likely affect the feasibility of a future sale. Lack of familiarity with foreign exchange requirements and conflict-of-law issues regarding minority shareholder protections and squeeze-out thresholds would likely make a US buyer hesitant.

4. Sale as a Liquidity Event

4.1 Liquidity Event: Sale Process
Auctions and bilateral negotiations are both common methods when selling a company. The choice largely depends on the specifics of the situation, including the seller's strategic goals and existing market conditions. Some companies may even explore a hybrid approach that combines elements of both methods. The use of hybrid processes is increasing, especially in uncertain markets, to bridge gaps between parties and manage risk. Auctions often allow sellers to maximise the purchase price and negotiate more favourable deal terms, which could make this process more desirable. Alternatively, a private negotiated sale might be chosen when there is a relatively small pool of potential buyers or for confidentiality reasons. However, the negotiations may take longer and the purchase price might be lower.

4.2 Liquidity Event: Transaction Structure
When selling a privately held healthcare company in the USA, there are several common transaction structures (most often, an asset sale, a stock sale or a merger). Asset sales involve the sale of specific assets and liabilities, allowing sellers and buyers to tailor the acquisition to their needs. Stock sales involve selling ownership interests in the company, with the buyer assuming all assets and liabilities. Hybrid structures blend elements of asset and stock sales. Mergers involve two entities combining to form one new entity. The chosen structure depends on a number of factors, including tax implications, regulatory requirements, deal timeline and investor interests. For a business with venture capital investors, it is also common to see a buyout structure, whereby the private equity fund, management investors and any co-investors contribute cash or stock to a new holding company, which then pays the seller the purchase price.

In the current landscape, there is a trend towards selling a controlling interest, enabling venture capital funds to remain shareholders. This approach allows venture capital investors to continue participating in the company's growth and potentially benefit from future success. On the other hand, some sellers opt to sell the entire company, allowing the buyer to assume full control and ownership. The choice between selling the entire company or a controlling interest depends on the company's financial needs, the business's future prospects and the strategic interests of the venture capital funds, among other factors.

4.3 Liquidity Event: Form of Consideration
The transaction structure varies significantly based on specific circumstances. When selling a healthcare company, strategic objectives, company nature and market conditions all play significant roles. Some transactions involve an outright sale of the entire company for cash, whereas others involve stock-for-stock exchanges. Rollover equity is routine in sponsor-led healthcare transactions and is frequently required for management, often alongside earnouts or other forms of contingent consideration designed to align incentives and bridge valuation gaps. By contrast, strategic mergers more commonly involve equity-based consideration, particularly in larger platform or public company transactions. In a cash sale, the buyer pays a predetermined cash amount to acquire ownership. In contrast, stock-for-stock transactions involve the seller receiving shares in the buying company as payment. Each method has its own advantages and considerations; the choice depends on factors such as

company size, type, market conditions and tax implications. Healthcare transactions also increasingly use earnouts tied to performance metrics.

4.4 Liquidity Event: Certain Transaction Terms

Whether founders and venture capital investors stand behind representations and warranties depends on the specifics of the deal structure and the negotiations between the parties. Founders and venture capital investors are typically expected to stand behind certain representations and warranties, particularly in stock sales where the buyer acquires all the target's stock directly from the selling stockholders, including all of the target's assets, rights and liabilities.

It is customary to use an escrow or holdback mechanism to secure indemnification obligations related to breaches of representations and warranties. Representation and warranty insurance (RWI) has become increasingly common to mitigate certain risks associated with such breaches. RWI is particularly beneficial for founders and venture capital investors looking to limit their post-closing liability exposure. For buyers, RWI can provide added assurance that they will have recourse for breaches of representations and warranties without placing undue burden on the founders and venture capital investors.

5. Spin-Offs

5.1 Spin-Off Trends

Spin-offs remain a common strategic tool across the USA industries, including healthcare and have experienced renewed interest in recent years. Companies pursue spin-offs to maximise enterprise value, improve strategic focus and streamline operations. Some key drivers for considering a spin-off in the healthcare industry include focusing on the core business, unlocking value, strategic realignment and optimising capital allocation.

Predicting future trends in spin-offs from generic pharmaceutical or OTC businesses is challenging. However, healthcare companies may choose to spin off these segments to sharpen their strategic focus on higher-growth market segments, such as speciality pharmaceuticals, biotechnology or medical devices.

The prevalence of spin-offs fluctuates with broader market conditions, such as capital markets, interest rates and the regulatory climate; however, they continue to play a central role in strategic portfolio reshaping.

5.2 Tax Consequences

Spin-offs in the USA can be structured as tax-free transactions at both the corporate and shareholder levels (under certain conditions). A tax-free spin-off allows a parent company to separate a subsidiary or division into a standalone entity without triggering immediate tax liabilities for the company or its shareholders. Tax–free treatment is governed primarily by Section 355 of the US Internal Revenue Code and related Treasury regulations, which impose detailed requirements that must be met to qualify for tax-free treatment at both the corporate level and the shareholder level.

5.3 Spin-Off Followed by a Business Combination

It is possible for a spin-off to be immediately followed by a business combination in the USA, commonly known as a "spin-off and merger" or a "Reverse Morris Trust transaction." This involves a two-step process: a company first spins off a subsidiary or division as a standalone entity and then merges the spun-off entity with another company.

The key requirements for a Reverse Morris Trust transaction are as follows.

- The parent company's shareholders must own at least 50.1% of the voting rights and economic value in the new merged company.
- The company cannot sell equity following the merger.
- Parent and subsidiary companies must have a history of actively undertaking trade or business for five years before initiating the Reverse Morris Trust structure.

5.4 Timing and Tax Authority Rulings

The timing of a spin-off can vary depending on factors such as the complexity of the transaction, regulatory requirements and the specific circumstances of the companies involved. Typically, the spin-off process

takes several months to more than a year, depending on the transaction's complexity and size.

To gain clarity on the tax consequences of a proposed spin-off, companies frequently request a private letter ruling from the Internal Revenue Service (IRS). However, obtaining an IRS ruling is not a prerequisite for all spin-off transactions. The IRS now allows rulings on all tax aspects of a spin-off, excluding the business purpose requirement. Some spin-offs may qualify for the IRS's fast-track programme, which aims to issue rulings within 12 weeks. However, the IRS can decline or delay requests in its discretion or approve a processing time lengthier than that requested.

6. Acquisitions of Listed Healthcare Companies

6.1 Stakebuilding

There is little tactical benefit in acquiring shares in a target company before making a tender or other takeover offer – although the risks are less acute in a friendly acquisition. Corporate mergers are governed by state law rather than uniform national law and many states (including Delaware, where many companies are incorporated) have anti-takeover statutes that inhibit shareholders' ability to use equity acquired in the public market to launch a takeover. In addition, under the Wellman and Hanson tests, certain acquisitions of stock on the open market may constitute a tender offer, requiring the buyer to comply with the SEC's Regulation 14D tender offer rules. In negotiated acquisitions of listed healthcare companies, market practice continues to favour confidentiality and early board engagement over pre-bid stakebuilding, particularly where access to due diligence and regulatory analysis is central to valuation and execution.

The reporting threshold is 5%. If a proposed acquisition will result in the bidder holding more than 5% of beneficial ownership in a class of voting securities, the bidder must make a beneficial ownership filing, typically on Schedule 13D, unless eligible to report on Schedule 13G. Since the SEC's beneficial ownership rule changes became effective in 2024, an initial Schedule 13D must be filed within five business days after crossing the threshold, with amendments required within two business days after a material change. Schedule TO requires disclosure of the purpose of the transaction and any plans to make material changes to the company's structure, such as an asset sale or a merger with another company. Schedule TO also requires disclosure of the material terms of the transaction, including the expiration date of the offer and possible extensions. If the offer includes securities of the bidder, the bidder must register those securities with the SEC (most commonly via a Form S-4) and submit the tender offer documents. There is no requirement under US law for a bidder to announce an offer or state that it will not proceed within a specified period after acquiring a stake.

6.2 Mandatory Offer

There is no legal requirement that an offer meet a certain threshold amount before being considered. Offers that would result in the offeror acquiring a beneficial interest in more than 5% of the target company's securities trigger compliance with the SEC's tender offer rules contained in Regulation 14D, including the requirement to file a Schedule TO. Unlike many non-US jurisdictions, the US does not impose a mandatory bid obligation solely as a result of crossing a specified ownership threshold. In practice, a bidder will rarely acquire 100% of the target company's stock through a tender offer and a subsequent merger into the bidder or affiliate will be necessary. For that reason, bidders customarily seek to acquire the amount of stock that would give the bidder the authority to approve a merger.

6.3 Transaction Structures

Typical transaction structures for the acquisition of a public company include asset purchases, stock purchases and mergers. Direct and indirect mergers are available and are used more often than the other typical structures. The predilection for mergers in this context stems from the fact that they typically require majority consent to the merger as opposed to unanimous consent of all stockholders to sell their stock. Mergers are largely governed by the law of the state where the company is chartered and involve federal disclosure requirements under SEC regulations. For listed healthcare companies, the choice between a one-step merger and a two-step tender offer followed by a back-end merger is increasingly informed

by anticipated antitrust and healthcare regulatory reviews. Where a transaction is likely to face extended regulatory scrutiny, parties may favour a one-step merger with a longer outside date rather than rely on repeated tender-offer extensions.

6.4 Consideration: Minimum Price

The decision on whether to structure a technology industry transaction as cash, stock-for-stock or both depends on a variety of factors, some generally applicable, such as interest rates and others specific to the parties. The recent trend of high interest rates is a factor in favour of all stock or stock-heavy deals, but parties invariably tailor the consideration in an acquisition to optimise their particular situation.

Cash may be used as consideration in a merger. Under federal law, there is no minimum price requirement. At the state level, anti-takeover statutes may require bidders that currently hold a prescribed percentage of company stock to comply with minimum or fair price requirements, which are often determined by reference to the market or the bidder's prior purchase of the target's shares. For tender offers, the highest consideration paid to any one stockholder must be paid to all stockholders.

Although contingent value rights (CVRs) are not common generally, event-driven CVRs – where the contingency is FDA approval or financial performance – are used in healthcare M&A more than any other industry. Government approval-based contingencies are often justified by the outsized impact such an event can have on the company's value. Performance-based contingencies often make sense because the industry is generally familiar with them, as they are frequently used across a variety of commercial transactions in the healthcare space.

6.5 Common Conditions for a Takeover Offer/Tender Offer

Offer conditions are matters of negotiation and usually depend on the general financial conditions at the time and the parties' relative bargaining power. Bidders commonly include a "minimum tender condition" in the offer to ensure that the deal only goes forward if the bidder acquires the amount of the target company's stock necessary to approve a merger because a tender offer will rarely result in acquisition of 100% ownership of the target company and the bidder will need to follow the stock acquisition with a merger (often referred to as a "two-step merger"). Other common conditions of the tender offer include:

- government approvals;
- accurate representations and warranties;
- an absence of legal restraints to the deal; and
- no material adverse change in the target company.

The SEC does require that all tender offer conditions be capable of satisfaction based on objective criteria that are not entirely within the bidder's control. Conditions that must be met to the "satisfaction" of the bidder "in its sole discretion" are considered illusory. In March 2025, the SEC published updated guidelines in this regard. The updated guidance also emphasised that termination of a tender offer should identify the specific failed condition and that discretionary conditions framed by reference to the bidder's judgment may be subject to challenge.

6.6 Deal Documentation

Public acquisitions will always require documentation – typically in the form of a merger agreement subject to shareholder approval and/or a tender offer. Target company directors and executive officers will usually be asked to agree to vote their shares in favour of a transaction or tender their shares in a tender offer and agree to post-closing lock-up agreements that typically prohibit the disposition of shares for at least six months. A target company may also be asked to comply with a no-shop or go-shop provision, as well as to adhere to strict notice and determination procedures in connection with the exercise of any fiduciary out in the event of a competing offer. Public companies do give representations and warranties, but these are generally limited to confirmation that the company has made all its required filings with the SEC in compliance with applicable law.

6.7 Minimum Acceptance Conditions

In the absence of super-majority voting requirements in a target's certificate of incorporation or certificate of designation for any class of preferred securities, a simple majority is the minimum acceptance condition. For transactions with conflicts of interest between

affiliated parties or a controlling stockholder on both sides of the transaction, it is customary for a committee of disinterested directors to oversee and approve the transaction or for the company to seek approval of a transaction from a "majority of the minority" so that courts will apply the business judgment rule – rather than the higher entire fairness standard of review – to any stockholder challenges to a transaction.

6.8 Squeeze-Out Mechanisms

Most states authorise a short-form merger procedure whereby the acquisition of a threshold amount of stock allows the buyer to effect a merger of the companies without a shareholder vote. By way of example, in Delaware, the acquisition of 90% of the outstanding shares of each class of stock enables a short-term merger. If the bidder cannot acquire 90% of the outstanding shares in the tender offer, the parties may agree to a "top-up" option in favour of the buyer in order to purchase enough new target company shares to reach the 90% threshold when aggregated with the stock acquired in the tender offer. Alternatively, Delaware provides a separate statutory mechanism to reach the same result if the bidder acquires sufficient shares to approve the merger under the target's governing documents and the merger agreement expressly references the statute. As a result, top-up options are now less central to Delaware-listed public company acquisitions than in earlier periods, although they may still appear in specific circumstances.

6.9 Requirement to Have Certain Funds/Financing to Launch a Takeover Offer

Acquisitions can be financed with the buyer's equity, in which case no bank documents are necessary. The ability to do equity financing is a matter of negotiation and depends on the transaction's circumstances and the parties involved. Even when the buyer relies on debt financing, there is no legal or other requirement that the loan be closed and funded before launching the offer. Instead, financing and the purchase agreement are typically negotiated on parallel tracks.

It is common for the buyer to have a signed commitment letter from the lender identifying the conditions that must be met for the lender to fund the deal. Commitment letters have become increasingly common in recent years as "financing out" provisions (allowing the buyer to walk away without penalty if it cannot secure financing) are being replaced by reverse break-up fees. In March 2025, the SEC clarified that a cash tender offer is treated as fully financed only where the bidder has a binding financing commitment in place and that obtaining committed financing after launch constitutes a material change requiring prompt disclosure and, where applicable, extension of the offer.

Accompanying the trend for higher commitment letter utilisation has been the inclusion of "SunGard" clauses, which limit the conditions to funding. The commitment letter is negotiated between the buyer and the lender, with the buyer being the party making the purchase offer. As noted previously, funding can be a condition to closing, as a buyer may not require specific performance of the deal, but buyers are increasingly likely to incur penalties for backing out of a deal owing to a lack of funding.

6.10 Types of Deal Protection Measures

Buyers commonly negotiate no-shop/non-solicitation provisions that restrict the seller or the target company from soliciting other bids during the period between signing and closing. No-shops are particularly important for buyers in public deals because these deals are vulnerable between the signing and closing. In this context, no-shops typically prohibit the target company's board from changing its position on the deal and prohibit the waiver of standstill agreements but also include "window-shops" (allowing the target to entertain unsolicited bids upon certain conditions) and fiduciary outs (allowing the target to consummate a deal based on a competing bid if the failure to do so would breach the board's fiduciary duties to the company). Fiduciary outs are invariably accompanied by break-up fees – another deal protection mechanism found in almost all public company transactions. Matching rights, force-the-vote provisions and stock options for the buyer are also common.

6.11 Additional Governance Rights

Acquiring 100% ownership in a takeover offer is rare. As a result, deals structured around a tender offer usually include a short-form merger – or, for Delaware corporations, an intermediate-form merger – following closing of the tender offer.

Short-form merger requirements vary by the target's state of incorporation, but usually require the buyer to hold 90% of the target's issued and outstanding shares to effect a merger without a shareholder vote. Top-up options bridge the gap between what the bidder is able to achieve through the tender offer and the 90% threshold by requiring the target, at the option of the bidder, to issue enough new stock to bring the bidder up to 90% when combined with the tender offer stock.

Alternatively, a bidder may negotiate for a majority of board seats and/or veto/approval rights over material transactions to bolster its governance authority.

6.12 Irrevocable Commitments

Irrevocable commitments from principal shareholders to support the deal are often referred to as voting agreements or lock-up agreements. These agreements are common in public company transactions, but the parties must proceed with care to ensure they do not result in a breach of fiduciary duty by the target's board. When a lock-up agreement (alone or together with another provision, such as a force-the-vote) prevents the board from pursuing a better transaction, the lock-up agreement may be held to be unenforceable. To avoid this result, parties often include fiduciary out provisions in the lock-up agreement, which allow the board to withdraw approval and terminate a merger agreement if proceeding with that agreement would prevent the board from:

- accepting a better deal for the stockholders;
- responding to an intervening event that renders the current deal problematic; or
- fulfilling its fiduciary duties generally.

In 2025, the SEC staff eased its prior position on certain sign-and-consent structures in stock transactions, confirming that written consents from target insiders can coexist with the subsequent registration of bidder securities under specified conditions.

6.13 Securities Regulator's or Stock Exchange Process

In a stock-for-stock transaction in which the buyer's securities are registered under Form S-4, the registration statement is subject to SEC review and the transaction cannot close until the SEC completes its review and declares the registration statement effective. This process generally takes between two and three months from the filing date of the registration statement.

In a tender offer, the SEC will review the Schedule TO and offer documents and may require a buyer to supplement its tender offer materials with additional disclosure. However, only material changes would restart the 20-business-day minimum offer period for tender offers.

If a transaction constitutes a change in control of a listed company, the stock exchange will require the submission of a new listing application for the company to continue its listing post-closing. This process generally takes between two and three months and runs concurrently with the SEC review of Form S-4.

6.14 Timing of the Takeover Offer

For all-cash offers, SEC reviews are typically not extensive enough to require extensions and the antitrust waiting period is 15 days (subject to extension by the FTC). For exchange offers in which a tender offer includes the bidder's securities as consideration, the offer period must remain open until the SEC declares the bidder's registration of the securities effective. Since February 2025, the revised HSR filing form has required substantially more upfront information, increasing preparation time and making early antitrust analysis more central to transaction planning, particularly for healthcare companies operating across multiple service lines or regulated markets.

Deals meeting the Hart-Scott-Rodino Act (the "HSR Act") thresholds for value and size of parties need to be cleared by the FTC. For 2025, deals in excess of USD126.4 million may need to be reported, depending on the size of the parties in terms of volume of sales or value of assets; generally speaking, however, deals in excess of USD505.8 million will be reportable. Recent enforcement activity in the healthcare sector, including challenges to provider and roll-up transactions, has reinforced the need for longer outside dates and more detailed regulatory covenants in public healthcare acquisitions.

7. Overview of Regulatory Requirements

7.1 Regulations Applicable to a Healthcare Company

When starting and operating a new company in the healthcare industry, navigating regulatory requirements is crucial. Regulatory oversight in the healthcare industry involves both the US federal government and individual state governments. Federal requirements are enforced nationwide, resulting in relatively consistent standards across the country. In contrast, state laws primarily focused on patient safety, such as physician licensing, can differ significantly from state to state, directly impacting deal structures and transaction planning.

At the federal level, the United States Food and Drug Administration (FDA) plays a central role in the bio-health and life sciences sector by ensuring the safety and efficacy of medical devices, drugs and biologics. Compliance with FDA standards ensures that healthcare products meet quality benchmarks. FDA approval of a Class III medical device can be lengthy and complex, taking several years. Many devices, however, can take advantage of the 510k clearance procedures if they are the "substantial equivalent" of existing devices that have already been approved. 510k clearance can take three to six months.

The federal government is also the largest purchaser of healthcare services. Companies that will be seeking reimbursement from the Medicare and/or Medicaid government-funded health care programmes must comply with the US Department of Health and Human Services (HHS)' conditions of payment and conditions of participation as enforced by its Centres for Medicare and Medicaid Services (CMS). New providers must apply for enrolment and/or certification before the government will authorise payment. This process can take between six and nine months and significantly affect cash flow if arrangements are not made in advance.

These government programmes also have the authority to impose significant civil and criminal penalties through the US Department of Justice and the HHS Office of Inspector General. These penalties address conduct ranging from false statements in a claim for payment to business ventures designed to reward increased utilisation. These penalties can have a devastating impact on the business moving forward and therefore warrant intensive due diligence regarding claim submission practices as well as internal and external financial relationships, which often result in protracted negotiations over indemnities and escrows.

Additionally, HHS' Privacy Rule, Security Rule and Breach Notification Rule govern how healthcare companies create, use or disclose patient information. Enforcement of these rules has intensified as healthcare information becomes more digitised. Consequently, diligence must address cyber preparedness and vendor-management controls.

At the state level, licensing laws impact deal timing by prohibiting the assignment of licenses from sellers to buyers in an asset purchase. As a result, buyers must obtain a new facility license, which can take between six months and a year. In states that require facilities to obtain a certificate of need (CON) before licensure, an additional five to six months or more, is added to the process. Many parties in these cases enter transition service arrangements, which allow the deal to close and the parties to cooperate in operating the facility while the buyer's license is pending.

More recently, transaction reporting laws in some states have extended the pre-closing timeline. Many of these new laws expressly target private equity and physician practice management organisations and some require advance notice and approval before the deal can proceed. Currently, Massachusetts, New Mexico, Oregon and California have enacted notice and approval laws, while other states, including Texas, have enacted notice-only laws. In either case, these laws require extensive transaction and ownership disclosures and can delay closing,

In addition, state laws under the "corporate practice of medicine" doctrine impact whether a corporate buyer may employ physicians and deliver medical care directly or create an intermediate management layer which separates business functions (provided by the company) from physician services (provided by inde-

pendent physicians) and receives a service fee rather than direct payment for medical care.

7.2 Primary Securities Market Regulators

The SEC is the primary securities market regulator for M&A transactions in the USA.

7.3 Restrictions on Foreign Investments

The Committee on Foreign Investment in the United States (CFIUS) is a government body responsible for reviewing foreign investments in US businesses and assessing potential national security risks. CFIUS has the authority to suspend or prohibit certain transactions. Although most CFIUS notifications are voluntary, certain transactions involving US businesses that deal with critical technologies are subject to a mandatory filing requirement. In 2024, CFIUS passed a final regulation expanding its authority and increasing penalties for violations.

In addition, the DOJ has finalised regulations which restrict or prohibit transactions with covered countries or persons that involve access to personal health data and other sensitive categories of information. These new regulations will have a significant impact on cross-border deals which leverage patient data.

7.4 National Security Review/Export Control

CFIUS conducts national security reviews of private commercial acquisitions. As mentioned in **7.3 Restrictions on Foreign Investments**, although most CFIUS notifications are voluntary, certain transactions involving US businesses that involve critical technologies require a mandatory filing. Although CFIUS does not specifically target particular countries, it evaluates transactions based on unique circumstances and certain regions may face heightened scrutiny due to geopolitical factors or specific risks. In addition, as noted above, the DOJ has assumed an active role in policing transactions with countries of concern that involve personal health data.

7.5 Antitrust Regulations

The HSR Act requires reporting certain transactions exceeding specified thresholds to the FTC and the Department of Justice (DOJ). On 21 February 2025, the HSR Act's size-of- transaction threshold increased to USD126.4 million. Deals that exceed this USD126.4 million threshold may need to be reported to the FTC and the DOJ, depending on the size of the parties to the transaction (as measured by the volume of their sales or the value of their assets). Generally, transactions in 2024 with a value greater than USD505.8 million will be reportable under the HSR Act, regardless of the volume of sales or value of assets of the parties.

The HSR filing covers essential details of the proposed transaction, including:

- the parties involved;
- the nature of the transaction; and
- the financial terms.

Parties reporting transactions under the HSR Act must observe a 30-day waiting period after reporting the transaction before they can close the deal. The HSR Act imposes these notification and waiting period requirements so that the FTC and the DOJ can assess the potential competitive effects of the proposed transaction before the deal is consummated.

Notably, the FTC's 2024 amendments to the HSR Act went into effect on 10 February 2025. These amendments substantially expand the information and documents required at filing in regards to:

- transaction rationale;
- overlap narratives;
- ownership information; and
- ordinary-course materials.

These new requirements will materially increase the time and cost of premerger preparations.

7.6 Labour Law Regulations

The primary labour law impacting health care transactions in the USA is the National Labour Relations Act (NLRA), a federal law that gives private sector employees the right to form or join unions and engage in protected, concerted activities to address or improve their working conditions. There are strict regulations and related case law concerning how employers may respond to such activities, so it is important to understand these requirements and their limitations.

The NLRA is interpreted and enforced by the National Labour Relations Board (NLRB), a federal agency that often takes a very pro-union approach to its administrative duties. The NLRB has been especially active in the past several years in seeking to expand what constitutes protected employee conduct and the labour law landscape impacting healthcare transactions and employers has changed significantly. There is no "works council" or similar administrative labour consultation required prior to completing M&A in the USA; however, any alleged unfair labour practices associated with such transactions will be litigated before the NLRB.

7.7 Currency Control/Central Bank Approval

The USA does not have specific currency control regulations for M&A transactions. However, various regulatory frameworks, approvals and oversight mechanisms can impact different aspects of such deals. These include obligations under antitrust laws (eg, the HSR Act), compliance with securities law requirements and CFIUS scrutiny for foreign investments. The Federal Reserve, as the USA's central bank, primarily applies to M&A transactions involving financial institutions.

8. Recent Legal Developments

8.1 Significant Court Decisions or Legal Developments

On 5 March 2024, the FTC, the Antitrust Division of the DOJ and the HHS issued a joint request for information (RFI) on consolidation in healthcare markets. In summary, the RFI requests public comments on the goals, objectives and effects of transactions involving healthcare providers, healthcare facilities or ancillary products or services conducted by private equity funds or other alternative asset managers, health systems or private payors. In the RFI, the applicable agencies expressed concern that such transactions could generate profits for those firms at the expense of patients' health, workers' safety and affordable healthcare for patients and taxpayers.

Notable among the respondents to the RFI have been Attorneys General from 11 states, who share the FTC's concern about private equity's involvement in the healthcare industry and detail their states' own measures to address the issue. As a result, parties to healthcare M&A transactions in these states and others, not just private equity funds, must make disclosures to those states' governments for deals over a certain value, in addition to any reporting obligations imposed by the FTC under the HSR Act.

More generally, the HSR Act itself underwent significant revisions in 2024. As a result, pre-merger notifications to the FTC have become more burdensome and complex in terms of the extent of information to be provided – for example, the strategic rationale for the proposed transaction and the documents that must be submitted in support of the notice (including explanatory documents for letters of intent that lack "sufficient detail"). Although these changes are not specific to healthcare M&A, they apply to these transactions with equal force and effect.

9. Due Diligence/Data Privacy

9.1 Healthcare Company Due Diligence

Healthcare companies present heightened due diligence considerations for acquirers due to the high level of regulation in the healthcare industry. In a healthcare transaction, an acquirer will typically evaluate a range of regulatory, operational and compliance matters, including the following:

- identifying the types of professional services and any ancillary or administrative services provided by the company, including whether the business operates through professional entities, management services organisations (MSOs) or other regulated structures;
- determining the jurisdictions where the company operates and assessing state-specific regulatory requirements;
- if applicable, verifying that the company and all individuals who provide professional services on behalf of the company have maintained all required licences, permits and certifications in good standing;
- if applicable, determining the company's payor mix, whether the company receives reimbursements from a governmental payor programme and

whether the company has had any material refunds or adjustments of over-payments to any payors;
- determining whether the company buys or sells sales and marketing services and, if so, understanding the compensation structure for such arrangements;
- determining whether the company has ever been the subject of any governmental audits, complaints or inspections;
- determining whether the company maintains a compliance programme that satisfies applicable Office of Inspector General (OIG) guidance;
- determining whether the company performs initial regular screenings to ascertain whether any of its employees or agents are excluded or debarred from participating in a federal or state healthcare programme;
- determining whether the company is subject to any court or administrative agency orders, judgments, settlements, consent decrees or related rulings or is otherwise party to any ongoing litigation;
- determining whether the company has been subject to any fraud and abuse claims or other actions pending or threatened by a governmental agency, including – but not limited to – the OIG, the CMS, a state Attorney General's office or a state's HHS Commission (or similar agency);
- determining whether the company has ever been the subject of any actual or threatened "whistle-blower" or qui tam complaints;
- if applicable, determining whether the company maintains written privacy, security and breach notification compliance policies and procedures implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA)'s Privacy, Security and Breach Notification Rules; and
- if applicable, determining whether the company's operations are in compliance with applicable state privacy and security laws – some of which impose stricter obligations than HIPAA.

Evaluating the above-mentioned healthcare-specific issues would require reviewing the company's contractual agreements and policies, as well as substantive discussions with the company's management team regarding operations, compliance practices and regulatory history.

9.2 Data Privacy

There is no single, comprehensive federal data protection statute in the USA. Instead, the USA adopts a sector-specific and state-specific approach to data privacy. The FTC plays a leading role in enforcing consumer privacy rights by addressing unfair or deceptive practices under its general consumer protection authority. Healthcare data, in particular, is generally protected at a higher level than non-health data. This is because of the higher likelihood of adverse effects on the individual through the misuse of such data. These protections come from a variety of different sources. The USA tends to use "sectoral" or "context-specific" data protection regulation. For example, health data processed by a doctor is protected under HIPAA. As such, the source of data protection is generally associated with the nature of the processor rather than the nature of the data.

Various states have passed medical information privacy laws, some of which are more rigorous than the federal HIPAA laws. Generally, these differ from HIPAA in how they define "covered entities" and conduct that requires disclosure and authorisation, but not in how they define health data versus protected health information. Similarly, many states have updated their security breach notice laws in order to include an affirmative obligation to provide reasonable security for any data collected about the individual. This would also include health data.

In addition to medical data-specific laws, several states have passed omnibus privacy laws that now include medical information within their broader scope of protected data.

10. Disclosure

10.1 Making a Bid Public

Public disclosure is generally not required under SEC rules until a material definitive agreement for a transaction has been executed between the parties. However, early selective disclosure of an offer to a party reasonably likely to trade on the information and not obligated to keep it confidential will require compliance with Regulation FD. In addition, stock exchange rules require a listed company to publicly address

rumours or reports (true or false) that contain information that is likely to have (or has had) an effect on the trading in its securities or would be likely to have a bearing on investment decisions.

10.2 Prospectus Requirements

Generally, the issuance of shares in a public merger must be covered by a registration statement that is filed with and declared effective by the SEC. Form S-4 is designated for use in business combinations and is the most common form of registration statement used in stock-for-stock transactions. There is no requirement for the buyer's shares to be listed on any exchange or quoted in any OTC market.

10.3 Producing Financial Statements

Audited financial statements for at least the two most recently completed fiscal years and unaudited financial statements for the most recently completed fiscal quarter are required for both the buyer and seller, in addition to pro forma financial statements. Financial statements of US companies must be prepared in accordance with US Generally Accepted Accounting Principles (GAAP). Foreign private issuers may prepare their financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the International Accounting Standards Board (IASB) or home country GAAP with a reconciliation to US GAAP.

10.4 Disclosure of Transaction Documents

Copies of the transaction documents must be filed as exhibits to the SEC filings of both the buyer and seller, including a current report on Form 8-K, the quarterly report on Form 10-Q or the annual report on Form 10-K for the quarter in which the transaction documents were executed, as well as the registration statement registering the buyer's shares to be issued as consideration in the transaction. SEC rules permit the exclusion of immaterial exhibits or schedules from the copies of the transaction documents that are publicly filed with the SEC. Confidential terms may be redacted from transaction documents filed with the SEC so long as they are not material and are the type of information the company treats as private or confidential.

11. Duties of Directors

11.1 Principal Directors' Duties

In a business combination, such as a merger or acquisition, directors have a fiduciary duty to act in the best interests of the corporation and its shareholders. These duties are typically owed to the company itself and its shareholders, but they can also extend to other stakeholders (eg, employees, customers and creditors), depending on the jurisdiction and specific circumstances. For a public company, the board of directors must also comply with the SEC's governance requirements and the applicable stock exchange rules, including disclosure obligations and processes for managing conflicts of interest.

11.2 Special or Ad Hoc Committees

Special or ad hoc committees are common in business combinations and are typically formed when boards of directors face complex or sensitive transactions or when conflicts of interest arise, such as in related-party transactions or management-led buyouts. These committees are typically composed of independent and disinterested directors and are tasked with evaluating, negotiating or approving specific aspects of the transaction. The formation of a special committee helps mitigate litigation risk by demonstrating that independent directors oversaw the transaction and acted in the corporation's and its shareholders' interests.

11.3 Board's Role

The role of the board of directors in negotiations for a business combination varies depending on the specific circumstances of the transaction and the company's corporate governance practices. Generally, the board's involvement in negotiations (and its ability to actively defend the company) will depend on:

- the structure of the transaction;
- the board's level of expertise and engagement; and
- any conflicts of interest that may arise.

In many cases, the board plays an active role in negotiating the terms of a proposed transaction and in defending the company's and its shareholders' interests.

Shareholder litigation challenging the board's decision to recommend an M&A transaction is not uncommon, particularly if shareholders believe the board failed to fulfil its fiduciary duties or acted in a manner not in the best interests of the company and its shareholders. Therefore, it is important for the board to carefully follow all requirements and procedures set out in the relevant corporate laws and the company's governance documents. Key considerations for a buyer in such situations include understanding the legal standards that govern director conduct in M&A transactions, including the duties of care, loyalty, disclosure/candour and oversight. Additionally, buyers should conduct thorough due diligence to assess potential litigation risks associated with the transaction, including the likelihood of shareholder challenges to the board's decisions.

11.4 Independent Outside Advice

In the USA, where corporate governance standards are high, directors involved in a takeover or business combination are commonly advised by independent outside advisers to ensure they fulfil their fiduciary duties and act in the best interests of the company and its shareholders. Some common forms of independent outside advice provided to directors in connection with a takeover or business combination include:

- financial advisers – often investment banks or advisory firms – to provide strategic advice and financial analysis throughout the transaction process; and
- legal counsel to provide legal advice and guidance, including drafting and review of transaction documents.

These advisers, in particular, assist the board in navigating complex transactions and ensuring that the interests of the company and its shareholders are protected.

In public business combinations, independent financial advisers commonly provide fairness opinions to the target company's board. These opinions assess whether the consideration offered to shareholders in the transaction is fair from a financial standpoint. Although fairness opinions are not legally required, they offer valuable insights to the board and help demonstrate that the board has acted prudently and in the best interests of the company and its shareholders. In contrast, private company transactions less frequently involve formal fairness opinions, but boards may still seek third-party financial advice where valuation issues are complex or conflicts exist.

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