

# USA



## Law and Practice

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**Seyfarth Shaw LLP**

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a digital marketing and advertising agency on behalf of a healthcare solutions company, the sale of Series A convertible preferred shares to an affiliate of a Nasdaq-listed biopharmaceuticals company, and the acquisition and development of physician practices in Arizona, California, Colorado, Connecticut, Florida, Maryland, Missouri, Ohio, Pennsylvania, South Carolina, Texas, Virginia, and Washington, DC for a strategic buyer. In addition to the authors profiled, Seyfarth thanks attorneys Mark Coffin and Tom Posey for their contributions.

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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 besting 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 an increase in value of 19%. 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 in key trends for M&A from both an industry sector perspective and a regulatory perspective. 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 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 services for business formation 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 financial needs of the new company, especially regarding operating expenses.

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## 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 and cost-effective organisation and management, as well as 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 some 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 develop-

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ment – 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 themselves as LLCs or other entity types may be advised to convert to a Delaware C corporation so as 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 would be more likely to run a sale process as the quickest path to a liquidity event. The choice is typically made at the outset. The choice of pursuing a sale or IPO exclusively or on a dual-track process continues to be highly dependent on the seller's existing circumstances and long-term goals.

### 3.2 Choice of Listing

This would depend on the available home exchange and the pros and cons of listing on that exchange. It is common for a company to list on a US exchange if eligible because of the depth, breadth and liquidity of the US markets.

### 3.3 Impact of the Choice of Listing on Future M&A Transactions

The choice of a foreign exchange for listing can affect the feasibility of a future sale for reasons of regulatory requirements, minority sharehold-

er protections, squeeze-out thresholds, and exchange-specific practices.

## 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, combining elements of both methods. 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. An asset sale, stock sale or merger are most common. Asset sales involve selling specific assets and liabilities, allowing sellers and buyers to tailor the acquisition. Stock sales involve selling ownership interests of the company, where the buyer assumes all assets and liabilities. Hybrid structures blend asset and stock sale elements. 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

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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, which enables the venture capital funds to remain as 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 financial needs of the company, the future prospects of the business, 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 a significant role. Some transactions involve an outright sale of the entire company for cash, whereas others take the form of stock-for-stock exchanges. 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.

### 4.4 Liquidity Event: Certain Transaction Terms

Whether founders and venture capital investors stand behind representations and warranties can depend on the specifics of the deal structure and the negotiation between 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 USA industries, including healthcare, and have seen 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 re-alignment, and optimising capital allocation.

Predicting future trends regarding spin-offs related to generic pharmaceutical or OTC businesses is challenging. However, healthcare companies may choose to spin off these segments in order to sharpen their strategic focus on higher-growth segments of the market, such as specialty phar-

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maceuticals, biotechnology, or medical devices. While the use of spin-offs remains cyclical and subject to broader market conditions (eg, capital markets, interest rates, regulatory climate), 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 level and the shareholder level 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. The tax-free treatment of a spin-off is governed by the United States Internal Revenue Code, which provides specific 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. This type of transaction, commonly known as “*spin-off and merger*” or “*Reverse Morris Trust transaction*”, involves a two-step process whereby 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 for a spin-off can vary depending on various factors, including 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.

Companies often seek a private letter ruling from the Internal Revenue Service (IRS) - although some spin-offs are conditioned on receipt of an IRS tax ruling. 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’ fast-track programme, aiming 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 to no 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, as opposed to a 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 on the public market to launch a takeover. In addition, under the Wellman and Hanson tests, certain acquisitions of stock on the open market may be considered a tender offer, requiring the

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buyer to follow the SEC's Regulation 14D tender offer rules.

The reporting threshold is 5%. If a proposed acquisition will result in the bidder holding more than 5% of beneficial ownership in the company, the bidder must comply with the Regulation 14D tender offer regulations, including filing a Schedule Tender Offer (TO) as soon as practicable once the subject offer is communicated. Schedule TO requires disclosure of the purpose of the transaction and disclosure of any plans to make material changes to the company's structure, such as conducting an asset sale or merging it into 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), along with the submission of the tender offer documents.

## 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 security trigger compliance with the SEC's tender offer rules contained in Regulation 14D, including the requirement to file a Schedule TO. 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 law of the state where the company is chartered and involve federal disclosure requirements under SEC regulations.

## 6.4 Consideration; Minimum Price

The decision as to whether to structure a technology industry transaction as cash or as stock-for-stock depends on the financial maturity of the bidder. Established companies typically prefer cash transactions to avoid dilution of their current positions. Start-ups with high market caps and limited liquidity tend to structure transactions as stock-for-stock.

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

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in general is familiar with such contingencies, given that they are frequently used in 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 "*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 "*two-step merger*"). Other common conditions to 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.

## 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 also may be asked to comply with a no-shop or go-shop provision, as well as adhere to strict notice and determination procedures in connection with the exercise of any fiduciary out in connection with 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 to seek approval of a transaction from "*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 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, acquisition of 90% of the outstanding shares of each class of stock enables a short-term merger. Other states may have different thresholds, but 90% is common. If the bidder cannot acquire 90% of the outstanding shares in the tender offer, the parties may agree to "*top-up*" option in favour of the buyer in order to purchase enough new

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target company shares to reach the 90% threshold when aggregated with the stock acquired in the tender offer.

In addition, Delaware provides a mechanism for “*intermediate-form*” mergers under Section 241 (h) of its corporations statute. This mechanism allows the purchaser to effect a short-form merger without acquiring 90% of the outstanding stock of the target company if:

- the purchaser acquires enough stock to approve a merger under the company’s governing documents (invariably less than 90%);
- the merger agreement expressly states that it is governed by Section 241 (h) and that the merger will be completed as soon as possible after the tender offer closes; and
- the target company’s certificate of incorporation does not expressly require a shareholder vote for a two-step merger.

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

Acquisitions can be financed through the equity of the buyer – in which case, no bank documents are necessary. The ability to do equity financing is a matter of negotiation and depends on the circumstances of the transaction and the parties. Even when the buyer relies on debt financing, there is no legal or other requirement that the buyer have the loan 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.

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 in that a buyer may not require specific performance of the deal, but buyers are increasingly more likely to suffer penalties for backing out of a deal owing to lack of funding.

## 6.10 Types of Deal Protection Measures

Buyers commonly negotiate no-shop/non-solicitation provisions, which restrict the seller or the target company from soliciting other bids during the period between the 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,

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for Delaware corporations, an intermediate-form merger - following closing of the tender offer.

Short-form merger requirements vary by the state of the target's incorporation but usually require the buyer to hold 90% of the issued and outstanding shares in order 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 included with the tender offer stock.

In Delaware, where a majority of US corporate activity takes place, buyers can use an intermediate-form merger. This allows the buyer to complete a short-term merger without acquiring 90% of the target's stock (through the tender offer and/or top-up option) by acquiring enough stock to approve a merger and following the requirements of Section 241 (h) of the Delaware Corporate Laws.

Alternatively, a bidder may negotiate for a majority of board seats and/or veto/approval rights on material transactions in order 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 that the agreement does not result in a breach of fiduciary duty by the target's board. When a lock-up agreement - alone or together with another provision (eg, 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.

## 6.13 Securities Regulator's or Stock Exchange Process

In a stock-for-stock transaction where the buyer's securities are being registered via Form S-4, the registration statement is subject to SEC review, and the transaction cannot close until the SEC has completed its review and declared 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

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where a tender offer includes securities of the bidder as consideration, however, the offer period must remain open until the SEC declares the bidder's registration of the securities is effective.

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.

## 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. In the biohealth and life sciences sector, the United States Food and Drug Administration (FDA) plays a central role in 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 long and complex, taking up to 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.

Healthcare sectors involving direct patient care must comply with the local state licensing boards that oversee physicians, nurses, other professionals, and facilities. Some states require hospitals and other facilities to go through a cer-

tificate of need (CON) process before licensure. Although licensing boards directly impact the individual professional or facility, they can also impact the structure and operations of the entire business. Initial licensure can take between six months and a year. The CON process can take five to six months under normal circumstances but up to a year or more if the agency has questions or the application documents need to be resubmitted.

Any provider that will be seeking reimbursement from the Medicare and/or Medicaid government-funded health care programmes must comply with the Centers for Medicare and Medicaid Services (CMS)' conditions of payment and conditions of participation. 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.

Healthcare companies that create, use or disclose patient information must comply with the Department of Health and Human Services (HHS)' Privacy Rule, Security Rule and Breach Notification Rule as implemented and enforced by the department's Office for Civil Rights (OCR).

### 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

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transactions involving US businesses that deal with critical technologies are subject to a mandatory filing requirement. In 2024, CFIUS passed a final regulation increasing its scope of authority and increasing the penalties for violations.

## 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, even though most CFIUS notifications are voluntary, certain transactions involving US businesses dealing with critical technologies have a mandatory filing requirement. 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.

## 7.5 Antitrust Regulations

The HSR Act requires the reporting of certain transactions exceeding specific thresholds to the FTC and the Department of Justice (DOJ). The 2025 threshold for applying the HSR Act's size-of-parties test 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 about the proposed transaction, such as the parties involved, the nature of the transaction, and financial terms. Parties reporting transactions under the HSR Act must observe a 30-day wait-

ing 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. In 2024, the FTC passed amendments to the HSR Act regulations that significantly increase the extent of information provided in pre-merger notifications.

## 7.6 Labour Law Regulations

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

The NLRA is interpreted and enforced by the National Labor Relations Board (NLRB), a federal agency that 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, vari-

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ous 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, functioning as the central bank of the USA, 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 comments from the public related to the goals, objectives and effects of transactions involving healthcare providers, healthcare facilities, or ancillary products or services that are 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 individual states sharing the FTC's concern over private equity's involvement in the healthcare industry and detailing 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 come with heightened due diligence concerns for acquirers due to the high level of regulation in the healthcare industry. The typical aspects that acquirers will review in the due diligence process are the following:

- determining the types of professional services that the company provides or ancillary services that it provides to healthcare companies;
- determining the list of states where the company operates;
- determining whether the company enters into agreements with individuals or entities that provide professional services and, if so, understanding the compensation structure for such arrangements;
- 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

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- had any material refunds or adjustment 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 the HIPAA.

Evaluating the above-mentioned healthcare issues would require the acquirer's counsel to review the company's agreements and also have conversations with the company's management team.

## 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 "sectorial" or "context-specific" data protection regulation. By way of example, health data that is processed by a doctor is protected under the 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 the 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

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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, which now include medical information as part of the larger 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 when disclosed to a party reasonably likely to trade on the information and not obligated to keep the information confidential will require said disclosure to comply 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.

## 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. In the case of a public company, the board of directors must also comply with the SEC governance requirements and the applica-

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ble stock exchange rules, including disclosure obligations and the 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 are faced with 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 interests of the corporation and its shareholders

## 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 corporate governance practices of the company. 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 interests of the company and its shareholders.

Shareholder litigation challenging the board's decision to recommend an M&A transaction is not uncommon, particularly if shareholders believe that the board failed to fulfil its fiduciary duties or acted in a manner that was 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 corporation laws as well as in 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 in order to ensure that 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

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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.