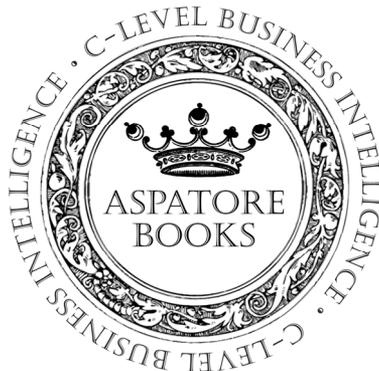


I N S I D E T H E M I N D S

Structuring Health Care Partnerships, Agreements, and M&A Transactions



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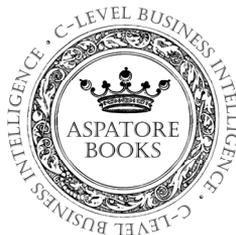
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Strategic Alliances and Partnerships in Health Care

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Introduction

It is not uncommon in the health care industry today for two or more parties to form an alliance for commercial and strategic purposes. “Strategic partnership” and “strategic alliance” are terms that are commonly referred to and are now very popular among health care consultants and advisers.¹

In health care, strategic alliances and partnerships among providers—in particular, competitors—have been a common approach to branching into new markets, acquiring costly technology or services, combining capacity or purchasing power, and achieving economic efficiencies in health care for decades. Hospital-physician joint ventures, joint operating agreements among hospital competitors, joint ventures over hospital cost centers, group purchasing organizations and shared service organizations, joint management arrangements, and operating leases are all common forms of strategic alliances that have been utilized in health care by and among providers.

This chapter looks at strategic alliances and partnerships among health care providers and suppliers (e.g., administrative or technical service providers, outsourcing firms, manufacturers, technology companies), describing the purpose, types, and approaches to developing strategic partnerships in health care. We will also discuss the role of the lawyer as deal maker in the context of a strategic partnership, as well as the principal laws and regulations that need to be considered as part of the development of any strategic partnership among providers and suppliers in health care. Finally, we will identify the elements of a successful strategic partnership and suggest some ways health care deal makers can enhance the strategic partnership’s chances for success.

Strategic Partnership and Affiliations Defined

As stated in the introduction, for purposes of this chapter, we will focus our discussion on strategic affiliations between health care providers, more specifically health systems or hospitals, and third-party supplier or business

¹ For purposes of this chapter, the terms “alliance” and “partnership” are not intended to be referred to in the technical legal sense. The intent here is to describe a business relationship that may take the form of a contract or joint venture entity that is a vehicle for a multi-faceted, strategic agreement.

partners that are not competitors of the health system. For purposes of this chapter, strategic alliances or partnerships are contractual arrangements that may or may not involve the development of a separate joint venture entity in which a long-term relationship is established for the purpose of creating a linkage between the provider and the supplier that transcends the typical commercial relationship and provides one or more strategic or competitive advantage to the parties.

Like beauty itself, the strategic aspect of the alliance/partnership is therefore in the eye of the beholder. In other words, the strategic value and purpose of a particular arrangement may be different for the two parties to the agreement. However, more and more manufacturers, distributors, and service providers in the health care industry are looking for ways to achieve strategic partnership relationships with hospitals and health systems to better bond with and support those customers. Likewise, many forward-thinking health systems have concluded that in certain circumstances, direct, multi-faceted relationships with business partners can offer meaningful value.

For example, a strategic relationship may center on the health system and a device manufacturer or distributor developing a solution to a problem that requires the input and capabilities of both parties that neither party, on its own, can fully address in an effective manner, but for which the solution provides meaningful value to each. Other strategic alliances are characterized by input into product development, joint investment in new technology or processes, research, product commercialization, alpha site or beta site testing and input, and most favored nations' pricing or terms and conditions.

There are dozens of other elements of a strategic alliance or relationship. The specific features of a strategic alliance will depend on the parties to the arrangement and their goals and objectives. From the provider's perspective, often the main objectives of a strategic partnership or alliance are to:

- Reduce costs
- Improve quality
- Gain access to a knowledgeable resource for purposes of benchmarking performance or identifying trends and strategies used by the supplier's other customers or sophisticated buyers inside or outside health care
- Generate operational efficiencies
- Develop a solution to a particular issue within the health system

On the other hand, suppliers are likely to seek:

- Security from a long-term customer relationship
- Penetration into new or previously closed markets
- Test sites for new products
- Regular feedback from valued customers on new product ideas
- Input on value-added services or pricing models or new approaches to the health care market
- Access to research and testing of any number of processes, features, and products that might have commercial value once fully developed

Accordingly, the parties to a strategic alliance may come to the table with different definitions of “strategic” and may have different priorities for the value to be obtained from the relationship. However, even where that is the case, properly structured and thought-out strategic alliances in health care among suppliers and health care systems are effective and do provide meaningful value and return on investment for each of the parties.

It is worth noting that for purposes of this chapter, we contrast the aforementioned strategic purposes from the more garden-variety arrangements, which are strictly commercial and not strategic, limited in scope and applicability, and typically short-term. For example, a standard product-purchasing arrangement where a medical device manufacturer and a health system agree to a one- or two-year commitment to offer specific products for sale at a pre-arranged price under standard terms and conditions (e.g., payment, ordering, service, repair, replacement, warranty, indemnification, termination, assignment, licensure of intellectual property rights) would not, in and of itself, constitute a strategic agreement or alliance.

A strategic alliance involving the same device manufacturer might include, for example, a long-term commercial relationship that is designed to drive product standardization among the health system’s inpatient and outpatient facilities, cost savings in the clinical environment beyond simply the particular device cost, physician in-service training and education, operational efficiencies through logistics, stocking, ordering, or perhaps utilization controls and reporting/tracking, marketing assistance, and brand development and brand recognition strategies and would also involve the study of certain additional applications of the device or use of the device in conjunction with other processes to reduce post-operative infection rates (to be monitored under the arrangement) and lower the cost of each case

without any negative impact on quality of care or patient outcomes. The by-product of this strategic alliance would be a specific solution for the partnering health care system but would also potentially create a new approach for the supplier to package its product, technology, and services to achieve measurable value for hospital or health system customers that has applicability to other current and prospective health care customers.

The Role of Strategic Affiliations in Health Care

Because of the competitive nature, low margins, and constant need for innovation in patient care and the need to meet and exceed cost and quality metrics and benchmarks, the health care industry (specifically, the hospital industry) is particularly suited for strategic alliances with suppliers and third-party non-competitive business partners. In fact, many of the outsourcing relationships that have been present in health care for dozens of years represent early-stage strategic affiliations and partnerships.

For example, hotel service outsourcing, information systems and data storage outsourcing, bio-medical equipment service outsourcing, patient accounts and collections, billing, coding, and health information management, and medical transcription are functions that have been outsourced by health care providers, including large and small health care systems, for many years. Valuable solutions to management, efficiency, cost, and accountability problems have evolved from these outsourcing arrangements. Some of these solutions have applicability outside the individual health system context and can be commercialized.

In many cases, the by-product of the strategic alliance will be intellectual property that can be commercialized and sold to other similarly situated health care providers. Below we discuss the legal implications of addressing ownership, licensure, control and financial responsibility, and risk allocation relating to the residual intellectual property produced through a strategic alliance or partnership. In some cases, technology or processes used in other industries are imported into the health care setting first as a “proof of concept,” and later as a commercial joint venture focused on health care as a vertical industry. This is not uncommon in the non-clinical functions of the health care business. Many improvements in health care food service (patient meals and nutrition), technology, data management, product sourcing, procurement, logistics/distribution, equipment service and maintenance, and electronic records management and file sharing were originally developed and perfected for other industries but imported into health care.

Strategic alliances and partnerships can involve providers and suppliers of any size. The arrangement is not specific to health systems or even hospitals of a certain size. However, as significant resources, including personnel and funding, are often necessary to accomplish the strategic objective of an alliance, health systems with minimal financial resources are less able to fully support a strategic affiliation. Further, since suppliers and vendors are not likely to perceive a benefit to certain strategic relationships (e.g., product testing, product development, or certain types of clinical research) on a small or limited scale, strategic alliances are more likely to be an option for large customers with significant demand for the vendor's products and services.

Creating Strategic Alliances

The genesis for a strategic alliance is often necessity. It is the rare exception, for example, that a health system follows a plan to create strategic affiliations with a series of suppliers as part of its annual business or strategic plan. Often, the case is that a supplier first approaches the health system with a proposal designed to attract the system as a new customer with a more expansive relationship that provides additional value to the health system beyond the traditional relationship. Having said that, for certain health systems that have significant research capabilities or that are adept at contracting and focused on maximizing value from each commercial relationship, every significant area of supply spend or overhead is a potential target for conversion to a strategic arrangement with a supplier, and those providers have planned for and solicited select vendors to engage in those relationships. Like health systems, certain suppliers are capable of and focused on turning even routine customer relationships into strategic alliances or partnerships. Strategic relationships and alliances are born from each party recognizing an unrealized potential and an opportunity to create a needed solution or value that will provide meaningful return to each party.

There is no single approach to creating strategic alliances. Generally, affiliations between provider and suppliers are for the most part opportunistic, but have the potential to be much more. The health care dealmaker plays the role of understanding the value of a particular relationship to all parties involved, as well as the benefits of the relationship to each of the parties. The dealmaker's role is to know the direction the parties are headed with respect to their respective goals and objectives and to see, at the outset, the benefit of the alliance to each party to the affiliation and the value that a broader relationship or alliance may bring.

The Health Care Law Analysis

Health care is a heavily regulated industry. There are federal and state statutes and regulations that apply to health care providers; the provider's ability to provide services and the reimbursement for those services; the provider's desire to expand or develop its business; and the nature, structure, terms, and conditions of a provider's relationships with third parties, including, without limitation, suppliers of products and services ultimately reimbursed by the federal- and state-sponsored health care programs. In many cases, what would otherwise be permissible in a non-health care context is not permitted under one of the many health care laws and regulations. Understanding the regulatory landscape and being able to structure and design strategic alliances and partnerships that comply with the federal and state health care laws and regulations is an invaluable role the health care lawyer plays relative to the development of strategic alliances or partnerships.

Since the form and substance of a strategic affiliation are varied, there is no way to provide a complete list of legal issues to consider in structuring and designing strategic alliances between health systems and suppliers. The laws and regulations governing the structure, design, and operation of a strategic alliance will depend on the parties involved, whether a new provider or third party entity is created, and the location (i.e., state) where the alliance will operate.

Structuring the Relationship to Address the Legal Restrictions

The Federal Anti-Kickback Laws

The federal anti-kickback statute, 42 U.S.C. Section 1320a-7b(b) (the "anti-kickback law") prohibits persons from paying or soliciting remuneration in order to induce another to refer business reimbursed under the federal health care programs (which include, but are not limited to, Medicare, Medicaid, CHAMPUS, TriCare, and CHIPs). More specifically, it is a felony for a party to make any type of payment, whether that payment is made directly or indirectly, overtly or covertly, in cash or in kind, that is knowingly and willfully intended to induce another to refer federal health care program patients or to order goods or services reimbursable under a federal health care program. See 42 U.S.C. Section 1320a-7b(b).

Violations of the anti-kickback law are punishable by fines of up to \$25,000 and imprisonment for up to five years. Suppliers and health care providers convicted under the anti-kickback law are subject to mandatory exclusion

from participation in the federal health care programs. 42 U.S.C. 1320a-7. In addition to criminal prosecution, the enforcement authorities may elect to pursue violations through civil actions and seek civil monetary penalties of up to \$50,000, plus three times the remuneration offered or may pursue administrative permissive exclusion proceedings. 42 U.S.C. 1320a-7a(a)(7) (civil monetary penalties and exclusion); 42 U.S.C. 1320a-7(b)(7) (permissive exclusion only)

As a criminal statute, the anti-kickback law is intent-based. In other words, to be convicted or found civilly liable under the law, the government must prove that the alleged violator knowingly and willfully intended to induce a referral or business prohibited under the law. The courts have interpreted the intent standard broadly to cover any arrangement where even one purpose of the remuneration is to obtain referrals.² Although the courts have differing interpretations of the degree of knowledge required to be shown by the government to meet the burden of proof under the anti-kickback law, the courts have generally construed there to be a requirement that the party knows that his or her conduct is wrongful.³

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services enforces the anti-kickback law. There are a few exceptions to the statute for certain discount arrangements and a small number of other arrangements.⁴ The OIG has promulgated regulations stipulating the terms and conditions of a number of narrowly drawn exceptions to the anti-kickback law.⁵ The regulations are commonly referred to as the safe harbors.

² See *United States v. Lahue*, 261 F.3d 993, 1003 (10th Cir. 2001); *United States v. David*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985).

³ The courts are split as to the level of intent the government must establish to satisfy the intent requirement of the anti-kickback law. Some courts have developed a stricter standard in which the government must show that the defendant knowingly intended to violate the anti-kickback law. See *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995); *United States v. Bay State Ambulance & Hosp. Rental Serv. Inc.*, 874 F.2d 20,33 (1st Cir. 1989); *Feldstein v. Nash Community Health Servs.*, 51 F. Supp.2d 673, 681 (E.D.N.C. 1999).

⁴ The statutory exceptions are for: (1) properly disclosed discounts or other reductions in price; (2) payments to bona fide employees; (3) certain payments to group purchasing organizations; (4) waivers of coinsurance for Medicare services for individuals who qualify for certain Public Health Service programs; and (5) certain risk-sharing and other arrangements with managed care organizations. 42 U.S.C. §1320a-7b(b)(3) (2007).

⁵ There are a total of eleven safe harbors covering the following arrangements: (1) investments in certain large or small entities; (2) investments in entities in underserved areas; (3) space rentals; (4) equipment rentals; (5) personal services and management contracts; (6) sales of physician practices in health professional shortage areas to hospitals or other entities;

Failure to meet a statutory exception or a safe harbor exception is not conclusive evidence of a violation of the anti-kickback law. Rather, the statutory exception and the safe harbors are intended to provide immunity from prosecution if all elements of the safe harbor are fully met. The problem is that the safe harbors do not cover all types of arrangements and offer only a very limited approach and structure to complicated arrangements (e.g., space and equipment rental arrangements, investment arrangements, management and service agreements, employment agreements, discounts). Therefore, a provider seeking immunity from prosecution relating to the development of a complex strategic alliance may not fit within a safe harbor, but may still be free from prosecution under the anti-kickback law.

The OIG and other federal enforcement authorities exercise prosecutorial discretion with respect to pursuing providers and suppliers under the anti-kickback law. Accordingly, there may be circumstances under which a strategic alliance between a health system and supplier implicates the anti-kickback law, no safe harbor applies, or a relevant safe harbor cannot be fully satisfied, the parties do not have the requisite intent to violate the law, and the government, therefore, determines that the law is not violated.

Because of the lack of certainty and high stakes associated with proceeding with transactions that implicate the statute but are not intended to be kickback arrangements, the OIG provides for a fact-specific business advisory opinion process through which it will issue opinion letters analyzing the specific facts and circumstances under the anti-kickback law and related civil monetary penalties provisions. The OIG advisory opinion letters are not intended to be legal precedence for a particular practice or arrangement. The OIG limits the applicability to the specific parties and facts considered in the opinion. However, the OIG publishes its advisory opinions, which are used by health law practitioners as guidance for what

(7) sales of practices by one practitioner to another; (8) referral services; (9) warranties; (10) discounts; (11) bona fide employment arrangements; (12) group purchasing organizations; (13) coinsurance and deductible waivers; (14) increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans; (15) price reductions offered to health plans; (16) practitioner recruitment activities in underserved areas; (17) subsidies for obstetrical malpractice insurance in underserved areas; (18) investments in group practices; (19) cooperative hospital service organizations; (20) investments in ambulatory surgical centers (ASCs); (21) referral arrangements for specialty services; (22) price reductions for eligible managed care organizations; and (23) price reductions offered to managed care organizations by contractors with substantial financial risk. 42 C.F.R. §1001.952 (a) – (u) (2007).

position the OIG may take with respect to arrangements that are similar, factually, to those reviewed and analyzed in one or more OIG opinion. Also, the OIG publishes fraud alerts in which specific areas of concern within the industry are identified and addressed. These alerts tend not to be specific to one party, but rather serve to inform the entire industry of trends that the enforcement authorities view as potentially problematic.

In the context of strategic alliances between providers and suppliers, there is the potential for the anti-kickback law to be implicated, depending on the particular arrangement, since the provider may be purchasing, leasing, or ordering, and the supplier may be arranging for or recommending the purchase, lease, or order of products or services ultimately paid for under a federal health care program. Consequently, the strategic alliance or partnership will need to be evaluated to make sure the anti-kickback law risk associated with the arrangement can be mitigated. As a general rule, to the extent that the strategic alliance or partnership combines several separate transactions or component deals into one relationship, health care counsel will need to ensure, at a minimum, that each component part of the deal is defensible and does not involve the payment of remuneration in exchange for referrals or other business paid for by the federal health care programs. Accordingly, being able to demonstrate through independent third-party valuation that the consideration exchanged between the parties as part of the transaction is fair market value for the services, space, assets, equipment, supplies, etc., is a principal element of the defense of any arrangement under the anti-kickback law.

The health care lawyers involved in structuring the relationship and negotiating and documenting the transaction will need to be comfortable that the risk of their client being prosecuted under the anti-kickback law is minimal and the transaction is defensible. Each client will have its own risk tolerance level. However, since the statute is criminal, and the penalties can include federal health care program exclusion, creating a deal structure, economic terms, and other terms and conditions that comply with or are defensible under the anti-kickback law is paramount to any strategic alliance involving health systems and suppliers.

Tax-Exempt Organization Requirements

The majority of hospitals and other institutional health care providers in the United States are nonprofit organizations that are exempt from federal income taxation under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the Code). Exempt status under Section 501(c)(3)

connotes an array of economic and operational advantages. In addition to avoiding federal (and, generally, state) income taxation, Section 501(c)(3) providers also may receive charitable contributions that are tax-deductible for donors, may borrow funds at preferred rates through tax-exempt bond financing, are not subject to federal unemployment tax provisions, and often may avoid state and local property and/or sales taxes. Collectively, these advantages to U.S. health care providers have been valued in the billions of dollars. Thus, in structuring strategic relationships, tax-exempt providers must exercise extreme caution in ensuring that the terms of such relationships do not inadvertently jeopardize continued exempt status or result in other adverse tax consequences.

Private Benefit, Inurement, and Excess Benefits

Section 501(c)(3) provides exemption for organizations that are organized and operated exclusively for charitable purposes (which include the promotion of community health). In situations where an exempt organization operates to further private interests on a more than insubstantial basis, the organization may be said to have engaged in prohibited “private benefit.” In cases where private benefit accrues to persons who are “insiders” in relation to the organization (for example, its founders, directors, officers, or key employees), the organization may be found to have engaged in prohibited “inurement.” Inurement may be best viewed as a subset of private benefit. At least in theory, any amount of inurement is sufficient to risk an organization’s Section 501(c)(3) tax-exempt status; by contrast, private benefit can exist on an insubstantial basis.

Until 1996, the only remedy available to the IRS to deal with situations involving private benefit and/or inurement was the revocation of the organization’s exempt status. That remedy, however, was often disproportionate to the degree of harm and, moreover, was misdirected in the sense that it punished the organization and its charitable beneficiaries rather than the wrongdoers. In 1996, Congress enacted new Code Section 4958, allowing the IRS to impose penalty taxes known as “intermediate sanctions” in effectively the same circumstances in which inurement can be said to occur. Specifically, when a tax-exempt organization engages in an arrangement with a person who holds a position of influence in relation to the organization (referred to in this context as a “disqualified person”), and the terms of that arrangement are at other than fair market value or other than reasonable compensation (at the organization’s expense), an “excess benefit transaction” has occurred. In these cases, the IRS may impose penalty taxes on the participating disqualified person at a rate of 25 percent,

and, if the transaction is not undone, through a process known as “correction,” in a timely manner, another tax at a rate of 200 percent. The IRS also may assess penalty taxes on the leadership of the organization (referred to as “organization managers”) who knowingly approved the arrangement, at a rate of 10 percent up to a maximum of \$20,000 per transaction or arrangement.

Because health care institutions are among the largest tax-exempt organizations in the United States today, and regularly undertake substantial financial transactions, the concepts of private benefit, inurement, and excess benefits necessarily loom large. Providers seeking to structure arrangements with strategic partners must consider whether, based on past and continuing relationships, either the strategic partner or its representatives could be considered to occupy a position of substantial influence in relation to the provider (and thus may be classified as disqualified persons)—if so, the stakes are ratcheted up, since a deal later found to be at other than fair market value may result in the imposition of substantial taxes to players on both sides of the arrangement. An exempt health care provider may undertake certain procedural measures to reduce the risk of a future IRS challenge, involving the submission of the proposed arrangement to the organization’s board of directors or an independent committee thereof (that is, acting free of conflicts of interest), with that board or committee reviewing independent data confirming that the terms of the proposed arrangement are comparable to fair market levels, and the board or committee’s conclusions contemporaneously documented.

Even in cases where a strategic alliance does not involve disqualified persons, however, it is possible that the arrangement might be said to result in substantial private benefit. The devil will be in the details, undoubtedly, with the first inquiry being the organizational structure to be used. In particular, strategic arrangements structured as legal partnerships, limited liability companies, or S corporations present various tax complexities and should undergo thorough tax analysis. See, e.g., Rev. Rul. 98-15, 1998-1 CB 718; Rev. Rul. 2004-51, 2004-22 IRB 974.

Unrelated Business Income Tax

Although Section 501(c)(3) organizations generally are exempt from federal income taxation, it is often the case that a Section 501(c)(3) organization will engage in certain activities that go outside the sphere of its exempt purposes. In such cases, the organization must pay tax (known as unrelated business income tax, or UBIT) on its income from those activities. See

Code §§ 511-514. The purpose of the UBIT is to ensure that tax-exempt organizations do not obtain an unfair competitive advantage against their commercial, for-profit counterparts undertaking substantially the same activities but on a taxable basis.

The UBIT is imposed on an organization's net income from "unrelated trade or business" activities. To be an unrelated trade or business, the activity must constitute a "trade or business" (generally meaning that there must be a profit motive), must be "regularly carried on" (in a manner akin to that employed by commercial counterparts), and must be "not substantially related to exempt purposes." If those three requirements are met, revenues from the activity will constitute unrelated business income. An organization's gross unrelated business income, however, may be offset by deductions for expenses directly connected with the conduct of those activities.

As a general matter, the consequences of UBIT are limited to the payment of income tax. However, in cases where an organization derives a substantial portion of its overall revenues (on either a gross or net basis) from unrelated trade or business activities, such circumstances may suggest that the organization has a substantial non-exempt purpose. This could jeopardize the organization's continued tax-exempt status.

Tax-exempt health care providers considering strategic relationships must evaluate whether proposed arrangements have the potential to result in unrelated business income. If so, the provider will need to consider the economic and operational implications, including the potential tax liability and implications for the provider's other activities. In some cases, it may be advisable for the provider to cause the strategic relationship to be undertaken through an affiliated for-profit, taxable subsidiary in order to avoid potential adverse tax consequences for the provider itself.

Private Use of Bond-Financed Facilities

As indicated above, health care institutions described in Code Section 501(c)(3) often are eligible to borrow funds through tax-exempt bond offerings. In substance, such arrangements typically involve a state or local body or authority that issues bonds through a sale to investors. The proceeds of the bonds are lent by the governmental body or authority to the tax-exempt health care provider. Under various Code provisions, the investors who purchased the bonds are not subject to federal (and sometimes, state) income taxes on the interest payments they receive on the bonds. See Code §§ 103, 141 and 145. As a result, the investors are willing to accept a lower

rate of return in comparison to what they might demand from other investments; this translates into a lower cost of borrowing for the health care provider.

Given the benefits of tax-exempt financing, however, various rules exist to ensure that for-profit, taxable persons or organizations cannot effectively share in those benefits. This so-called private use may arise in a variety of forms, including leases and certain management arrangements or service contracts. In fact, if the exempt organization itself is using a bond-financed facility in an activity that constitutes an unrelated trade or business, that, too, will constitute private use. Private use is not altogether prohibited. However, no more than 5 percent of the total proceeds of a bond issuance may be used to finance facilities that are subject to private use. See Code §§ 141(b)(1) and 145(a). In practice, this threshold generally is further reduced by issuance costs, which are frequently counted against this number.

Accordingly, if a proposed strategic relationship between a tax-exempt health care provider and one or more for-profit parties will involve any use or occupancy of a bond-financed facility, the arrangement must be reviewed to determine whether it would result in private use. In some cases, the particular activities contemplated to be undertaken may be among those deemed by regulation not to result in private business use, such as contracts for services that are solely incidental to the primary functions of the facility (for example, arrangements for janitorial services, office equipment repair, hospital billing). See Treas. Reg. 1.141-3(b)(4)(iii)(A). In other cases, contractual arrangements may need to be structured to fall within certain safe harbors that have been established. See Rev. Proc. 97-13, 1997-1 CB 632. If an arrangement fits within a safe harbor, it will not be considered by the IRS to result in private use. Generally, the safe harbors focus on the duration of the arrangement, the nature of the compensation to be provided by the health care organization to the service provider, and whether there are any relationships between the parties that may preclude the effective exercise by a party of its rights under the arrangement.

Antitrust Law Considerations

Health care providers contemplating strategic alliances need to be cognizant of restraints imposed by antitrust law. Failure to do so can lead to litigation or an investigation and possibly enforcement actions by federal and state authorities. Antitrust litigation is often expensive, and the law provides for three times actual damages in such cases, so money spent on sound advice to avoid antitrust risks is often well spent. That is particularly true when a

firm engages in a venture with another firm that, in the absence of the venture, would be an actual or potential competitor. Even strategic alliances with suppliers and customers, however, can raise antitrust concerns risks.

Antitrust Safe Harbors

Antitrust fears, however, should not prevent providers from considering joint ventures. Collaborative activities that create pro-competitive efficiencies that benefit consumers are encouraged by antitrust authorities. Indeed, most hospital ventures to purchase or share the ownership cost of, operate, and market high-tech or other expensive equipment do not create antitrust problems. Antitrust concerns may arise, however, where hospitals that could recover the costs of individually purchasing equipment nonetheless enter into a venture. The federal government has published guidelines that govern such ventures, as well as ventures involving specialized clinical and other expensive health care services and joint purchasing arrangements to guide businesses to comply with the law.⁶

Most Favored Nations Pricing and Bundling

One element of many strategic partnership transactions that warrants antitrust review but is often pro-competitive is best price or most favored nation (MFN) clauses. Such clauses are standard devices used to obtain low prices, but they may be challenged by the government when they discourage price-cutting or encourage coordinated pricing by competitors.

Transactions that contemplate bundled pricing can also raise antitrust concerns and have received substantial attention in recent years. Bundled discounts or rebates are similar to volume discounts, but they are awarded when customers purchase products across multiple product lines, and some have expressed concern that they may impair competition when the discount cannot be matched by firms that compete in only one product line. Bundled pricing is most likely to be problematic when engaged in by firms with large market shares, and its prices would be predatory if the entire discount were attributed to the products on which the firm faces competition.⁷ Recently, there have been several bundling cases filed against

⁶ *Statements of Antitrust Enforcement Policy in Health Care*, issued on August 28, 1996, 4 Trade Reg. Rep. (CCH) ¶13,153.

⁷ See *Lepage's Inc. v 3M*, 324 F.3d 141 (3d Cir. 2003)(en banc), cert. denied, 540 U.S. 807 (2003). See also, Compl., *Genico, Inc. v. Ethicon Inc.*, (E.D Tex. Filed Oct.

major suppliers in the health care field relating to alleged bundling in all different forms, supporting the reality that antitrust bundling disputes are prevalent and of great concern in the health care industry today.⁸

Own Use

Because many health care providers are nonprofit institutions and frequently purchase commodities at preferential prices, in structuring ventures, they should be cognizant of the Non-Profit Institutions Act.⁹ That statute provides that antitrust restrictions against discriminatory pricing do not apply to purchasers of supplies by hospitals and other charitable institutions if the purchases are “for their own use.” As hospitals have become comprehensive health systems and transfer commodities purchased at favorable prices to affiliated and non-affiliated entities, they must consider whether the exemption applies.¹⁰

Consequently, as highlighted above, careful antitrust review by competent antitrust counsel should be conducted in the early stages of developing and structuring a strategic alliance or partnership.

Intellectual Property Rights and Issues

Perhaps the most overlooked legal aspect of strategic alliances and affiliations is the intellectual property issues. In virtually all health care alliance and partnership deals between providers and suppliers, the issue of what becomes of the residual intellectual property shared with or created by the parties to the alliance is a vital concern that is often not given enough attention. Further, the issue of protecting the intellectual property brought to the alliance by the constituents to the deal is important, as well. Accordingly, health care dealmakers need to consider early the intellectual

15, 2004) (No. 5:04-CV-00229) (complaint challenging discounted bundles of surgical sutures and instruments).

⁸ On February 21, 2007, a putative class action suit was filed against C.R. Bard Inc. and affiliates of Tyco International, claiming that bundling discount and rebate tactics were used to eliminate competition from catheter manufacturers. On March 28, 2007, a suit was filed against Becton, Dickinson and Company alleging that bundling discount tactics were employed to eliminate competition for syringes.

⁹ 15 U.S.C.A. § 13c.

¹⁰ See *Abbott Laboratories v. Portland Retail Druggist Ass’n*, 425 U.S. 1 (1976) (holding that sales fitting within the “own use” exemption are sales to inpatients, emergency room patients, outpatients for use on hospital premises, inpatients and outpatients for use at home, hospital employees and medical students for their own use and medical staff for their own personal use).

property issues in structuring, negotiating, and documenting alliances or partnerships between health care systems and suppliers.

Depending on the purpose of the affiliation, intellectual property will be shared or created because of the affiliation between the parties. In some cases, a legal entity may be developed for the purpose of conducting research, developing a commercial use for a product or idea, or modifying existing intellectual property that is the property of one of the parties to the alliance.

The intellectual property used or created may come in the form of copyrightable subject matter, trademark or service-marked goods or services, “work for hire,” or patentable products or processes. To be sure, there is no single formula for dividing or sharing intellectual property rights in the intellectual property that results from a strategic alliance or partnership. The guiding principal is what will make sense and what is fair and reasonable for the parties under the circumstances. What is at risk is the rights to own, control, and exploit the residual intellectual property and the intellectual property that is contributed to the alliance or partnership. Often, this is the entire value of the partnership in commercial terms. Accordingly, the parties to the alliance or partnership must be careful to articulate the particulars of ownership, control, and use for any intellectual property contributed to or produced by the alliance. Failure to address these issues will result in the law appropriating ownership and control, which may impose a harsh reality on one or more of the parties to the alliance. For example, the law would provide ownership and control of copyrightable subject matter (e.g., computer-readable source code, research data, or process manuals) to the author, which appropriation may not necessarily account for the time, investment, and contribution of others. Trademarks, for example, are appropriated under the law to the first to use in commerce, which may not account for the contribution or development of all parties to the alliance that may otherwise have a claim to ownership and control of the marks. Patents are appropriated to the inventor, which may not take into account contributions of certain foundational technology or development funding, beta site testing, or scientific research, all of which was contributed under the premise that certain ownership and control rights in the patented work would be shared with the contributor.

Accordingly, resolving the ownership, control, and other rights specific to intellectual property is essential to any strategic alliance. Not dealing with these issues may result in significant hardship and financial loss to the injured party that may not be recoverable. Pushing these matters to the front of the discussions between the parties to a strategic alliance or

partnership is a “best practice” for the health care lawyer to consider in order to ensure the important elements of the partnership are not left undecided until the end, when the negotiating leverage and circumstances have changed or, worse, never addressed and left for the law to appropriate.

The Key Drivers of Success

As you can see from the brief summary of legal issues above, there are a number of legal issues to consider in structuring strategic alliances. Not only are there a number of legal issues to consider, but there are also a number of business and operational issues. Since strategic alliances and partnerships may take many forms, having varied purposes, and cover any number of topics, from technical or scientific research to testing of a commercial application of a particular product and re-engineering the work flow and cost structure of a hospital department, there is not one standard approach to ensuring a successful strategic alliance. However, a number of factors are common to the most successful alliance relationships. The list below attempts to summarize the key success factors.

To properly set the stage for the key success factors, you need to have in mind the flow of the typical deal and the point in time in which health care counsel is typically brought in to the matter. In the great majority of cases, the strategic alliance or partnership is proposed by a supplier or third-party vendor to the provider. The supplier makes a proposal to the chief financial officer, vice president of business development, or vice president of corporate purchasing in an attempt to solidify the relationship with the customer through a transaction or partnership that reaches deeply into the organization, covers several different areas and products, stipulates a seven- to ten-year term, and generates significant “value-added” benefits for the health system. The health system desiring to move ahead has already informed the supplier’s sales team that they want to move ahead, would like to look at the supplier’s form template sales agreement, and would be willing to agree to the relationship if certain price concessions, in addition to those offered in the original proposal, can be agreed to by the supplier. The health system’s medical staff may also be aware at this time of a pending alliance with the supplier, and those on the medical staff with influence over their colleagues who are of the opinion that the alliance would be helpful to them are pushing for the health system to complete a transaction and affiliate or partner with the supplier. With this as the typical foundation, the health care lawyer and dealmaker will be asked to “get the deal done quickly.”

With that as background, the following is a list of best practices health care lawyers may deploy in developing and managing a strategic alliance or

partnership transaction on behalf of either their health care system or supplier client. Additional detail and examples are provided on some of these points in the Deal Strategies section of this chapter, below.

1. Start at the top of your client's organization; get appropriate and clear direction; vet the direction internally; understand the major pressure points; and determine, on the front end, alternatives for handling issues that arise in negotiations that are acceptable to your client.
2. Form an internal team of subject matter, finance, supply chain, information technology, and operations experts who are accountable for the success of the strategic alliance or partnership. Use this internal team to educate yourself on your client's needs, the strategy and the approach likely to be taken by your counterparts on the other side, and the operational details that will need to be addressed as part of any definitive strategic agreement.
3. Make sure senior management supports your negotiating strategy and approach to the strategic alliance or partnership before you proceed.
4. Review carefully, with competent legal experts, the antitrust, anti-kickback, state licensure, or certificate of need law requirements, tax, and other legal implications of the proposed relationship. Focus on the intellectual property being contributed, licensed, or created, and document the specifics of those rights each party will have relative to the constituent and residual intellectual property.
5. Communicate and test your proposals and deal terms with your proposed partner before finalizing, and be prepared to answer the question, "Does your partner benefit equally in this deal, and how?" Do not surprise your proposed partner in the negotiations with major sea change in a written counter-offer without first broaching the concept in discussion and briefing them on the intent and objective.
6. Reduce the risk of and potential negative fallout from miscommunication and over-communication by centralizing the point of contact in one representative of your client.
7. Keep in mind (and reflect it in your deal structure, contract or partnership governance, and performance accountability terms and conditions) that virtually all of strategic alliances and partnerships depend on leadership support, quality managers involved, and excellent institutional "chemistry" (i.e., open lines of communication and a collegial, fair approach to the relationship) from each of the constituent

components of the alliance/partnership. Together these factors form the secret ingredients to success for strategic relationships. Note that it cannot be created, and it cannot be mandated by contract, but its absence is the leading cause of failure in those strategic alliances or partnerships that fail.

Deal Strategies

The Health Law Attorney's Role and Value in Developing Strategic Alliances

As dealmaker and health lawyer, your value to a strategic affiliation is in structuring the transaction to comply with the law and meet the parties' objectives, negotiating the terms and conditions, and documenting the transaction. This is what your client will expect. In addition, significant value to your client can be added in this role to the extent that you can work with your client to understand how this alliance or partnership fits with its ongoing business plan. Moreover, understanding the client's technical and operational requirements specific to the equipment or technology being purchased or furnished or the services being outsourced or provided, for example, will be important to add to a definitive agreement and will provide for a clear statement of intent in unambiguous terms. Finally, understanding the benchmarks, service levels, and performance metrics applicable to the products or services covered by the alliance or partnership will result in better constructed agreements that are easier to enforce.

You need to start at the top of the organization to get the necessary direction. Meeting with the senior leadership in charge of the initiative (e.g., chief executive, chief financial, chief information, or chief operating officer) to fully comprehend and appreciate the business objective for the strategic alliance or partnership is highly recommended. You will need to ask for any documents or internal materials generated in support of the strategic transaction prior to your involvement. Further, any previous strategic partnership contracts or organizational documents prepared or agreed to by your client will be useful and will illustrate how another arrangement may have been structured by the client in the past. Prior agreements will also give you an idea of the primary business and legal issues and what your client has been willing to agree to in the past.

Armed with an understanding of where your client desires to go with the strategic transaction, you will now be in a good position to begin to expose

yourself to the additional details of the strategic alliance or partnership and the important legal, structural, and operational issues you will need to address and/or resolve. To be effective in your role as attorney and dealmaker, you will need to understand the legal issues, have an excellent comprehension of the key business drivers, understand the unique characteristics that each alliance partner brings to the table, have knowledge of how similar arrangements are structured and defined by the competition, and have a keen understanding of how to generate leverage in the negotiations that will further your client's interests. The most effective way to achieve the appropriate level of knowledge and experience in all these areas is to have firsthand experience earned through being involved in several similar strategic transactions.

However, short of having a number of similar deals under your belt, the next best approach is to build a team of internal resources that collectively constitute the requisite knowledge required to conduct effective fact-finding and due diligence relating to the proposed strategic relationship.

The most effective way to ensure the appropriate knowledge transfer and insight is to build internal strategic alliance teams among the technical, legal, and operational experts within your client's organization. This team should be staffed to constitute the subject matter experts, financial experts, and market experts relating to the strategic initiative and its component pieces. All of the background work, market studies, reimbursement analysis, competitor analysis, industry benchmarks, performance metrics, and operational needs should be directed to and shared with this team. As legal counsel, your highest and best use will be to ask the right questions; understand the market and environment; understand the issues and problems the alliance is designed to address; understand the potential shortcomings, fallout, and downside of the alliance or partnership and where your client may be exposed to business, legal, or financial risk; and then use that information to develop the roadmap and the outline for the business deal, agreement, and legal structure. In addition, as legal counsel, you will need to devise a strategy to consummating the alliance or partnership, including where it applies to your client, a strategy for exerting leverage through competition, or, in the alternative, achieving only some of the benefits of the desired alliance or partnership if a full-fledged alliance or partnership cannot be agreed upon by the principals.

Your skills in asking questions, conducting fact-finding and due diligence, and critically reviewing business plans, strategic plans, financial statements, and market analysis will be tested. The purpose of the team approach is to

have a group of friendly experts able to guide your understanding and help you “tease out” what is vital to the strategic alliance or partnership in terms of economic results, performance outcomes, service levels, final product, research, technology development, and other similarly important aspects of the deal.

Once you have a comprehensive understanding of your client’s objectives relative to the strategic alliance or partnership, its operational requirements, performance standards, economic requirements, alternative plan, and options if a strategic alliance cannot be agreed upon with the preferred partner, and the other relevant issues, you will need to brief your client’s leadership team on your understanding of the deal and the issues and obtain senior management’s approval of the deal structure, terms and conditions, and negotiating strategy to be deployed. Approval and buy-in from senior management accountable for the outcome of the strategic alliance or partnership are vital to you as legal counsel, since not having clear direction and a complete understanding of how far your client wants to go to facilitate this strategic alliance, as well as its minimum expectations, is essential to your establishing an effective negotiating strategy and posture.

It is also important at this juncture to make sure that the operations team is in sync with senior leadership. This is the second purpose of revisiting the strategy, approach, and key issues with senior leadership. Sometimes this exercise identifies a major divergence of opinion within the client’s organization. In this case, legal counsel will need to identify the issue or potential issue and facilitate a final decision being made by senior management. For example, it may be that senior management has decided that the market-leading health system should be the candidate in a particular market with a right of first opportunity for being offered a specific strategic partnership opportunity with the supplier. The operations team may view the offer as exclusive to the market-leading health system and not appropriate for the other health systems in the market. This discrepancy needs to be articulated and confirmed, and if there is a divergence of opinion, legal counsel will need to understand the rationale for both sides and ensure that senior management is fully informed of the issues and desires to proceed according to the original plan in light of the merits of the operations team’s arguments to the contrary.

Negotiating Strategy

When negotiating and structuring a deal, it is also important to understand what motivates both parties and the strategy, goals, and financial expectations of each party to the transaction. Not understanding the

motivations from each side will hinder your ability to explain and persuade the other side of the merits of your position.

The goal with any strategic alliance or partnership is long-term success and return on investment. Therefore, pushing ahead with a zero-sum approach, as opposed to a win-win approach, will not achieve the goal. Having said that, as legal adviser and dealmaker, your job is to know the market and to prepare alternatives if your client reaches its limit and negotiations end. If you are counsel to the health system party, you will need to have alternate suppliers and offers from willing suppliers. Sometimes the use of a request for proposal (RFP) process is useful in knowing the market, the players, and the willingness of certain suppliers to concede to your client's demands. In other cases, an informal process where non-binding term sheets are prepared or general agreement in principal is reached is equally effective.

If you are counsel to the supplier, you will need to be secure in your knowledge of what structure, terms and conditions, and economic results make sense to your client and how much the relationship means. The best counsel to suppliers is very clear and up front on the limits they are not able to exceed with a particular arrangement for business or legal reasons. These counsel have alternative solutions available to consider and also are quick to go back to their clients during negotiations and confirm the client's position and offer additional advice, reinforcing either the client's position or an alternative position, whichever is in the client's best interests from a legal and business risk perspective.

Easy and Challenging Negotiations

In health care negotiations, the allocation of business risk, allocation of intellectual property rights or other assets brought to or produced by the alliance or partnership, accountability (penalties) under performance benchmarks or standards, and the economic terms of the relationship are often the most heavily negotiated aspects of a strategic alliance or partnership. This should not be surprising, as these areas are typically hard fought in any negotiation. Further, any non-solicitation, exclusivity, or rights of first opportunity provisions consume significant amounts of time.

Other commonly negotiated areas include the termination provisions, legal compliance and record-keeping, audit and reconciliation provisions, and assignment, change of control, and confidentiality (including HIPAA requirements applicable to protected health information) provisions. These may not always be the most important aspects of a deal, but generate a lot

of interest, since each is an important right and has embedded in it a meaningful aspect of the value of the deal.

More challenging negotiation points are issues that may involve the structure of the transaction, the tax aspects, the impact on the health system's bond covenants or tax-exempt status, issues that affect the supplier's accounting or revenue recognition, or control of the partnerships or other legal entities created as part of the strategic alliance. These issues are more challenging because typically there are a limited number of ways to resolve the problem, and they each represent an extreme. For example, lack of control of a related entity for the health system or a subsidiary, in the case of the supplier, will create tax and accounting exposure for each that cannot be resolved by sharing control or "splitting the baby in two." In fact, in both cases, that reasonable standard approach will create a significant problem for each side. Therefore, in this case, control by one party with meaningful minority partner veto rights is a solution likely to be deployed, as opposed to giving neither party to the joint venture control over the entity.

The Client-Attorney Relationship: Best Communication Practices

Preventing miscommunication and inappropriate communication by centralizing the source of contact among the parties and limiting each side's ability to "go above the head" of a party negotiating the deal is a common and proven tactic. For each side to the strategic alliance, there will be moments in the negotiation where, to resolve an issue or push acceptance of a request for an important concession, one party seeks to make contact and influence a leader in the other party's organization who is not intimately involved in the discussions or the initiative. This technique is very common and has resulted in the breaking-off of many negotiations and has destroyed many excellent business relationships in the past.

For the health care lawyer managing the negotiation of a strategic alliance, it is important to understand the complex nature of the constituencies and politics within every health system. The fact is each health system has board members, management and administration, the patient community, the rank and file staff, the medical and clinical staff, payers and insurers, and the business community to consider with every transaction, every program, and every decision. As you will quickly note, these constituencies have differing interests that are not necessarily aligned.

As a supplier or counsel to a supplier, it is more effective for you to work within the system and not irritate the politics among the constituencies.

Having said that, it is human nature to want to remove barriers and expedite solutions. There is no right way to approach this problem.

One suggestion would be to build a central point for all communication who is the chief negotiator for each party. All communication, internal and external, would be circulated through that individual (or individuals) and, in the case of a stalemate or breakdown in negotiations, the parties would also agree to elevate the matter to one or more senior executives and their counterparts on the other side for resolution of the deadlock or removal of any barriers in the negotiations. This is a similar approach to the deadlock resolution process used in partnership agreements. The concept would be to agree to work through a central channel and agree on those issues that could be discussed outside the central channel.

The key element of any effective deadlock resolution process is to have knowledgeable outlets in the chain of command who review the matter on behalf of each party. Neither party is served well if the executive asked to intercede to resolve an impasse is not fully briefed on the relationship or the specific deadlock issue and/or the rationale behind the position his or her side has taken and one or more acceptable alternatives to resolving the impasse, which may or may not have already been discussed by the principals involved in the day-to-day discussions.

In the end, business people respond to well-devised rules and processes. Rules, process, and order create a sense of openness and fairness that business people appreciate and will abide by, assuming it is applied across the board. Therefore, health system counsel should approach many aspects of negotiating a strategic affiliation with a supplier with a mind toward creating structure, process, and rules and in applying those rules evenly among all suppliers engaged in negotiations or competitive bidding specific to a strategic alliance or partnership with the health system.

Final Thoughts: Role and Enhancing Effectiveness

In order to keep an edge in this industry as health care counsel, the best advice is to constantly stay up-to-date, and seek and digest information in the following areas and through the following means:

1. *Legal:* In addition to understanding the law and developments aforementioned, principal legal areas described in the section on structuring the relationship, it is important for counsel to both the

health system and the supplier to be familiar with the OIG's advice on hospital corporate compliance plans and corporate compliance plans for suppliers. Staying abreast of the OIG advisory opinions and fraud alerts relative to the anti-kickback law and the civil monetary penalties provisions is also worthy of time investment, irrespective of whether you represent health systems or suppliers to the industry.

2. *Post-implementation performance, performance issues, and results:* Following up with your clients on the actual post-implementation performance and outcome is vital to the health care attorney and dealmakers. Knowing the pitfalls, performance issues, and strategies deployed to resolve conflicts or operational issues will educate you on the issues that can or should be better addressed in agreements and how, in practice, the parties ultimately overcome stumbling blocks.
3. *Network development:* Periodically, you should touch base with counsel for the other side of the strategic transaction to understand how the strategic partnership is proceeding from the other side's perspective and what other similar transactional relationships have been developed since the transaction with your client. Knowing how business for the other side has been affected and what is going on in the market is useful information, to the extent it is not confidential and can be disclosed by counsel for the other side.
4. *Database development:* Seek, collect, and categorize information from public sources, including trade journals, SEC filings, subscriber databases, newspapers, press releases, and consultant reports relative to the type, nature, number, and key economic characteristics of strategic relationships and each of the component parts. Having a reliable database will give you a lexicon of cutting-edge alternative strategies and approaches to strategic transactions, potential business opportunities and areas to exploit, unique organizational structures, important industry metrics and benchmarks, and alternative ways to align economic incentives.

This chapter is not intended as a comprehensive how-to manual with respect to either the full spectrum of legal issues or the deal making strategy or alternatives. However, the summary of the legal issues, best practices, and deal strategies contained in this chapter form the basic foundation for structuring, negotiating, and completing strategic alliances and partnerships between health systems and suppliers.

Strategic alliances and partnerships are and will continue to be important relationships for health care suppliers and health systems. Understanding the various issues and approaches to take with respect to strategic relationships before moving forward with these very complex arrangements is recommended and the main objective of this chapter.

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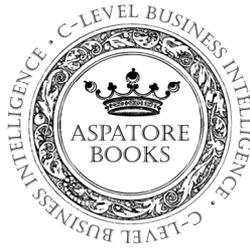
From 1992 until 1998, Mr. Olderman served as associate general counsel to Premier Health Alliance (now Premier Inc.), one of the largest group purchasing organizations. Since then, he has counseled and advised group purchasing organizations, suppliers, and providers regarding procurement, outsourcing, and affiliation strategies designed to reduce supply-chain costs, maximize efficiencies, and achieve or maintain best practices.

Mr. Olderman is also vice president of Innovative Health Strategies LLC (IHS), the procurement and outsourcing consulting firm affiliated with the firm. In his role with IHS, he structures, negotiates, and oversees the implementation of procurement and outsourcing arrangements on behalf of hospitals, health systems, and academic medical centers, with a principal focus on materials management, hotel services, revenue cycle, HIM, and temporary staffing.

Additionally, Mr. Olderman represents hospitals, academic medical centers, faculty practice plans, group practices, medical device manufacturers, provider joint ventures, and health care technology companies in corporate, health care compliance, managed care contracting, and merger and acquisition transactions. Recently, he has undertaken the representation of a technology joint venture seeking strategic advice and guidance relative to its launch into the health care market.

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