Health Care Antitrust Alert

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FTC/DOJ Issue Proposed Statement of Antitrust Enforcement Regarding Accountable Care Organizations

BY BRUCE D. SOKLER, CHRISTI J. BRAUN, AND ROBERT G. KIDWELL

On March 31, 2011, the Federal Trade Commission and Department of Justice issued a joint proposed antitrust enforcement policy statement (Proposed Antitrust Policy Statement) to accompany the release by the Department of Health and Human Services of its proposed regulations to cover Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program. The agencies ask for comment on the proposed statement by May 31, 2011. While additional details and insights will emerge in the coming weeks, we thought it was important to provide interested parties an initial summary and analysis of the Proposed Antitrust Policy Statement.

The Proposed Antitrust Policy Statement only applies to competitor collaborations formed after March 23, 2010 that seek to participate in the Shared Savings Programs. Physician practice groups or integrated health systems that form ACOs through merger transactions will be evaluated under the Agencies' Horizontal Merger Guidelines.

Antitrust enforcement officials have stated that their review of proposed ACOs will ultimately turn on the question of whether the ACOs will have high enough shares of their markets to raise price above competitive levels. Initial reactions suggest that there are many controversial elements to the Proposed Antitrust Policy Statement. We anticipate that many comments will be filed by May 31st, and the final Statement may ultimately be modified in some important respects.

To distill the Proposed Antitrust Policy Statement to its essence, it:

- Indicates that, if an ACO is approved by the Centers for Medicare & Medicaid Services (CMS) to participate in the Medicare Shared Savings Program, the antitrust enforcement agencies will analyze the arrangement under the more lenient rule of reason standard, which balances harm to competition against procompetitive benefits to consumers. Importantly, the rule of reason treatment will extend to such an ACO's activities in the commercial market if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes it uses to qualify for and participate in the Shared Savings Program. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.
- Creates an antitrust safety zone for ACOs in the Shared Savings Program. If an ACO falls within the safe zone, the agencies will not challenge its activities, absent extraordinary circumstances. ACOs in the safety zone have no obligation to contact the antitrust agencies. For an ACO to fall within the safety zone, independent ACO participants (e.g., physician group practices) that provide the same service (a "common service") must have a combined share of 30% or less of each common service in each

participant's primary service area (PSA), wherever two or more ACO participants provide that service to patients from that PSA. The PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75% of its patients for that service."

To be in the safety zone, any hospital or ambulatory surgery center participation in an ACO must be non-exclusive to the ACO. There is a rural exception that preserves qualification for the safety zone where an ACO may include one physician per specialty for each rural county if done on a non-exclusive basis, even if the ACO's share exceeds 30%.

- Addresses the situation under the CMS regulations where the proposed ACO will need to submit to a mandatory antitrust review by either FTC or DOJ in order to obtain CMS approval to qualify for the Shared Savings Program. The threshold for the mandatory antitrust review is reached if the ACO's share exceeds 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA. When conducting a review, the agencies will consider information or data suggesting that the PSA shares may not reflect the ACO's likely market power, and will also consider any substantial procompetitive justification for why a higher PSA share is needed to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market.

  The enforcement agencies commit that, if they receive certain enumerated categories of information, they will provide the ACO, within 90 days, with a statement indicating either no present intention of recommending a challenge to the ACO or, conversely, that they are likely to recommend an antitrust challenge if the ACO proceeds. The information that agencies want before the 90-day expedited clock will start includes:

  1. The proposed CMS application;
  2. Documents relating to the ability of ACO participants to compete with the ACO, either individually or through other ACO entities, or relating to financial or other incentives to encourage ACO participants to contract with CMS or commercial payers through the proposed ACO;
  3. Business strategy documents and documents assessing the likely impact on prices, costs, and quality;
  4. ACO formation documents;
  5. The ACO's PSA share calculations for each common service;
  6. Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract through the ACO; and
  7. Information to permit the antitrust agency to contact the five largest commercial health plans or other payers regarding the proposed ACO.

  Some of these requirements are sufficiently imprecise that there can foreseeably be controversy as to whether the 90-day expedited period has begun. The Statement cautions that all of the above material must be received by the reviewing agency at least 90 days before the last day on which CMS has stated that it will accept ACO applications to participate in the Shared Savings Program for the relevant calendar year.

- Acknowledges that ACOs that are outside the safe zone and below the 50% mandatory review threshold may frequently be procompetitive. To the agencies, the key issue is whether the ACO, on balance, will provide consumers with high-quality, cost-effective health care, or instead, increase price and reduce consumer choice and value. The agencies will permit ACOs who are not required to undertake the mandatory review to

avail themselves of the same expedited review process if they provide the required information. The agencies estimate that between mandatory and voluntary applications, they may be asked to undertake up to 200 reviews.

- Provides additional antitrust guidance for ACOs by identifying five types of conduct that an ACO can avoid to reduce significantly the likelihood of an antitrust investigation:

    1. preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity," or similar contractual clauses or provisions;
    2. tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with *all* the hospitals in the same network as the hospital that belongs to the ACO);
    3. with an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks;
    4. restricting a commercial payer's ability to make cost, quality, efficiency, and performance information available to its health plan enrollees if that information is similar to the cost, quality, efficiency, and performance measures used in the Shared Savings Program; and
    5. sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.

The Proposed Policy Statement contains a detailed appendix indicating how to calculate the PSA shares of common services, and some potential data sources for the calculation.

This alert represents merely a quick overview of an important and anticipated proposed policy statement. We would be happy to discuss its content and implications in more detail.

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