Client Alert: DOJ and FTC Release Antitrust Policy for ACOs

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On October 20, 2011, the Department of Justice ("DOJ") and Federal Trade Commission ("FTC") (collectively, the "Agencies") jointly issued their *Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the "Policy Statement") in conjunction with the final rule issued by the Centers for Medicare and Medicaid Services ("CMS") implementing provisions of the Medicare Shared Savings Program for Accountable Care Organizations ("Final Rule") created in last year's Health Reform legislation.[i] The Policy Statement, which largely mirrors the Agencies' proposed policy statement issued on April 19, 2011,[ii] outlines how the agencies will enforce U.S. antitrust laws with regard to accountable care organizations ("ACOs"). However, the final policy statement differs from the proposed policy statement in two material respects. First, the final policy statement applies to all collaborations that are eligible or have been approved to participate in the Medicare Shared Savings Program (the "Shared Savings Program"). The proposed policy statement was limited to collaborations formed after March 23, 2010. Second, the Shared Savings Program no longer requires a mandatory antitrust review for certain collaborations as a condition of entry. Therefore, the final policy statement no longer contains provisions relating to mandatory antitrust review. However, the Agencies did state that they will continue to vigorously enforce the antitrust laws to protect competition in markets served by ACOs participating in the Shared Savings Program. Specifically, CMS will provide the Agencies with data and information to help the Agencies assess the competitive effects of all ACOs, including aggregate claims data regarding allowed charges and fee-for-service payments and copies of all the applications to the Shared Savings Program formed after March 23, 2010.

As in the proposed April policy statement, the Agencies will not challenge as *per se* illegal a Shared Shavings Program ACO that jointly negotiates with private insurers to serve patients in commercial markets if the ACO satisfies certain conditions. Specifically, the ACO must meet CMS's eligibility requirements for, and participate in, the Shared Savings Program and use the same governance and leadership

structures and clinical and administrative processes to serve patients in both Medicare and commercial markets.[iii] For ACOs that meet those criteria, the Agencies will apply a "rule of reason" analysis in analyzing a potential antitrust violation. According to the Agencies, a rule of reason analysis will evaluate whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws.

The final policy statement also preserves an antitrust "safety zone" for certain ACOs, as described in the earlier proposed policy statement. The safety zone is intended for ACOs that are highly unlikely to raise significant competitive concerns. The Agencies will not challenge ACOs that fall with the safety zone, absent extraordinary circumstances.[iv] An ACO's safety zone eligibility is determined by the combined Primary Service Area ("PSA") shares of ACO participants that provide a common service (e.g., the same physician specialty or the same inpatient service) to patients from the same PSA. 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 each common service in each participant's PSA, wherever two or more participants provide that service to patients from that PSA. An appendix to the Policy Statement explains how to calculate the PSA shares of common services. Hospitals and ambulatory surgical centers must be non-exclusive to the ACO regardless of share. Any ACO participant with greater than a 50 percent share must also be non-exclusive. An ACO that exceeds the 30 percent PSA shares may still fall within the safety zone if it qualifies for a rural exception, which is further described in the Policy Statement. In addition, the Policy Statement clarifies that ACOs that fall outside the safety zone may still be procompetitive and legal. An ACO that does not impede the functioning of a competitive market should not raise competitive concerns.

The Policy Statement does provide examples of conduct to avoid. Specifically, the Agencies note that all ACOs should refrain from, and implement safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO. Further, for ACOs that may have market power, the Policy Statement identifies additional conduct that, depending on the circumstances, may prevent private insurers from obtaining lower prices and better quality services for their enrollees.

Finally, the Agencies will offer voluntary expedited 90-day reviews for newly formed ACOs that are seeking additional antitrust guidance. Parties seeking expedited review must submit their request for review prior to entering into the Shared Savings Program, and they will be required to produce strategic business strategies or plans and other materials as stated in the Policy Statement before the 90-day review period will begin. Within 90 days of receiving the required documents and information, the reviewing agency will advise the ACO if its formation and operation as described in the documents and information raises competitive concerns. The reviewing agency may extend the review beyond 90 days if requested by the applicant.

Further analysis and implications of the Final Rule and other guidance will be forthcoming.

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[i] Patient Protection and Affordable Care Act ("ACA"), Pub. L. 111-148, 124 Stat. 119, as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 115-152, 124 Stat. 1029. Please refer to our previous Client Alert on October 21, 2011 regarding the Final Rule.

[ii] 76 Fed. Reg. 21, 894 (April 19, 2011).

[iii] The eligibility criteria set forth in ACA has been further defined by CMS through regulations. Medicare Program; Medicare Shared Saved Savings Program: Accountable Care Organizations, 42 C.F.R. pt. 425 (2001). The Agencies have articulated the standards for both financial and clinical integration in various policy statements, speeches, business reviews, and advisory opinions. See, e.g., U.S. Dept. of Justice & Fed. Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (1996), available at http://www.ftc.gov/reports/hlth3s.pdf.

[iv] The Policy Statement states that extraordinary circumstances could include, for example, ACO participants engaging in collusion or improper exchanges of price information or other competitively sensitive information with respect to their sale of competing services outside the ACO.