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Health Law Client Newsletter

Enforcement Policy Statement May Limit ACO Participation in Medicare Shared Savings Program

A key element of the Patient Protection and Affordable Care Act is the Medicare Shared Savings Program, which will provide increased payments to qualifying "Accountable Care Organizations" ("ACOs"). A critical hurdle to the development of ACOs has been the federal antitrust laws, which prohibit joint decisions on prices and other competitively significant matters by competing providers, regardless of any procompetitive benefits. The problem has been a lack of clarity as to whether this so-called "*per se*" rule of illegality applies to ACOs that are "clinically integrated." To address this issue, the U. S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") have jointly issued a Proposed Statement on Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "Statement"). The Statement includes provisions that could dramatically affect the composition of ACOs.

The most direct limitation is that, if two or more ACO participants (physician groups, hospitals or others) that provide "common services" furnish more than 50% of the services of that type in the Primary Service Area ("PSA"), the ACO cannot participate in the Medicare Shared Savings Program without prior approval from the FTC or the DOJ. The Statement was issued on the same day as the proposed ACO regulations issued by the Centers for Medicare and Medicaid Services, which incorporate this prohibition. A participant's PSA is "the lowest number of contiguous postal zip codes from which [the participant] draws at least 75%" of patients for the services in question. This requirement will apply to any ACO if any type of services will be provided by independent participants that furnish more than 50% of the services of that type in the PSA, but will not apply if there is only one ACO participant that provides that type of service. The market share percentage will be determined based on total Medicare allowable charges for each type of service by all providers in the PSA. To commence participation in the program on the anticipated January 1, 2012 start date, an ACO will need to apply for such a letter by August 3, 2011. The ACO must submit detailed information to the reviewing agency concerning market characteristics, business strategies of the ACO, and the likely impact on prices, cost, quality and market shares in both government and commercial markets, among other things.

Most importantly, the Statement provides that the FTC and DOJ will not apply a "*per se*" rule of antitrust illegality to any ACO that participates in the Medicare Shared Savings Program if, in the commercial market, it "uses the same governance and leadership structure and the same clinical and administrative processes" that it uses to qualify for the Medicare Shared Savings

Program. This means that the ACO will be deemed sufficiently integrated that any enforcement decision will be based on a more flexible standard--whether procompetitive benefits will likely outweigh any anticompetitive effects.

The Statement also provides that if an ACO qualifies for an antitrust "safety zone," the FTC and DOJ will not take enforcement action against it for ACO-related activities "absent extraordinary circumstances." The requirements to qualify include the following:

1. Any participating hospital or ambulatory surgery center must be able to participate in other ACOs as well.

2. Two or more independent participants that provide a "common service" must provide less than 30% of the services in *each* participant's PSA. (There is a limited exception for rural areas that allows participation by one physician per specialty per county and by any critical access hospital or sole community hospital if such physician or hospital can also participate in other ACOs.) An integrated group practice is considered a single participant for this purpose.

3. If a single ACO participant provides more than 50% of any service in its PSA, it must be able to participate in other ACOs, and the ACO cannot restrict a commercial payor's ability to deal with other ACOs or provider networks.

Qualifying for a safety zone does not prevent private parties from bringing legal actions based on injuries to them resulting from antitrust violations, or limit enforcement actions by state attorneys general under state antitrust laws; therefore, it should not be assumed that qualifying activities will necessarily be safe. For ACOs that do not qualify for a "safety zone" but are not required to obtain a written approval for the FTC or DOJ, the Statement lists five types of conduct that an ACO can avoid "to reduce significantly the likelihood of an antitrust investigation." Such an ACO can seek an agency letter even though it is not required to do so.

Public comments on the Statement will be accepted until May 31, 2011. The Statement will be issued in final form after the public comments are considered.

We will be sending you a separate newsletter concerning the CMS regulations concerning ACOs and the Medicare Shared Savings Program.

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If you have questions concerning this newsletter, please call Dennis Witherell, Michael Briley or Jenifer Belt at 800-444-6659, or Ron Christaldi or Erin Aebel at 800-677-7661.