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Client Alert

Antitrust & Litigation Practice Group

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FTC and DOJ Release Policy Statement Regarding Accountable Care Organizations

On March 31, 2011, the Federal Trade Commission (FTC) and Department of Justice (DOJ) (collectively, the "Agencies") released for public comment a joint Policy Statement regarding how the agencies will enforce the antitrust laws regarding Accountable Care Organizations (ACOs). The Policy Statement accompanies the release on the same day by the Centers for Medicare and Medicaid Services (CMS) of its proposed regulations to cover ACOs participating in the Medicare Shared Savings Program. The FTC's press release regarding the Policy Statement is available at: http://www.ftc.gov/opa/2011/03/aco.shtm. The proposed CMS regulations are available at: http://www.ofr.gov/OFRUpload/OFRData/2011-07880_PI.pdf). Comments are due by May 31, 2011.

The joint Policy Statement covers five areas: (1) the ACOs to which it will apply; (2) when the FTC and DOJ will apply particular antitrust analyses to those ACOs; (3) an antitrust safety zone for certain ACOs; (4) a mandatory antitrust review process for certain other ACOs; and (5) how the agencies will review proposed ACOs that fall outside the safety zone but below the mandatory review threshold.

The joint Policy Statement applies to ACOs formed after March 23, 2011, and defines ACOs as collaborations among otherwise independent providers or provider groups that seek to participate in the Affordable Care Act's Shared Savings Program. Importantly, provider mergers will continue to be evaluated pursuant to the FTC/DOJ Horizontal Merger Guidelines, and other types of provider joint ventures (*e.g.*, Group Purchasing Organizations) will continue to be examined under the 1996 FTC/DOJ Statement on Enforcement of Healthcare Policy (Healthcare Statements) and the FTC/DOJ Competitor Collaboration Guidelines issued in 2000.

According to the Policy Statement, ACOs that use the same governance and leadership structure and the same clinical and administrative processes they use to qualify for, and participate in, the Shared Savings Program will involve sufficient integration to warrant Rule of Reason review by the Agencies. This is an important expansion upon the existing paradigm in which provider collaborations involving joint managed care contracting needed to demonstrate (a) financial and/or clinical integration, and (b) that an agreement on price/price-related terms was reasonably necessary for such integration. Now, in addition to financial and clinical integration, integration

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incorporating the processes required for the Shared Savings Program can also qualify for sufficient integration for federal antitrust purposes. These processes include: (1) a formal legal structure that allows the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promoted evidence-based medicine and patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care for beneficiaries.

Other features of the Policy Statement concern the extent of the Agencies' review. Specifically, some types of ACOs can qualify for "safety zone" treatment, meaning that the provider collaboration will almost never raise antitrust issues and therefore, there is no obligation to contact the Agencies to seek clearance for the proposed ACO. For an ACO to fall within the safety zone, the independent ACO participants must have a combined share of 30 percent or less of each common service in each participant's Primary Service Area (PSA), which is defined as "the lowest number of contiguous postal zip codes from which the ACO participants draws at least 75 percent of its patients." Moreover, any hospital or ambulatory surgery center must be non-exclusive to be considered in the safety zone. There is also an exception to the 30 percent rule for non-exclusive ACOs in rural counties.

In contrast, ACOs that have more than 50 percent market share for any common service must undergo mandatory review by the one of the Agencies pursuant to applicable CMS regulations. As part of this review, the DOJ or the FTC will conduct an antitrust analysis involving market power and the competitive effects of the ACO to ensure that the proposed ACO is lawful under federal antitrust law. The Policy Statement describes how the parties can obtain an "expedited review" by submitting certain types of information and documents to the relevant Agency at least 90 days before the last day that CMS has stated it will accept ACO application for the relevant calendar year. As part of this expedited review, the notified Agency will provide its opinion (*i.e.* that the ACO is permissible or that the Agency will challenge the ACO) within 90 days of receiving all of the information from the parties.

Finally, for ACOs that fall between the safety zone and the mandatory review, the Policy Statement indicates that ACOs that avoid certain types of conduct are unlikely to raise competitive concerns. These types of conduct include the following:

- Preventing commercial payers from directing patients to choose certain providers
- Tying sales of the ACOS services to other services
- Contracting on an exclusive basis
- Restricting a commercial payers' ability to make available to its enrollees const, quality and efficiency data; and
- Sharing competitively-sensitive information among provider participants.

Key Takeaways

- The joint Policy Statement is the first major healthcare policy pronouncement from the Agencies since the FTC/DOJ Competitor *Collaboration Guidelines* were issued in 2000 and it is the first time the Agencies have affirmatively stated that an entire type of provider collaboration will be subject to rule of reason treatment if

certain specific integration criteria are met. In the past, the Agencies have instead responded to detailed integration proposals from the providers.

- The issuance of the Joint Policy Statement marks a return by DOJ to healthcare provider enforcement. Prior to this, the FTC has been almost the exclusive Agency investigating provider networks. For this reason, FTC Commissioner J. Thomas Rosch dissented, citing DOJ's "far less expertise or experience" and greater susceptibility "to lobbying and other political pressure."

- The Agencies understand that ACOs have significant potential pro-competitive benefits but remain concerned about provider combinations that involve high market share.

- Although the Joint Policy Statement sets forth a framework for optional antitrust review, ACOs with 30-50 percent market share should consider whether such review offers any meaningful benefits, especially when weighed against the intrusiveness of the Agency's review, the likely requirement to produce significant volumes of data and documents, and the limited value of a non-binding statement that the Agency will not move against a proposed ACO. In many cases, such middle-range ACOs can hope to achieve the same reassurance simply by following the Policy Statement and adopting in the commercial market the processes required for participation in the Shared Savings Program.