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Antitrust Alert

May 9, 2012

ACOs, Clinical Integration and Managing Antitrust Risk

AUTHORS

Andrew E. Bigart
Robert P. Davis
Lisa Jose Fales
Leonard L. Gordon

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Last week, at the Antitrust in Healthcare Conference held by the American Bar Association (ABA), the Federal Trade Commission (FTC) and the Department of Justice (DOJ) affirmed their commitment to monitoring the competitive effects of accountable care organizations (ACOs). ACOs are established under the Medicare Shared Savings Program administered by the Centers for Medicare & Medicaid Services (CMS). ACOs are groups of doctors and other healthcare providers who aim to improve healthcare delivery and reduce costs, in part, through "clinical integration," broadly defined as the coordinated delivery of clinical care to patients.

Notwithstanding the potential benefits of ACOs, collaborations among competitors can raise concerns under the antitrust laws. At the ABA's Antitrust in Healthcare Conference, FTC Chairman Jon Leibowitz explained that the FTC would continue to scrutinize ACOs to ensure that they actually provide the promised cost savings and quality improvements. Likewise, Joshua H. Soven, Chief of the DOJ's Litigation I Section, noted that the DOJ is paying close attention to the "ACO phenomenon." In this regard, the two antitrust enforcement agencies underscored that they will continue to monitor collaborations in the healthcare industry and provide guidance, as needed.

The FTC and DOJ's comments follow on the heels of CMS's announcement of the first 27 ACOs approved to participate in the Medicare Shared Savings Program. The goal of the program is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services, preventing medical errors, and reducing overall healthcare costs.

This article provides healthcare providers interested in ACOs – and clinical integration in general – with a brief overview of the antitrust laws that govern such arrangements and suggests best practices to minimize the antitrust risk of a collaboration with clinical integration.

The Antitrust Laws and Clinical Integration

The Sherman Act prohibits firms, including competing healthcare providers, from engaging in concerted action that restrains trade. Under Section 1 of the Sherman Act, some activities are treated as illegal "per se," including agreements between competitors (such as hospitals or physicians) to fix prices or agree not to deal with customers. Agreements that, on their face, do not unambiguously injure competition are analyzed under the "rule of reason," which examines the totality of the circumstances to determine the likely overall effect of the agreement on competition. Both civil and criminal sanctions may be imposed for a violation of the Sherman Act as well as treble damages and reasonable attorneys' fees.

Because clinical integration can reduce costs and improve quality, the FTC and DOJ typically analyze such arrangements under the rule of reason. Under this test, the FTC and DOJ consider, among other factors, whether the proposed integration offers a new and different product, the degree of financial risk sharing, and whether the joint venture members have integrated the delivery of care. For arrangements involving large market shares, the two agencies look to ensure that the members will not use their market power to raise prices or engage in anticompetitive conduct. The antitrust agencies have issued numerous advisory opinions and other guidance on the types of clinical integrations that are likely to be found procompetitive under a rule of reason analysis. *See, e.g.*, FTC and DOJ, Improving Health Care: A Dose of Competition (July 2004); **click here to see that report.**

With respect to ACOs, in October 2011, the FTC and DOJ issued a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "Policy Statement") in conjunction with final rules issued by the CMS under the Medicare Shared Savings Program. To view the Policy Statement, **click here**. The Policy Statement provides healthcare providers with a framework for the formation of ACOs that participate in both the Medicare and commercial markets, recognizing that health care providers are likely to prefer clinical integrations that cover both markets. For ACOs looking for additional guidance, the Policy Statement offers a

voluntary expedited 90-day review program.

Perhaps most importantly, the Policy Statement establishes a limited antitrust safety zone for ACOs participating in the Medicare Shared Savings Program. Healthcare providers looking to form an ACO for participation in the Program (as well as the commercial market) should consult with counsel to determine whether the proposal falls within the safety zone because those that do are unlikely to be challenged by the FTC and DOJ, absent extraordinary circumstances. To fall within the safety zone, an ACO's independent participants that provide a common service must have a combined share of 30 percent or less of the common service in each participant's primary service area. Determining market share is a fact-intensive process that involves identifying the relevant medical services and the appropriate geographic market, among other factors.

Best Practices for Effective Clinical Integration

Determining whether a collaboration, such as an ACO, includes sufficient integration to justify the pricing-related provisions of an agreement is a complex task. Taken as a whole, the FTC and DOJ's Policy Statement on ACOs and guidance on clinical integration in general suggest that the following best practices minimize the risk of a proposed collaboration running afoul of the antitrust laws:

Require Financial Integration

- Develop formal procedures for receiving and distributing payments among members, including risk sharing and similar financial incentives to motivate members to achieve network goals;

Network Development and Management

- Implement a non-exclusive network, meaning that members of the network remain free to contract with payors outside of the network context;
- Membership should be open to both primary care physicians and specialists;
- Implement appropriate firewalls to ensure that members do not share competitively sensitive information concerning operations outside the scope of the collaboration;
- Avoid use of anti-steering provisions that discourage private payors from directing or incentivizing patients to choose certain providers;
- Avoid "tying" the sale of the collaboration's services to the private payor's purchase of other services outside the scope of the collaboration;

Implement Quality/Clinical Integration

- Develop clinical practice guidelines for participating members, including credentialing/re-credentialing, patient education programs; and clinical protocols and/or disease registries;
- Share patient and treatment information within the collaboration; further, the collaboration should not discourage payors from making performance information available to its members;
- Implement health information technology systems to facilitate the sharing of patient and treatment information;
- Require physicians to serve on clinical and oversight committees; and
- Discipline or expel members that do not comply with the program requirements, and develop standards and accountability for quality, cost and overall care.

In conclusion, as the healthcare industry continues to explore ACOs and other integrated healthcare delivery systems as ways to improve quality and lower costs, healthcare providers should consult with legal counsel to ensure that the proposed collaborations do not violate the antitrust laws.

If you have any other questions regarding this or other antitrust concerns, please contact one of the attorneys in our **Antitrust Practice Group**.