AntitrustConnect Blog

Federal Antitrust Agencies Offer Guidance to Health Care Providers Forming Accountable Care Organizations

Jeffrey May (Wolters Kluwer) · Thursday, October 20th, 2011

Today, several federal agencies, including the federal antitrust agencies, issued rules and guidance for assisting health care providers in the formation of new accountable care organizations (ACOs).

An ACO is a group of health care providers or suppliers or a network of groups—often affiliated with a hospital—collaboratively manage and coordinate care for Medicare beneficiaries. Under the Patient Protection and Affordable Care Act, ACOs will serve fee-for-service beneficiaries through Medicare's Shared Savings Program (MSSP) and must sign up with the Centers for Medicare & Medicaid Services (CMS) to participate in the program for at least three years, starting January 1, 2012. ACO participants receive bonuses when they provide exceptional or low-cost care and are penalized for low-quality or high-cost care. Some ACOs may operate in the commercial market as well as in the Medicare program. The federal antitrust agencies' guidance is intended to 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 Department of Justice Antitrust Division and the Federal Trade Commission jointly issued their "Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" on October 20. The policy statement offers insights into how the agencies will enforce U.S.antitrust laws with regard to ACOs.

The agencies issued a proposed policy statement in March and received more than 100 public comments. While there was support for the agencies' efforts, the comments were critical of a number of proposals. Many comments focused on the costs of mandatory antitrust review for ACOs that might have market power. In addition, some health care provider groups called for a larger antitrust safety zone, while other commenter suggested that the current safety zone should be reduced.

The agencies have seemingly considered the comments, and the final policy statement reflects some changes from the March proposal. The final policy statement no longer contains provisions relating to mandatory antitrust review because the MSSP final rule no longer requires a mandatory review. The FTC and Antitrust Division will now offer voluntary expedited 90-day reviews for newly formed ACOs that are seeking additional antitrust guidance. During expedited review, the reviewing agency will examine whether the ACO will likely harm competition by increasing the ACO's ability or incentive profitably to raise prices above competitive levels or reduce output,

quality, service, or innovation below what likely would prevail in the absence of the ACO.

Moreover, the policy statement no longer applies only to collaborations formed after March 23, 2010 (the date on which the Affordable Care Act was enacted). Commenters had suggested that the limitation could have harmed providers that were already collaborating before the law was passed and wished to form a Medicare ACO.

Antitrust Safety Zone

The Antitrust Division and FTC have decided to maintain the antitrust "safety zone" for ACOs as described in the earlier draft policy statement. The safety zone is intended for ACOs that are highly unlikely to raise significant competitive concerns. The ACO's share of services in each ACO participant's Primary Service Area (PSA) is considered to determine whether the ACO falls into the safety zone. An ACO would fall within the safety zone, if independent ACO participants that provide the same service have a combined share of 30 percent or less of each common service in each participant's PSA. An appendix to the policy statement explains how to calculate the PSA shares of common services.

An ACO that exceeds the 30 percent PSA share may still fall within the safety zone if it qualifies for a rural exception, under the policy statement. In addition, it should be noted that ACOs outside the safety zone do necessarily present competitive concerns. The policy statement points out that they may still be procompetitive and lawful so long as they do not impede the functioning of a competitive market.

Rule of Reason Approach

As proposed in the draft policy statement issued in March, 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 agencies do not establish their own criteria for clinical integration. The policy statement notes that generally antitrust laws treat naked price-fixing and market-allocation agreements among competitors as per se illegal.

In addition to the antitrust policy statement, a final CMS rule and a joint CMS/Department of Health & Human Services Office of Inspector General interim rule were issued today relating to ACOs.

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