Antitrust Enforcement Policy Statement

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The Federal Trade Commission ("FTC") and the Department of Justice's ("DOJ") (collectively, the "Agencies") response to Accountable Care Organizations ("ACOs") is not surprising: more regulation. On March 31, 2011, the FTC and the Antitrust Division of the DOJ issued a proposed Statement of Antitrust Enforcement Policy ("Policy Statement") regarding ACOs participating in the Medicare Shared Savings Program (the "Shared Savings Program"). The Agencies requested public comments regarding the Policy Statement to be received on or before May 31, 2011, a short 60-day window period. The Policy Statement applies to collaborations among otherwise independent providers and provider groups ("ACO participants") formed after March 23, 2010, the enactment date of the Patient Protection and Affordable Care Act, who seek to participate or otherwise have been approved to participate in the Shared Savings Program.

Generally, the antitrust laws treat price fixing and market allocation agreements among competitors as "per se illegal." See *Arizona v. Maricopa County Medical Society*. However, through the Policy Statement, the Agencies have determined that they will provide a "rule of reason" treatment to providers splitting fees as part of an ACO's performance in the Shared Savings Program, if certain criteria are met and the market share held by the independent competitive physicians and health care providers is not too great. In particular, the Agencies have designated three types of ACOs: (i) those that are in the safety zone; (ii) those facing mandatory antitrust review; and (iii) those in between the safety zone and antitrust review. This article discusses the characteristics and the consequences of being a particular type of ACO.

**ANTITRUST SAFETY ZONE**

First, the Agencies believe that organizations meeting the ACO requirements of the CMS Program are reasonably likely to be bona fide arrangements to improve quality and reduce costs through the ACO participants' joint efforts. Therefore, the Agencies have created a new "antitrust safety zone" for ACOs that meet the CMS eligibility criteria to
participate in the Shared Savings Program and certain additional requirements of the Agencies.

The ACOs that meet the antitrust safety zone requirements will not be challenged by the Agencies absent extraordinary circumstances. Moreover, ACOs that fall within the safety zone have no obligation to contact the Agencies prior to forming the ACO.

For an ACO to fall within the proposed safety zone, independent ACO participants (for example physician group practices) that provide the same service ("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. Any hospital or ambulatory surgery center ("ASC") participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA market share. Therefore, to fall within the safety zone, each hospital or ASC must be allowed to contract individually or affiliate with other ACOs or commercial payers.

The Policy Statement Appendix describes: (i) how an ACO would calculate its market share of services in the relevant PSAs; (ii) provides examples of correct calculations; and (iii) identifies the data sources available. The safety zone calculation and subsequent determinations will remain in effect for the duration of the ACO's agreement with the CMS unless there is a significant change to the ACO's provider composition. An ACO whose market share increases because it attracts more patients will not lose its safety zone status, if the ACO was not within the rural exception (discussed below) and later exceeds the 30% share limitation.

The safety zone for physicians and other provider services will also, to some extent, be dictated by whether they fall within the rural exception or are subject to the dominant provider limitation. Under the rural exception, an ACO may include one physician per specialty from each rural county on a non-exclusive basis and qualify for the safety zone even if inclusion of those physicians causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service. In a similar fashion, the ACO may include rural hospitals on a non-exclusive basis and qualify for the safety zone even if the inclusion of the rural hospital causes the ACO's share of a common service to exceed 30% of any ACO participant's PSA for that service.

In connection with a dominant provider limitation, a new set of rules apply. If an ACO has a participant with a greater than 50% share in its PSA for any service that no other ACO participant provides to patients in that PSA, then under those conditions the ACO participant (the dominant provider) must be non-exclusive to the ACO to fall within the safety zone. So, for example, if a group of neurosurgeons had a greater than 50% share in its PSA of the common service of neurosurgery that no other ACO participant provides, then the group must be non-exclusive in the ACO to fall within the safety zone. In addition, in order to fall within the safety zone, an ACO with a dominant provider cannot require a commercial provider to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to contract or deal with other ACOs or provider networks.
MANDATORY ANTITRUST REVIEW

On the opposite side of the continuum from the safety zone, the Agencies require a mandatory antitrust agency review of ACOs which exceed a 50% PSA share threshold. An ACO that does not qualify for the rural exception cannot participate in the Shared Savings Program if its share exceeds 50% for any common service that two or more independent ACO participants provide to patients in the same PSA, unless as part of the CMS application process, the ACO provides CMS with a review letter from one of the Agencies stating that the reviewing agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws.

When conducting a review, the Agencies will consider any information or alternative data suggesting that the PSA shares do not reflect the ACO's likely market power and will also consider any substantial pro-competitive justifications why the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market. To conduct such a review, the ACO must submit the following documents and information to the reviewing agency:

1. The application and all supporting documents that the ACO has submitted to CMS as part of the Shared Savings Program application process.
2. Documents or agreements relating to the ability of the ACO participants to compete with the ACO, either individually or through other ACOs.
3. Documents discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets and the ACO's likely impact on prices, cost or quality of any service provided by the ACO.
4. 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.
5. Information sufficient to show the following:
   1. 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 calculations based on Medicare data;
   2. Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract with the ACO;
   3. The identity, including points of contact, of the five (5) largest commercial health plans or other payers (actual or projected for the ACO services); and
   4. The identity of any other existing or proposed ACO known to operate or planning to operate in any PSA in which the ACO will provide services (i.e., a list of competing ACOs).

All of this information must be received by the reviewing agency at least 90 days before the last day on which CMS will accept ACO applications to participate in the Shared Savings Program for the relevant calendar year. Within 90 days of receiving all of the information, a reviewing agency will advise the ACO that the agency has (1) either no present intent to challenge or recommend challenging the ACO or (2) is likely to challenge or recommend challenging the ACO. Pursuant to recently released CMS regulations, CMS will not approve for its program any ACO that has received a disapproving letter stating that the reviewing antitrust agency is likely to
challenge or will recommend challenging the ACO if it proceeds.

**ACOS THAT ARE BETWEEN THE SAFETY ZONE AND MANDATORY REVIEW**

The Agencies concede that ACOs that are outside of the safety zone and below the 50% mandatory review threshold may still be pro-competitive. Specifically, the Agencies believe that an ACO is highly unlikely to present competitive concerns if it avoids the following conduct:

1. Preventing or discouraging commercial payers from directing or incentivizing patients to choose providers including those who 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, including providers affiliated with the ACO participants. (For example, an ACO may not require a purchaser to contract with all of 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 and 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 available to its health plan enrollees cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan if that information is similar to the information and performance measures used in the Shared Savings Program; and

5. Sharing among the ACO 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 Agencies conclude that any ACO that wishes further certainty concerning the antitrust laws on its formation and planned operation may seek an expedited review that is similar to the mandatory review for ACOs above the 50% threshold.

**CONCLUSION**

The result of this proposed antitrust Policy Statement is that ACOs who apply for the CMS Shared Savings Program will need to do an analysis of market share for its physician groups, in-patient services provided by hospitals, and out-patient services; and to make a determination of the applicability of the safety zone and whether there has to be a mandatory review. Remember if only one common service provided by two or more independent ACO participants exceeds 50% in any PSA, then, if not in a rural county, the ACO would be required to obtain an antitrust review from one of the Agencies before even participating in the CMS Shared Savings Program. CMS has estimated that there will be a range of 300 to 800 ACOs and it would appear that all ACOs will need to go through an analysis of their respective market share after recruiting physicians, physician groups and other health care providers and the calculations and potential filing may be similar in magnitude to a pre-merger notification filing under the Hart-Scott-Rodino ("HSR") Act (an analogy used by the Agencies in their proposed Policy Statement). The Policy Statement gives ACOs some additional certainty under the antitrust laws, but only after a fair amount of analysis and some potential agency review.