# The Reformed Health Care Industry: Creative Structures and Alliances Can Yield Great Benefits, but Also Great Risks

Since the Affordable Care Act (the "ACA") was enacted in 2010, the health care industry has been on the edge of its proverbial seat waiting to see which care delivery models are best suited to sustain all the changes: to consolidate or not consolidate; to affiliate or not affiliate; to sell or not to sell. These debates—all of which were regular topics of discussion at the recent American Health Lawyers Association annual meeting in New York City—are all worthy of far more than this brief overview of some of the routes various health care industry players have explored in transforming the health care market. But with these innovative models—some tried and true, some tried and failed under pre-ACA regimes—comes familiar regulatory risks and considerations of which industry players need to be ever-mindful.

**Joint Operating Agreements**

Joint operating agreements act as "virtual mergers" that establish relationships between the manager or joint operating company ("JOC") and the participating sponsors and providers. Joint operating agreements have gained popularity among smaller hospitals and health systems seeking to retain their separate existence, boards of directors, and certain governance authorities, while gaining economies of scale, payor negotiating strength, back-office support, and management of day-to-day operations. Smaller providers with limited personnel and resources can gain key efficiencies through joint operating agreements, such as sophisticated legal and compliance departments necessary to navigate the ever-increasing and complex intricacies of the health care regulatory minefields. A lack of expertise in the regulatory realm can quickly put a provider out of business as a result of massive qui tam judgments and increased government enforcement of fraud and abuse offenders.

One of the key regulatory considerations with joint operating agreements is whether antitrust regulators will treat the JOC participants as a single entity for purposes of antitrust laws, or whether the arrangements pose collusion risks. Nonprofit JOC participants must also be careful not to undermine their tax-exempt status when affiliating with non-tax-exempt providers.

**Payor-Provider Convergences**

The health care industry has also seen a significant uptick in provider/payor integration over the last few years. Blue Cross, Cigna, Wellpoint, Highmark, United Healthcare and Humana have all joined the provider game by acquiring or affiliating with various health systems and physician groups treating significant members of their existing plans. The upsides of this model of integration include: (i) strategic alignment between providers and payors to control costs and increase the quality of care rendered to patients; (ii) creation of an alternative revenue stream for health systems through premium income in addition to reimbursement for care rendered to the insured population; and (iii) a renewed focus on population health management and preventive medicine to lower the costs of rendering care to the insured population. Provider/payor integration is taking several forms: acquisitions, de novo health plan creations, equity joint ventures between providers and insurers, or more limitedly, a lease or outsource model where a provider "leases" a payor's license to offer insurance products, where permissible under state insurance laws and regulations.



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But it's business as usual on the regulatory front. These models are not without regulatory hurdles, including compliance with fraud and abuse laws (such as the Stark Law and Anti-Kickback Statute), antitrust restriction (though this type of vertical integration is less likely to draw antitrust scrutiny), tax exemption requirements, and perhaps most predominantly, state insurance regulations that prohibit anyone other than a licensed insurer from bearing financial risk in the provision of care. These issues must be carefully navigated based on the specifics of the payor-provider venture and the jurisdiction in which the venture elects to operate.

**Accountable Care Organizations**

An Accountable Care Organization ("ACO") is a group of health care providers who deliver coordinated care and disease management services to improve the quality of care rendered to patients. Participants in an ACO are paid in a manner tied to the ACO's achievement of certain health care quality goals and outcomes that result in cost savings. Similar to the Medicare Shared Savings Program, an ACO program created pursuant to the ACA, commercial payors are also driving ACO structures designed to incentivize network providers to provide more integrated and higher quality care at a lower price. Perhaps reminiscent of the HMO era of managed care, payors and providers alike are seemingly willing to bear some of the financial risk. In turn, this likely encourages some of the other affiliations discussed herein to make sure that efficiencies are maximized through these alliances to best capitalize on the cost savings opportunities presented by integration.

While certain fraud and abuse legal waivers were created for the Medicare Shared Savings Program ACOs, commercial ACOs have not been afforded similar waiver protections from potential Stark Law or Anti-Kickback Statute enforcement. Certain exceptions and safe harbors may protect some aspects of the commercial ACO (e.g., the risk-sharing exception to the Stark Law), but there is no one-size-fits-all list of requirements to ensure the legality of a commercial ACO's legal structure or operations. Additionally, antitrust risk remains high for integrated multi-provider networks that are not formally deemed "clinically integrated" like the Medicare Shared Savings Program ACOs, subjecting them to continued scrutiny by the Federal Trade Commission and its enforcement initiatives against illegal price-fixing operations. Moreover, providers who have experimented with commercial ACOs have not experienced much financial success from the model, causing many of those providers to exit the arrangements. For these reasons, structuring considerations are key in the uncertain regulatory landscapes in which commercial ACOs currently operate.

**New Platform Joint Ventures**

The health care industry has also recently seen unprecedented growth in nontraditional and innovative alliances involving diverse groups of industry players, including physicians and physician groups, hospitals and health systems (both for-profit and not-for-profit, and both religious and nonsectarian), health plans, health care management companies, and various niche players. These "outside-the-box" joint ventures that enable industry players to expand their service portfolios to new service platforms seem to be driven by federal and state health care reform initiatives and declining revenue and reimbursement shifts, and present a viable alternative to many providers to traditional mergers and acquisitions. For example, the insurer Independence Blue Cross and provider DaVita HealthCare Partners recently formed Tandigm Health, a company that will provide analytical tools and data to primary care physicians to assist in the management of patients' chronic health conditions.

Of course, these joint ventures present unique regulatory risks that may be new to the players expanding their profiles. Joint venturers need to consider how the joint venture will bill and collect for its services, whether there are any Stark Law (or state physician self-referral law) issues that present an obstacle to the business model, and whether there is an applicable safe harbor to the Anti-Kickback Statute to the arrangement, such as the small investment interests or investment in underserved areas' safe harbors. Moreover, state corporate practice of medicine and fee-splitting prohibitions may also influence the structure of the venture. Finally, the usual antitrust concerns around information sharing, as well as tax implications, also must be considered in determining the right players and structures for these innovative opportunities.

**Bottom line:** While the health care industry desperately needs to find efficiencies, before getting too deep into any consolidation, integration or restructuring effort, consult with legal counsel to make sure you are on stable ground.

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