Driving Health Care Efficiencies Through Consolidation: Despite Reforms, The Usual Rules Apply

With almost 18 percent of U.S. GDP spent on health care, experts see consolidation as fundamental to reducing costs—by integrating care coordination and delivery, and by increasing scale to drive efficiencies, including with shared savings and relationships with payers and vendors. Indeed, consulting firm Booz & Company has predicted that of the nation's 5,000 hospital systems, at least 1,000 will merge or consolidate in the next five years.

Most businesses large and small are dedicated to commerce up and down the health care supply chain—hospitals, providers, insurers, medical device and pharmaceutical manufacturers and distributors, and caregivers. Although consolidation and integration may be key to a more efficient health care system, proceed with caution. Absent specific waivers or exemptions, all the usual rules 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, and 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, and any joint arrangement should be carefully analyzed prior to structuring the transactions to ensure compliance and evaluate the risks.

In addition to these ever-present antitrust considerations, the FTC has highlighted substantial antitrust hurdles to certain mergers and to creation of Accountable Care Organizations ("ACOs") under the Affordable Care Act ("ACA"). In a recent white paper,[1] 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

[1] Deborah L. Feinstein, Director, Bureau of Competition, Federal Trade Commission, *Antitrust Enforcement in Health Care: Proscription, Not Prescription*, Fifth National Accountable Care Organization Summit – Washington, DC, June 19, 2014.

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do not result in the accumulation of market power." Director Feinstein cited economic research[2] 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. 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 four to three, three to two, and two to one. 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.[3]

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."[4] With the FTC only taking 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/or 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?

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

[3] Department of Justice & Federal Trade Commission, 2010 Horizontal Merger Guidelines.

[4] ProMedica Health System, Inc. v. FTC, No. 12-3583 at 18 (6th Circuit April 22, 2014). Note that ProMedica filed for rehearing and en banc review on June 3, 2014.

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(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 can 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 as ACOs. 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. As a result, it is imperative for each new relationship to be considered under applicable federal and state laws and tailored 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.

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