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Overview of the FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

On April 19, 2011, the "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" ("Proposed Statement") was published in the *Federal Register*.[1] As noted in the Proposed Statement, the antitrust enforcement agencies (the Department of Justice Antitrust Division ("DOJ") and the Federal Trade Commission ("FTC")) issued the Proposed Statement in response to a perceived preference by potential accountable care organization ("ACO") participants to operate in both the Medicare and commercial markets. In order to "maximize and foster opportunities for ACO innovation, the Agencies wish both to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs in the Shared Savings Program and to coordinate the antitrust analysis with CMS review of those ACO applications."[2] This alert provides an overview of the Proposed Statement.

On May 9, 2011, the FTC hosted a workshop to discuss the Proposed Statement. As a result of comments made during that workshop, as well as comments provided during the public comment period, the FTC and DOJ may make changes to the Proposed Statement.

A. Application of "Rule of Reason" Analysis to ACOs that Meet CMS Requirements

ACOs seeking to participate in the Medicare Shared Savings Program ("MSSP") may require coordination among independent providers (unless an organization is already integrated so that it can operate efficiently as an ACO without the inclusion of independent providers). Generally, providers sharing pricing information or engaging in other collective activity could risk liability under Section 1 of the Sherman Act. Price-fixing and certain other collective actions are deemed per se illegal under the antitrust laws. In order to alleviate the risk of per se liability in the MSSP and commercial markets, the Proposed Statement provides that any ACO that meets the Centers for Medicare & Medicaid Services ("CMS") requirements to qualify for, and participate in, the MSSP will automatically be viewed under a "rule of reason" analysis, a proposal that is directly in line with the agencies' former guidance on clinical integration. The rule of reason approach applies to the ACO, regardless of the market share of its participants. Under a rule of reason analysis, the agencies would evaluate the collaboration to determine whether the procompetitive benefits of the collaboration outweigh any likely anticompetitive effects. Note that this presumption would apply to the ACOs activities in commercial as well as Medicare markets.

1 76 Fed. Reg. 21894 (April 19, 2011).
2 *Id*. at 21895.

While the review under the rule of reason analysis will be applicable only if the agencies decide to review a particular ACO, organizations should ensure that their ACO provides procompetitive benefits and document those benefits for both the Medicare beneficiaries and any commercial plans with which the ACO contracts.

B. The Antitrust Safety Zone for ACOs in the MSSP

The Proposed Statement also establishes a "Safety Zone" for certain ACOs in the MSSP. If an ACO falls within the Safety Zone, the agencies will not challenge the ACO, "absent extraordinary circumstances." If, for all providers within the ACO, any two or more independent providers have 30 percent or less of the combined market share[3] for shared services, the ACO is within the Safety Zone, provided that:

i. Any hospital or ambulatory surgery center ("ASC") in the ACO is non-exclusive – *e.g.*, allowed to contract or affiliate with other ACOs or commercial payors; ***and***

ii. Any dominant provider of any service that no other ACO participant is providing in the same market (greater than a 50-percent market share) is non-exclusive.

The Proposed Statement includes an Appendix to guide providers in determining the market share. But providers should note that the analysis contained in the Appendix is neither a traditional antitrust market share analysis nor simply based on the number of providers in the area. As a result, all providers should do an analysis based on the Proposed Statement's guidance.

a. Rural Exception

The Proposed Statement provides an exception to the general rule for the Safety Zone for those ACOs that may include rural providers, even if inclusion of those providers would put the ACO's market share for shared services above 30 percent. Thus, the Proposed Statement allows an ACO to maintain its Safety Zone status if it includes no more than one physician per specialty from each rural county, provided that the physician is non-exclusive. Similarly, the ACO may maintain its Safety Zone status if it includes a rural hospital on a non-exclusive basis even if inclusion of that hospital increases the ACO's market share for a shared service above 30 percent.

b. Dominant Provider Limitation

The Proposed Statement places certain restrictions on dominant providers. As is true for hospitals and ASCs, any provider with a market share of greater than 50 percent (in its Primary Service Area ("PSA")) must be non-exclusive to the ACO. Moreover, if a dominant provider is part of an ACO that falls within the safety zone, the ACO cannot require a commercial payor to contract with it only through the ACO or try to restrict a payor's ability to deal with other ACOs.

c. Duration of Safety Zone

Once an ACO qualifies for the Safety Zone, the ACO will remain in the Safety Zone for the duration of its agreement with CMS, unless there is a significant change in the ACO's provider composition. The Proposed Statement does not describe what the agencies would view as a "significant change." However, the Proposed Statement does acknowledge that an ACO would not lose its Safety Zone

3 As noted in the accompanying definition of "PSA share calculation," this is done using Medicare shares, although the safety zone has applicability to commercial contexts. (A "PSA share" refers to the share of services that each ACO participant provides in its Primary Service Area.)

status if its market share increases because it is attracting more patients to the ACO.

It is unclear how the requirements for non-exclusivity under the Proposed Statement are differentiated from the non-exclusivity requirement in the CMS proposed regulations. Those regulations state, "ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3-year agreement to the ACO, and the ACO participant must not be required to be exclusive to a single ACO." 42 C.F.R. §425.5(c)(2) and 425.5(c)(3); 76 Fed. Reg. 19642 (April 7, 2011). Thus, the FTC/DOJ limitations on non-exclusivity could be mooted by the CMS requirement.

C. Mandatory Review for ACOs Exceeding the 50-Percent Market Share Threshold

In contrast to the Safety Zone, the Proposed Statement also dictates when an ACO must seek a review from the antitrust agencies. Both the FTC and the DOJ will perform reviews, although only one agency will review each submission (at this time, the process for determining which agency will review a submission is unclear). An ACO that includes two or more independent providers that collectively have greater than a 50-percent market share for shared services must seek a review from the agencies. To expedite this process, the agencies have committed to a 90-day review period, although it is unclear whether the process can be delayed if the reviewing agency has questions regarding the proposal. In its submission for review, an ACO must include:

- The CMS MSSP application and supporting documents;
- Documents or agreements that relate to an ACO participant's ability to compete with the ACO, and documents and agreements that relate to any financial incentives to encourage ACO participants to contract through the ACO;
- The ACO's business strategies, such as plans to compete in the Medicare and commercial markets and the likely impact on price, cost, or quality of any service provided by the ACO;
- Documents showing the formation of any ACO or ACO participant that was formed in whole or in part, or otherwise affiliated with the ACO, after March 23, 2010; and
- Information sufficient to show the following:
    - The ACO's PSA share calculations for each common service and the ACO's PSA share calculations for each common service provided to commercial customers where those shares differ significantly from the PSA share calculations based on Medicare data (e.g., PSA share calculations for pediatricians or obstetricians);
    - Restrictions that prevent the ACO from obtaining sensitive pricing or other information related to commercial payors;
    - Points of contact for the five largest commercial plans that will, or are expected to, contract with the ACO; and
    - The identity of any other existing or proposed ACO that will be operating in any PSA in which the ACO provides services.

Note that the mandatory review applies only to ACOs that are participating in the MSSP; however, organizations that are developing ACO-type models for commercial payors can use the Proposed Statement for guidance on the kinds of conduct and market share that could increase the risk of antitrust scrutiny. In addition, note that the agencies have not described how ACOs should calculate market shares for commercial customers.

D. ACOs Outside the Safety Zone and Below the Mandatory Review

If two or more independent providers within an ACO have between 30 percent and 50 percent of the combined market share for shared services, the ACO is not within the Safety Zone of the Proposed Statement. The ACO may (although it is not required to) seek expedited review by the agencies. In addition, the Proposed Statement provides the following "tips" for avoiding an action by the FTC/DOJ:

- Don't prevent or discourage commercial payors from steering to particular providers;
- Don't tie sales of ACO services to a commercial payor's purchase of other services provided by ACO participants and providers;
- For providers other than the PCPs, don't have exclusive contracts (exclusive to the ACO or to payors);
- Don't restrict a payor's ability to make information available to members regarding quality, cost, efficiency, and performance measures; and
- Don't share competitively sensitive pricing or other data among participants (which they could use outside ACO).

The above list is intended to ensure that the ACO does not participate in anticompetitive conduct. While an ACO may not need to refrain from all of the above activities in order to mitigate the risk of antitrust exposure, it may want to consult antitrust counsel prior to making that determination.

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