FEDERAL TRADE COMMISSION/DEPARTMENT OF JUSTICE PROPOSED STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS

On March 31, 2011, the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") (collectively the "Agencies") issued a proposed Policy Statement setting forth the Agencies' guidance regarding the application of the antitrust laws to the formation of accountable care organizations ("ACOs") under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (together, the "Affordable Care Act"). As promised by the Agencies during a workshop on antitrust issues related to ACOs that was jointly convened by the FTC, DOJ, and the Centers for Medicare and Medicaid Services ("CMS") in October of last year, the Policy Statement would promote the formation of ACOs by (1) establishing that an ACO that satisfies CMS's criteria for participating in the Medicare Shared Savings Program is sufficiently integrated to qualify for analysis under the rule of reason in determining its competitive impact; (2) identifying specific criteria that will be used by the Agencies to calculate an ACO's share of its market for purposes of evaluating the competitive impact of the ACO; (3) creating an antitrust "safety zone" for smaller ACOs; and (4) providing for expedited review of larger ACOs, some of which will be required to obtain a favorable antitrust review from the Agencies before they can receive approval from CMS.

I. Background

The Affordable Care Act promotes the formation of ACOs, which the Affordable Care Act describes as organizations of providers that take responsibility for improving the health status, efficiency, and experience of care for a defined patient population. ACOs are intended to promote cooperation among providers in managing and coordinating patient care. An ACO that satisfies the requirements of the Affordable Care Act may enter into an agreement with CMS to participate in the Medicare Shared Savings Program and share in a portion of any savings created by the ACO, if it meets certain quality performance standards. The Policy Statement recognizes that the formation of ACOs to serve Medicare patients through the Shared Savings Program may also generate similar opportunities for ACOs to serve commercially insured patients. The Agencies will apply the same antitrust analysis to ACOs that serve both Medicare and commercially insured patients, provided that the ACO "uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program."

II. Applicability of the Policy Statement

The Policy Statement applies to collaborations formed after March 23, 2010 among otherwise independent providers and provider groups that are seeking to participate in the Shared Savings Program. The Policy Statement does not apply to mergers, nor does it apply to fully integrated entities seeking to participate in the Shared Savings Program, such as a hospital system with a wholly-owned employed physician practice. This is understandable because fully

integrated entities are not subject to Section One of the Sherman Act, which only applies to concerted activities. As a result, fully integrated providers do not receive the same level of antitrust scrutiny as collaborations among competitors. One of the likely consequences of the move toward ACOs will be further consolidation of health care providers. Implementation of the proposed guidance in the Policy Statement also will discourage large, fully integrated ACOs from collaborating with independent physicians and organizations because such affiliations would bring the ACO within the coverage of the Policy Statement.

III. Application of Rule of Reason Analysis to ACOs that Satisfy CMS's Eligibility Criteria

The single most important determination to be made with respect to physician networks and physician/hospital organizations under the Agencies' Statements of Antitrust Enforcement Policy and Health Care, originally issued in 1993, and amended in 1996 ("Health Care Statements"), was whether the collaboration was governed by the rule of reason, or considered a *per se* price fixing arrangement. Under the Health Care Statements, if providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the pro-competitive benefits of the collaboration, then the rule of reason would apply.[1]

The Policy Statement would establish a bright line for applying a rule of reason analysis: a CMS-approved ACO will be governed by the rule of reason. The Affordable Care Act provides that ACOs must include: (1) a formal legal structure that allows the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote evidence-based medicine and patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care for beneficiaries. The proposed regulations governing ACOs that were issued by CMS on March 31 include more detailed criteria for eligibility.[2] To the extent that an ACO meets the CMS criteria for participation in the Shared Savings Program, the Agencies have also stated that if the ACO provides the same or essentially the same services utilizing the same structure in the commercial market, then the rule of reason will also apply to the ACO's activities in the commercial market.

Essentially, this approach reflects the Agencies' determination that a bona fide ACO that meets the CMS' criteria will necessarily incorporate the practices, organizational structure, monitoring and enforcement mechanisms, incentives, etc., that the Agencies have previously stated are characteristics of a clinically integrated system.

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[1] The Health Care Statements provided some examples of financial integration, and advisory opinions issued by the FTC over the years have helped to identify the practices that the Agencies believe create sufficient clinical integration to qualify for rule of reason analysis. However, providers have continued to express frustration that the Health Care Statements and advisory opinions do not provide sufficient certainty and require significant expense to structure networks that may or may not satisfy the Agencies.

[2] *See* CMS Notice of Proposed Rulemaking, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528, 19640-654 (proposed Apr. 7, 2011) (to be codified at 42 C.F.R. pt. 425).

IV. Calculation of an ACO's Shares of the Market

The calculation of an ACO's share of services provided by each ACO participant in its Primary Service Area ("PSA") will be a key step in the Agencies' analysis of whether an ACO raises antitrust issues. The Agencies propose to calculate the share of services by focusing on "common services," which are any services that are provided by two or more independent ACO participants. The ACO applicant is responsible for calculating its PSA shares for common services as follows:

1. Identify each service provided by at least two independent ACO participants.

2. Identify the PSA for each common service for each participant in the ACO. The PSA is defined as the lowest number of contiguous postal zip codes from which the participant draws at least 75% of its patients for that service.

3. Calculate the ACO's PSA share for each common service and each PSA in which at least two ACO participants serve patients for that service, based on Medicare data to be provided by CMS.[3]

The Agencies propose to use an ACO's PSA shares of common services as a proxy for market share. This is problematic from an antitrust perspective for a number of reasons. Reliance on Medicare payments will yield larger shares to physicians who treat a greater percentage of Medicare-covered patients, and will not measure market shares attributable to commercially-insured patients. Availability of data may also create challenges, because not all services are regularly used by Medicare beneficiaries (e.g., pediatrics, obstetrics, etc.), and the Policy Statement would leave it to the ACO to propose alternative measures of relevant shares. Most importantly, the use of data measuring where a provider's patients are located is a flawed measure of that provider's relevant geographic market because the issue is not who a patient relies on for treatment, but to what providers a patient could reasonably turn if he is dissatisfied with his providers. However, properly calculating market share in a more theoretically sound manner is extremely difficult and expensive. Presumably, the Agencies opted for a measure that would be easier for applicants to utilize, and the Agencies will apply a more accurate measure of market share if they subsequently investigate an ACO's competitive impact.

[3] CMS is going to make Medicare fee-for-service data available that will be broken down by zip codes and each service, to enable ACOs to calculate PSA shares for physician services and outpatient services. For hospital inpatient services, the ACO applicant is to calculate its share of inpatient discharges using all-payer hospital discharge data, if available, and if not available, upon its share of Medicare fee-for-service payments. The Policy Statement directs ACO applicants to use other available data to determine the relevant shares when Medicare data is not available for a particular service.

V. The Antitrust Safety Zone

A. ACOs With Less Than 30% Share

The Agencies recognize that ACOs with smaller shares of common services are highly unlikely to raise significant competitive concerns and merit a presumption of *per se* legality. Consistent with how the Health Care Statements established safety zones for adequately integrated physician networks, the Policy Statement indicates that the Agencies will not challenge ACOs in which the combined share of common services is 30% or less in each participant's PSA. In addition, any hospital or ambulatory surgery center participating in an ACO that qualifies for the safety zone must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share (consistent with the Shared Savings Program regulations).

B. Certain ACOs Exceeding 30% Share

The Policy Statements identify two exceptions that would permit an ACO to fall within the safety zone, even if the ACO's share of services within a particular PSA exceeds 30%. Under the "rural exception," an ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) covered by the ACO, even if the inclusion of any of these physicians causes the ACO's share of any common service to exceed 30% in any ACO's participant's PSA for that service, provided that the rural physician contracts with the ACO on a non-exclusive basis. Likewise, an ACO may include Rural Hospitals, *i.e.,* a Sole Community Hospital or a Critical Access Hospital, as defined by the Medicare regulations, even if the inclusion of the Rural Hospital causes the ACO's share of any common service to exceed 30% in any ACO's participant's PSA for that service, as long as the Rural Hospital contracts with the ACO on a non-exclusive basis.

The Policy Statements also provide that the ACO may include a "dominant provider" with a greater than 50% share in its PSA, as long as no other ACO participant provides the same service as the dominant provider within the PSA, and the dominant provider contracts on a non-exclusive basis. In addition, any ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict the payer's ability to contract with other ACOs or provider networks.

The Policy Statements further provide that if an ACO falls within the safety zone when it first contracts with CMS, it will continue to be considered a part of the safety zone even if the ACO later exceeds the 30% share limitation solely because it attracts more patients. The Safety Zone will apply to a qualifying ACO's participation in the Shared Savings Program and in the commercial market, provided the ACO uses the same structure and processes for both Medicare and commercially-insured patients.

VI. Mandatory Antitrust Agency Review

Under the proposed CMS regulations, 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 the ACO provides CMS with a letter from one of the Agencies stating that the reviewing agency has no

present intention of challenging the ACO under the antitrust laws. In essence, this creates a 50% share threshold that requires mandatory pre-clearance of any such ACO. This will place the burden upon an applicant to establish a "substantial pro-competitive justification for why the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market."

In addition, this requirement will strongly discourage a large fully-integrated ACO from collaborating with smaller, independent providers, if the combination results in the ACO having a PSA share greater than 50% for any common service, as that would trigger the mandatory review requirement.

VII. ACO's Outside the Safety Zone but not Subject to Mandatory Reporting

ACOs that exceed the 30% safety zone for any common service, but are below the 50% mandatory reporting threshold, are not required to seek clearance from one of the Agencies before qualifying for the Shared Savings Program. Such an ACO can seek expedited Agency review, but if it chooses not to, the Policy Statement identifies five types of conduct, that if avoided, would significantly reduce the likelihood of an antitrust investigation.

1. Preventing or discouraging commercial payers from directing patients to choose providers that do not participate in the ACO;

2. Tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO;

3. Contracting with any ACO participant on an exclusive basis, except for primary care physicians;

4. Restricting a commercial payer's ability to share costs, quality, efficiency and performance information with enrollees; and

5. Sharing among ACO participants competitively sensitive pricing or other data that could be used to set prices outside of the ACO.

VIII. Expedited Agency Review

Regardless of whether a proposed ACO is required to obtain an antitrust review or requests an optional review, the Agencies have "committed" to provide an expedited review of ACOs within 90 days of submission of all required documents and information. To obtain expedited review, the ACO must submit:

1. The application and all supporting documents that the ACO plans to submit to CMS as part of its Shared Savings Program application;

2. Documents relating to the ability of the ACO participants to compete with the ACO, either individually or through other ACOs, or to any incentives to encourage ACO participants to contract with CMS or commercial payers through the ACO;

3. Documents discussing the ACO's business strategies or plans to complete in the Medicare and commercial markets and the ACO's likely impact on prices, costs or quality of service provided by the ACO;

4. Documents establishing that the ACO was formed after March 23, 2010;

5. Information sufficient to show

    1. the ACO's PSA share calculations for each common service;

    2. restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract through the ACO;

    3. the identity of the five largest commercial health plans or other payers for the ACO's 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.

Within 90 days of receiving all of the above documents and information, unless more information is requested, the reviewing Agency (the Policy Statement does not indicate how the FTC and the DOJ intend to assign responses to requests for expedited reviews), will advise the ACO that the Agency (i) has no present intent to challenge or recommend challenging the ACO, or (ii) that it is likely to challenge or recommend challenging the ACO if it proceeds.

IX. Public Comment

Public comments on the proposed Policy Statement must be submitted by May 31, 2011.