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Professional Perspective

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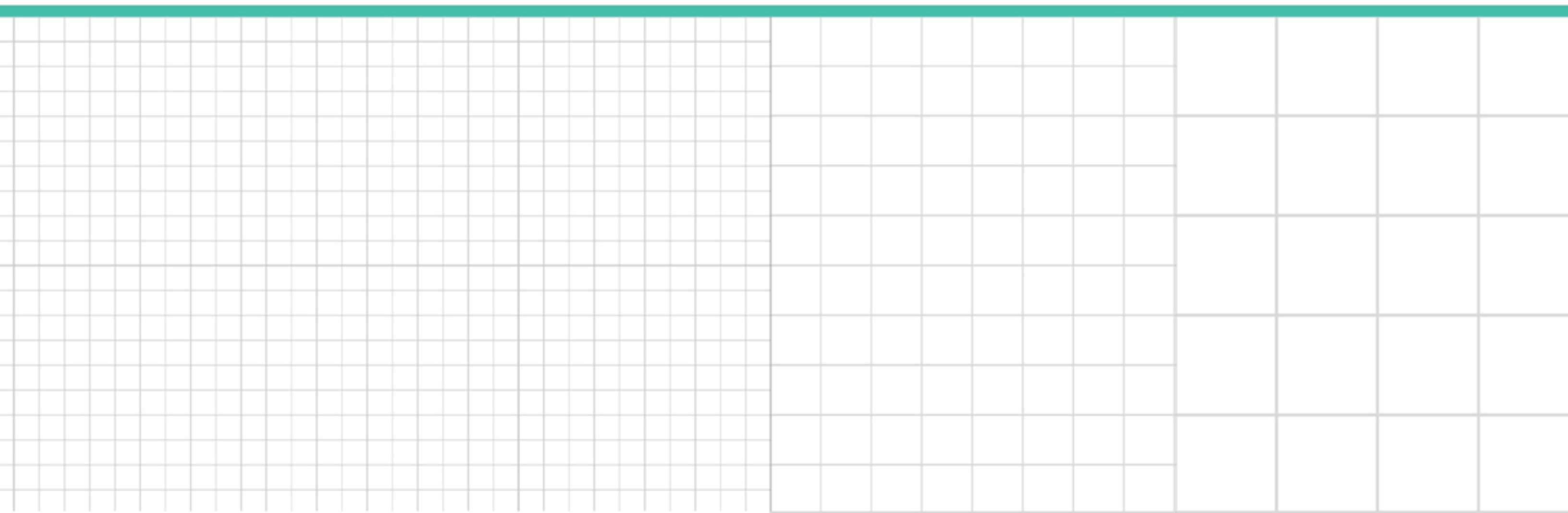

Vertical Integration and Firewalls in Health-Care Transactions

Contributed by Timothy M. McCrystal, Adrianne Ortega, David A. Young, Ropes & Gray

Driven by a desire to reduce cost, improve care, keep up with competitors, and participate in evolving reimbursement programs, health-care providers are increasingly undertaking vertical integration transactions. While these transactions present opportunities for health-care organizations to expand their operations, they may also present a variety of legal risks related to the sharing and use of information and data.

Vertical integration is an expansion up or down the service or supply chain beyond a company's current line of business. In the health-care industry, vertical integration translates to organizations offering, directly or indirectly, a broader range of services on the continuum of the delivery of health-care services. Examples of vertical integration in the health-care industry include CVS Health's acquisition of insurance company Aetna, UnitedHealth's planned acquisition of DaVita's physician group, Cigna's acquisition of Express Scripts, a pharmacy benefit manager, and Medtronic's 2015 acquisition of Diabeter, a diabetes clinic and research center.

Health-care organizations that seek to integrate vertically should consider the attendant legal risks, including antitrust, confidentiality, and conflict of interest concerns, among others. To address these issues, acquirers should consider whether organizational and/or operational separation of certain functions of the combined organization is appropriate. These structural and/or operational constructs are commonly referred to as "firewalls."

This article will discuss potential legal risks that arise in the context of vertical integration, and key issues to consider when creating firewall structures.

Firewalls

Firewalls may help mitigate the legal and conflict of interest risks involved with vertical integration by insulating an organization, or a part of it, from sharing information that increases an organization's exposure to risk. Examples of this type of information include personal health information, and data belonging to an entity that competes with an organization's vertically integrated business.

Firewalls may be set up within the different parts of an organization, as well as between companies and other parties. The elements of a firewall may include structural, technical, or operational separation of one or more of the following business components:

- Separate organizations, to create a clear line of demarcation between the operations of affiliates
- Management and employee teams, to ensure that business objectives, financial goals, pricing, and compensation are not connected with the performance of the firewalled organization
- IT systems and servers, to limit flows of sensitive or protected data between organizations, such as patient or competitor data
- Compliance programs, with separate policies and procedures, to ensure that proper reporting mechanisms are in place for each organization and to ensure that both organizations property maintain the firewall
- Marketing and sales, to create independent business strategies, reduce potential for conflicts of interest, and establish sufficient brand uniqueness
- Infrastructure and workspace, including independent office space and employee equipment, to ensure the limited sharing of information between organizations

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Regulatory Risks Related to Vertically Integrated Health-Care Organizations

There is a broad range of potential legal issues that may arise when organizations integrate vertically, including risks related to data sharing, antitrust, fraud and abuse laws, conflicts of interest, and corporate practice of medicine.

Privacy and Data Sharing Issues

Under the Health Insurance Portability and Accountability Act of 1996, as amended, covered entities and their "business associates" must comply with requirements regarding the privacy and security of protected health information. Neither a covered entity nor a business associate may share PHI other than as permitted by HIPAA. States may also have their own restrictions on the use and disclosure of personal health information.

A great advantage of vertical integration is that it allows for data to be shared across the integrated organization. Any covered entity or business associate within a vertically integrated organization, however, must comply with HIPAA's requirements regarding the privacy and security of PHI regardless of how the organization is managed and structured. However, vertical integration may increase the risk of inadvertent data sharing or PHI disclosure between entities that may share common systems. Technical and administrative firewalls may aid in the safeguarding of PHI, and in the proper execution of business associate agreements governing the use of PHI within a vertically integrated organization.

Antitrust

Antitrust law may also affect a vertical health-care transaction. As a general matter, vertical transactions typically have less antitrust risk than the horizontal merger of two competitors. The former is typically associated with pro-competitive efficiencies and has only an indirect effect on competition, while the latter directly reduces competitive intensity.

Nonetheless, vertical integration may still create concerns at the antitrust agencies. Of greatest concern is the possibility that an integrated entity might either "foreclose" downstream rivals by depriving them of a key input, or harm upstream competitors by foreclosing a substantial share of the downstream customer base. Another risk is that vertical integration could facilitate coordinated activity in the market by encouraging actual or tacit collusion. Such collusive activity may be encouraged if the vertically integrated firm does substantial business with its rivals, thereby enabling that firm to view competitively sensitive price or output information.

Where the risk of anticompetitive coordination is significant, the antitrust agencies may insist on strict information firewalls as part of a consent decree. The firewalls would need to ensure that competitively sensitive information such as pricing, output, and research and development information is not shared with personnel at the integrated company who could use it to their advantage. Notably, however, the antitrust agencies are increasingly reluctant to impose behavioral remedies such as firewalls instead of structural remedies such as divestitures because of the difficulties ensuring that such decrees are followed.

Federal Fraud and Abuse Statutes

Vertical integration has the potential to implicate various federal health-care fraud and abuse laws, including the federal Anti-Kickback Statute and the Stark Law.

The Anti-Kickback Statute makes it a felony to solicit, receive, offer, or pay any remuneration (including any kickback, bribe, or rebate) to any person in return for or in an attempt to induce patient referrals for services reimbursed under a federal health-care program or to arrange, recommend, or order any item or service reimbursed by any federal health-care program. Vertical integration may increase anti-kickback risk if different services lines run by the same company are in a position to influence referrals or induce the purchase of products from other parts of the company.

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The Stark Law prohibits physician referrals for a wide range of so-called designated health services if there is a financial relationship between the entity to which the referral is made and the referring physician, unless the arrangement meets an exception to the statute. Vertical integration may increase risk under the Stark Law if compensation paid to physicians is based on the volume or value of referrals made by the physician to the company.

To limit exposure to Stark violations, organizations must ensure that physician compensation generally is not based on any profits related to referrals for designated health services, and is based on the fair market value of the services. To the extent that physicians have ownership in a vertically integrated organization, the ownership interest should be structured consistent with the Stark Law.

Conflicts of Interest and Confidentiality Obligations

Conflicts of interests may also arise through vertical integration. Such conflicts may be actual or perceived conflicts. For example, conflicts of interest in vertical health-care transactions may arise with respect to medical decision-making in patient care and selection of best products or services for patients. Firewalls designed to limit the influence of medical decisionmakers by other constituencies within an organization, including sales and marketing, may aid in the mitigation of such potential conflict of interest risks.

Firewalls may also reduce the risk of a vertically integrated organization running afoul of its contractual obligations regarding information acquired by one component of a vertically integrated organization that may not be shared with other components. Separate contract management systems, along with policies and procedures related to the intra-company sharing of information subject to confidentiality restrictions, will reduce the risk of violating confidentiality and other similar contractual limitations.

Corporate Practice of Medicine and Fee-Splitting

Many states prohibit legal entities other than licensed physicians, such as corporations, from practicing medicine, employing physicians, and otherwise controlling a medical practice. These restrictions vary greatly by state. Companies that seek to integrate vertically through the acquisition of physician practices in corporate practice of medicine states must ensure that their physicians retain sufficient independence from the non-professional entity to comply with applicable state restrictions.

Although firewalls are effective at reducing the legal risk involved with vertical integration, they must be specifically tailored to the facts of the business structure at issue if they are to be successful. Each arrangement should be evaluated independently to determine the potential risks related to the arrangement, and the elements of a firewall that may mitigate such risks.

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