Achieving Health Care Efficiencies through Consolidation and Alternative Models: Irreconcilable Differences?

Innovators Beware: All the Old Rules Still Apply

While debate rages on Capitol Hill over "repeal and replace," only limited attention has been directed toward reforming the current "fee for service" model. Indeed, both the Affordable Care Act ("ACA") and proposals for its replacement focus primarily on the reach and cost of providing coverage for health care, rather than specifics for the delivery of health care. With almost 18 percent of U.S. GDP spent on health care, experts see consolidation and alternatives to "fee for service" as fundamental to reducing costs. Integrating care coordination and delivery and increasing scale to drive efficiencies allows organizations to benefit from shared savings and relationships with payers and vendors. Deloitte forecasts that, by 2024, the current health system landscape—which includes roughly 80 national health systems, 275 regional systems, 130 academic medical centers, and 1,300 small community systems—will morph into just over 900 multi-hospital systems.[1]

Even though health care market and payment reforms encourage organizations to consolidate and integrate, proceed with caution. Health care organizations attempting to drive efficiencies and bring down costs through mergers may run afoul of numerous federal and state laws and regulations. Calls for updates or leniency in these laws are growing, including the possible recognition of an "Obamacare defense" to antitrust restrictions[2] and speculation that the Stark law will be repealed.[3] In the meantime, however, absent specific waivers or exemptions, all the usual rules and regulations apply, including antitrust constraints, physician self-referral and anti-kickback laws and regulations, state fraud and abuse restrictions, and more.

Antitrust Considerations:

As a general matter, parties should consider whether exclusive contracts and arrangements between primary payers and providers are permissible under federal and state antitrust laws. These laws allow for private rights of action and, in certain cases, criminal liabilities. Therefore, the costs of violations can be significant.

Before discussing a merger with a competitor or sharing information, parties must determine whether federal antitrust filings and/or agency reviews will be necessary. The Hart–Scott–Rodino Antitrust Improvements Act ("HSR") provides that parties must not complete certain mergers, acquisitions, or transfers of securities or assets, including grants of exclusive intellectual property licenses, until they have made a detailed filing with the U.S. Federal Trade Commission ("FTC") and Department of Justice, and those agencies have determined that the transaction will not adversely affect competition under antitrust laws. An HSR filing is required if the transaction and parties exceed certain monetary thresholds for the size of merging parties and the size of transaction value. Other antitrust laws, such as the federal Sherman Act or the FTC Act (as well as state competition laws) could apply to various joint collaboration, operation, marketing or distribution agreements. Any joint arrangement should be carefully analyzed prior to structuring the transactions to ensure compliance and evaluate the risks.

410 17th Street, Suite 2200
Denver, CO 80202

In addition to these ever-present antitrust considerations, the FTC has highlighted substantial antitrust hurdles to certain mergers and to the creation of Accountable Care Organizations ("ACOs") under the ACA. In a white paper that squarely addressed claims that the ACA demands greater latitude in antitrust enforcement for health care, Deborah L. Feinstein, director of the Bureau of Competition of the FTC, asserted that "antitrust enforcers have made it clear that there is no tension between rigorous antitrust enforcement and bona fide efforts to coordinate care, so long as those efforts do not result in the accumulation of market power."[4] Director Feinstein cited economic research showing that higher concentration in hospital markets leads to significantly higher prices, noting price increases as high as 40 percent as a result of a system acquiring a hospital competitor.[5] The FTC strongly asserts that, as a market-based system, U.S. health care markets must be competitive for the players to innovate and implement new reforms.

The FTC has specifically targeted hospital mergers in its efforts to halt transactions that it believes will undermine clinical quality or push prices higher, focusing on situations where the number of providers decreases from 4-to-3, 3-to-2, and 2-to-1. While some financially distressed hospitals or other health care institutions will assert a "failing firm" defense to antitrust scrutiny, the FTC's Merger Guidelines establish an extremely arduous standard for this defense:

1. the company is unable to meet its obligations as they come due;
2. the company would not be able to organize successfully in bankruptcy; and
3. the company has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its assets in the relevant market and pose a less severe danger to competition than does the proposed merger.[6]

Parties have also claimed a "flailing firm" defense to antitrust scrutiny in an effort to minimize the competitive significance of a merger target, asserting that the target's weakened financial condition makes its market share misleading. In its successful challenge to ProMedica Health System's acquisition of rival St. Luke's Hospital, the FTC cast aside the "flailing firm" defense as the "Hail-Mary pass of presumptively doomed mergers."[7] Because the FTC only takes poor financial health into account in extremely rare instances, parties to health care mergers must seek to overcome FTC scrutiny by showing the procompetitive effects of the transaction, including improved efficiencies and patient care.

Meanwhile, in reviewing provider collaborations and ACOs, the FTC poses certain threshold questions:

1. Does the proposed arrangement offer the potential for pro-consumer cost savings or quality improvements in the provision of health care services?
2. Is there bona fide integration or is this simply a mechanism to enhance leverage with payers through joint negotiation?
3. Even if there is bona fide integration, are any agreements among ACO participants regarding their business terms with health care insurers reasonably necessary to achieve the benefits of the collaboration? If so, these kinds of agreements may still be viewed as improper price fixing.

The FTC has advised that it will evaluate these arrangements under a rule of reason standard, balancing whether the collaboration will likely benefit or harm competition and consumers. Specifically, the FTC evaluates whether its

clinical integration standards will be met, evidencing that the arrangement will likely improve quality of care and reduce costs. However, the FTC has indicated that certain conduct raises concerns, particularly for ACOs with high market share, including:

1. preventing payers from directing patients to certain providers;
2. tying sales of the ACO's services to the private payer's purchase of other services from providers outside of the ACO;
3. exclusivity requirements that discourage providers from contracting with payers outside the ACO; and
4. restricting a payer's ability to provide enrollees with information on cost, quality, efficiency, and performance.

Stark/Anti-Kickback Considerations:

When considering integrated provider relationships, one of the most difficult aspects may also be the most critical—structuring in a way that (1) complies with federal fraud and abuse and physician self-referral laws, and (2) won't invite undue regulatory scrutiny. The ACA has in many ways added to the complexity of compliance and has even created some misconception that the Stark Law, Anti-Kickback Statute, and other fraud and abuse laws don't apply to ACOs. Instead, the ACA only provides for certain limited waivers from those restrictions, available only for those ACOs participating in the Medicare ACO program formally known as the "Medicare Shared Savings Program." These waivers are not available to organizations simply fashioning themselves after ACOs but not formally participating in the Medicare ACO program. Whether the arrangement is a Medicare ACO or otherwise, it remains critical for providers to appropriately structure their relationships to avoid liability.

State Fraud and Abuse Considerations:

Providers must also continue to structure their joint ventures and other activities in accordance with state fraud and abuse laws. The wide variation in the existence and scope of these laws from state to state can be particularly challenging for providers operating in more than one state. For example, many states have Stark-like physician self-referral prohibitions, but with exceptions that may not be as broad as those available under Stark. Similarly, some states have anti kickback prohibitions that are based on federal law, but do not have the same safe harbor exceptions. Moreover, the ACO waivers described above apply only to federal fraud and abuse laws, but do not exempt organizations from compliance with state laws. As a result, it is imperative that parties analyze each new relationship under applicable federal and state laws and tailor the relationship appropriately.

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.

Brownstein Hyatt Farber Schreck's **Health Care Group** is comprised of a strong team of transactional attorneys, regulatory experts, litigators and government relations professionals highly experienced in the health care industry. We represent our clients on issues ranging from regulatory compliance and sophisticated transactions to managed care and health plan litigation, with offices across the West and in Washington, D.C.

Michael King, shareholder, Health Care Group. Health care transactional and finance matters, including structuring joint ventures and management arrangements, mergers and acquisitions and financing transactions.

410 17th Street, Suite 2200
Denver, CO 80202

Kathleen Snow, associate, Health Care Group. Health care regulatory, transactional and finance matters, including advising on operational, clinical and research compliance, as well as structuring joint ventures and management arrangements, mergers and acquisitions and financing transactions.

Michael W. King
Shareholder
mking@bhfs.com
303.223.1130

Kathleen C. Snow
Associate
ksnow@bhfs.com
303.223.1230

---

[1] *The Great Consolidation: The Potential for Rapid Consolidation of Health Systems*, Deloitte Center for Health Solutions (2014); Health Care 2020: Consolidation, HFMA (Fall 2016).

[2] *FTC v. Penn. State Hershey Med. Ctr*, 185 F. Supp. 3d 552, 564 (M.D. Penn. 2016) (recognizing "a growing need for all those involved to adapt to an evolving landscape of healthcare that includes, among other changes, the institution of the Affordable Care Act, fluctuations in Medicare and Medicaid reimbursement, and the adoption of risk-based contracting"), *rev'd on other grounds by* 838 F.3d 327 (3d Cir. 2016).

[3] Ayla Ellison, *Stark Law: The 27-Year-Old Act Killing Healthcare Reform Before It Can Begin?*, Becker's Hospital Review (Sept. 7, 2016).

[4] Deborah L. Feinstein, Director, Bureau of Competition, Fed. Trade Comm'n, *Antitrust Enforcement in Health Care: Proscription, Not Prescription*, Fifth National Accountable Care Organization Summit–Washington, DC (June 19, 2014).

[5] Martin Gaynor, *Competition Policy in Health Care Markets: Navigating the Enforcement and Policy Maze*, 33 Health Affs. 1088 (June 2014).

[6] *See* Dept. of Justice & Fed. Trade Comm'n, 2010 Horizontal Merger Guidelines.

[7] *ProMedica Health System, Inc. v. FTC*, 749 F.3d 559, 572 (6th Cir. 2014), cert. denied 135 S.Ct. 2049 (2015).