OBER | KALER
Attorneys at Law

April 6, 2011

Ober|Kaler ACO Update

John J. Miles | jjmiles@ober.com

William E. Berlin | weberlin@ober.com

This is part of Ober|Kaler's comprehensive overview of federal agencies' implementation of the Accountable Care Act's ACO and Shared Savings Program provisions: CMS Proposed ACO Implementing Regulations; Antitrust; Fraud and Abuse; Privacy; Tax-Exempt Organizations.

Antitrust Ramifications for ACOs: Clinical Integration, Safety Zone, and Expedited Reviews

Recently issued regulations and other notices for comments have given health care providers guidance on how to organize and operate accountable care organizations (ACOs) in order to be eligible to receive payments under Medicare's Shared Savings Program. The Affordable Care Act (ACA), signed into law in March 2010, included incentives for the creation of ACOs. Congress established the ACO Shared Savings Program in the ACA to promote accountability of providers to patient populations and to coordinate services under Medicare as well as to encourage providers to make investments in infrastructure and to design care processes for high-quality, efficient service delivery. Almost a year later on March 31, 2011, several federal agencies (CMS, OIG, DOJ, FTC and IRS) jointly announced the release of proposed rule making and guidance regarding the ACO program. The proposed rule and related guidance is expected to remove the existing legal impediments in the

areas of fraud and abuse, antitrust, tax and privacy to allow for the development of ACOs, and provide guidance on such issues as eligibility to participate, governance, legal structure, quality and privacy.

The FTC and DOJ proposed Antitrust Policy Statement regarding ACOs participating in the Shared Savings Program explains how those agencies will assess the antitrust ramifications of ACOs. The Antitrust Statement describes:

- the ACO structures to which the statement applies
- the methodology the agencies will apply to analyze the ACO's effect on competition
- an antitrust safety zone for ACOs that meet certain criteria
- an expedited antitrust review process for ACOs that fall outside of the safety zone, which will be mandatory for certain ACOs and optional for others that desire additional antitrust certainty
- an appendix explaining how to calculate ACO market shares

The public-comment period on the proposed Antitrust Policy Statement closes on May 31, 2011.

The Antitrust Statement applies to collaborations formed after March 23, 2010, among otherwise independent hospitals and physicians who seek to become, or have been approved to become, participating ACOs in the Shared Savings Program. The Antitrust Statement does not apply to mergers, which the agencies will analyze using their 2010 Merger Guidelines. The Antitrust Statement's analysis will apply to ACOs contracting with commercial insurers if they use the same governance and leadership structure and same clinical and administrative processes as they use to qualify for and participate in the Shared Savings Program. This analysis will apply to an ACO for the duration of its participation in the Shared Savings Program.

Although naked-price fixing agreements among competitors are per se, or automatically, illegal without requiring any analysis of actual effect on competition, joint pricing agreements among competing health care providers through the ACO's joint negotiation of contract prices with payors are evaluated under the "rule of reason" standard if the providers are financially or clinically integrated and their agreement is reasonably necessary to accomplish the pro-competitive benefits of their integration. The Antitrust Statement explains that, although the agencies do not want to dictate how clinical integration might be achieved, they will apply the rule of reason to ACOs meeting the CMS governance and leadership criteria for eligibility in the Shared Savings Program when those ACOs engaged in joint contract negotiations with commercial insurers. The FTC and DOJ will continue to consider other proposed clinical integration structures using the same consideration.

For those ACOs that meet CMS governance and leadership criteria and thus qualify for rule of reason treatment, the agencies will use a streamlined analysis to assess each ACO's market power based on its share of services in each ACO participant's Primary Service Area (PSA). The Statement provides an antitrust safety zone for ACOs with a combined participant market share of 30 percent or less in each common specialty, and in which all ACO hospitals participate on a non-exclusive basis. The safety zone includes a "rural exception" which permits rural ACOs, under certain conditions, to include rural physicians and hospitals even if their market shares exceed 30 percent. The Antitrust Statement also includes a "dominant provider limitation" which permits an ACO to include a single dominant provider with a greater than 50 percent share under certain conditions, including that the provider participate in the ACO on a non-exclusive basis.

The Antitrust Statement explains that ACOs not meeting the safety-zone requirements because they have market shares between 30 and 50 percent should not raise significant antitrust issues if they avoid certain exclusionary conduct specified in the Antitrust Statement and the sharing among participants of competitively sensitive information. For comfort, those ACOs may, at their discretion, obtain advisory opinions from DOJ or FTC, in which the agency will inform them whether it intends to challenge their formation or operations. An ACO whose market share exceeds 50 percent in any service that it provides must, as a condition for CMS approval, obtain a favorable advisory opinion from one of the agencies stating that the agency has no present intention to challenge the ACO's formation or operations.

The Antitrust Statement includes a list of documentation and other information that the ACO must provide when requesting an advisory opinion. The ACO must send requests to both agencies and the agencies decide which will respond. Whether the request is voluntary or mandatory, the agencies have committed to state whether an agency intends to challenge the ACO's conduct within 90 days after receiving all required information. CMS cannot approve any ACO obtaining an advisory opinion from an agency stating that the agency is likely to challenge the ACO if it proceeds, whether the request is voluntary or mandatory.

About Ober|Kaler

Ober|Kaler is a national law firm that provides integrated regulatory, transaction and litigation services to financial, health care, construction and other business organizations. The firm has more than 130 attorneys in offices in Baltimore, MD, Washington, DC and Falls Church, VA. For more information, visit www.ober.com.