

## Department of Justice

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## DEPARTMENT OF JUSTICE/FEDERAL TRADE COMMISSION ISSUE FINAL STATEMENT OF ANTITRUST POLICY ENFORCEMENT REGARDING ACCOUNTABLE CARE ORGANIZATIONS

Guidance Will Help Health Care Providers Form Procompetitive ACOs and Protect Health Care Consumers from Higher Prices and Lower Quality Care

WASHINGTON – The Department of Justice and the Federal Trade Commission (FTC) today issued the final version of a joint policy statement detailing how the agencies will enforce U.S. antitrust laws with respect to new Accountable Care Organizations (ACOs). An ACO is an organization of health care providers that jointly offer services to reduce costs and improve the quality of patient care. Under the Affordable Care Act, ACOs will serve Medicare fee-forservice beneficiaries under the Medicare Shared Savings Program.

Some ACOs may operate in the commercial market as well as in the Medicare program. While ACOs may allow health care providers to innovate and improve care for both Medicare and commercially insured patients, under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality care. Today's guidance will help health care providers form procompetitive ACOs that benefit both Medicare beneficiaries and patients with private health insurance while protecting health care consumers from higher prices and lower quality. The Centers for Medicare and Medicaid Services (CMS) will also provide the agencies with data and information to help the agencies assess the competitive effects of all ACOs. The agencies will use this data and information, together with their traditional enforcement tools, to evaluate competitive concerns about an ACO's formation or conduct and will take whatever enforcement action may be appropriate.

The Department of Justice and the FTC will continue to enforce vigorously the antitrust laws, consistent with the policy statement and with the goals of this innovative program to protect health care consumers from higher prices and lower quality care.

As proposed in a draft policy statement issued for public comment in March 2011, the agencies will not challenge as *per se* illegal a Shared Savings Program ACO that jointly negotiates with private insurers to serve patients in commercial markets if the ACO satisfies certain conditions. The ACO must comply with CMS's eligibility criteria and use the same governance and leadership structures and clinical and administrative processes to serve patients in both Medicare and commercial markets. For ACOs that meet those criteria, the agencies will apply a "rule of reason" analysis in analyzing a potential antitrust violation.

The final policy statement also preserves an antitrust "safety zone" for certain ACOs, as described in the earlier proposed policy statement. With some exceptions, safety zone eligibility is based on 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 to patients in that PSA.

The policy statement provides examples of conduct that, under certain circumstances, may raise competitive concerns. All ACOs should refrain from, and implement safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside of 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.

The Department of Justice and the FTC will offer voluntary expedited 90-day reviews for newly formed ACOs that are seeking additional antitrust guidance. The final policy statement includes detailed instructions for any newly formed ACO that wishes to take advantage of the voluntary expedited antitrust review process.

The final policy statement incorporates public input and differs from the original proposal in two significant respects:

• Expanded Coverage

The entire final policy statement, except voluntary expedited review, applies to all provider collaborations that are eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program. The policy statement no longer applies only to collaborations formed after March 23, 2010 (the date on which the Affordable Care Act was enacted).

• Shift from Mandatory to Voluntary Review

Because the Medicare Shared Savings Program final rule no longer requires a mandatory antitrust review for certain collaborations as a condition of entry into the Shared Savings Program, the final policy statement no longer contains provisions relating to mandatory antitrust review.

The agencies have made other minor modifications to the policy statement in response to feedback received during the public comment period.

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