

ALERT

ANTITRUST/HEALTHCARE

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DOJ and FTC Issue Final Policy Statement on Antitrust Enforcement RE: Accountable Care Organizations

The Federal Trade Commission and the Department of Justice (collectively, the Agencies) issued, on Oct. 20, 2011, the final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the Policy Statement). The same day, the Centers for Medicare and Medicaid Services (CMS) released the [Final Rule](#) governing accountable care organizations (ACOs) under the Medicare Shared Savings Program (the Shared Savings Program), as well as restated rules by the Internal Revenue Services (IRS) and the Office of Inspector General on the tax-exemption and antikickback implications, respectively, of the Shared Savings Program for ACOs.

ACOs, a creature of the Patient Protection and Affordable Care Act (PPACA), are collaborative healthcare provider networks. The Shared Savings Program was intended to increase quality and decrease costs for Medicare fee-for-service beneficiaries. The Policy Statement articulates the Agencies' antitrust enforcement posture as it relates to ACOs, providing "guidance [that will] help health care providers form procompetitive ACOs and protect health care consumers from higher prices and lower quality care," according to the Department of Justice.

The Policy Statement applies to joint venture provider networks that intend to participate in the Shared Savings Program. The Policy Statement made two significant changes from an earlier proposed version in response to public comment from the Agencies' March 2011 draft policy statement regarding the scope of its coverage and types of entities covered.

The Policy Statement gives guidance on when the Agencies will apply a "rule of reason" analysis, rather than imposing *per se* liability, in pricing arrangements among separate entities that form an ACO joint venture. Traditional antitrust principles forbid naked price-fixing and market-allocation agreements as *per se* anticompetitive (and, therefore, *per se* illegal). While the federal government will set the terms and price of services provided under Medicare, the Agencies provided guidance for ACOs when they are also contracting in the private market. The Policy Statement provides that joint price

arrangements among competing healthcare providers will be analyzed under a “rule of reason” analysis where such agreement effectively promotes clinical integration, which the agency considers a procompetitive benefit.

The guidance provided by the Agencies for the Shared Services Program has not differed greatly from their stated position in prior antitrust safety zones and specific review letters on the legitimacy of joint ventures seeking clinical integration to coordinate fee schedules, although the definition of what constitutes “clinical integration” has always been an issue that eluded a single formulation. Commentators contended, and the [Agencies acknowledged](#), that “[c]linical integration is needed to facilitate the coordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused.” The Agencies noted that, whatever form clinical integration may take from time to time, entities that meet federal requirements to become ACOs automatically meet that definition.

The Policy Statement, as did its draft predecessor, provides an antitrust “safety zone” for ACOs. To fall under this “safety zone,” an ACO’s participants may not collectively control more than a 30 percent share of common services within a “primary service area.” An ACO with collective control of greater than 30 percent of a primary service area may nonetheless be procompetitive and allowable, just not protected in the “safety zone.”

In the final Policy Statement, the Agencies expanded the Policy Statement’s scope of coverage. The draft policy statement contemplated the Agencies’ ACO enforcement policy as applying only to healthcare networks formed after the March 23, 2010 enactment of the PPACA, which defined ACOs. Now, the Agencies’ Policy Statement encompasses all qualified provider networks that plan to participate in the Shared Savings Program, regardless of their formation date. A second and significant departure from the draft Policy Statement was practical: it eliminated a mandatory antitrust review by the Agencies as a precondition for participation in the Shared Savings Program. Although eligibility is not contingent on antitrust review at the onset, the Agencies noted that they nonetheless maintain jurisdiction and oversight of ACOs in the antitrust arena.

Along with the Policy Statement and guidance from the OIG and IRS, the CMS Final Rule provides definitive regulatory direction for ACOs. The Final Rule reflects comments from more than 1,300 stakeholders.

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