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FTC/DOJ ISSUE JOINT PROPOSED STATEMENT OF ANTITRUST ENFORCEMENT POLICY RELATING TO ACOs

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Introduction

On March 31, 2011, contemporaneously with the Centers for Medicare & Medicaid Services (CMS) release of proposed regulations regarding the formation of Accountable Care Organizations (ACOs), the Federal Trade Commission (FTC) and Department of Justice (DOJ and, with the FTC, each an Agency and, collectively, the Agencies) issued a joint Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program (Policy Statement). This article summarizes the key provisions of the Policy Statement and its implications for ACO participants.

Summary

In sum, the Policy Statement provides that the Agencies will deem any ACO CMS qualifies for participation in the Medicare Shared Savings Program to be sufficiently integrated such that the activities of the ACO participants who contract with commercial payors will be judged under the rule of reason and not the per se standard of illegality–for as long as the ACO participates in the Medicare Shared Savings Program. In addition, the Agencies establish a safety zone providing that, absent extraordinary circumstances, the Agencies will not challenge an ACO comprised of independent ACO participants that provide a common service where the ACO's combined share of the common service is 30 percent or less in each ACO participant's primary service area (PSA). If the ACO's combined share of any common service is more than 50 percent in any ACO participant's primary service area, the ACO must undergo mandatory Agency review prior to applying to CMS for participation in the Medicare Shared Savings Program. An ACO that has a PSA share for any common service that exceeds 30 percent but is 50 percent or less may, but is not required to, seek Agency review. The attached flow chart identifies how the Agencies appear to be applying the Policy Statement to ACOs depending on their composition.

Background

Since Congress enacted the shared savings provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (Accountable Care Act) in March 2010, many commentators have expressed a variety of concerns regarding the application of the antitrust laws to the formation and operation of ACOs. At the extreme end, some suggested that the antitrust laws are a barrier to the formation and operation of ACOs, and argued that ACO participants needed legislative relief from the antitrust laws in order to seek to achieve the cost and quality mandates of the health reform legislation. Others simply suggested that the industry needed specific guidance for ACOs, and that existing Agency guidance did not clearly apply to ACOs, or provide enough assurance to ACO participants to encourage them to form ACOs. Under existing guidance, the Agencies view competing providers' collective price negotiation under the rule of reason and not per se standard of illegality when the provider participants are financially or clinically integrated and collective price negotiations are reasonably necessary to achieve the procompetitive benefits of their integration. The Agencies set forth standards for financial and clinical integration in their *1996 Statements of Antitrust Enforcement Policy in Health Care*,[1] advisory opinions and other guidance documents. Since ACOs and clinically-integrated networks share many common elements and are, in essence, collaborative ventures designed to achieve efficiency objectives, most believed that the Agencies should view ACOs as collaborative ventures subject to rule of reason analysis.

Agency Policy Statement

The Policy Statement reaffirms the basic principle that if providers sufficiently integrate through a legitimate joint venture, the Agencies will evaluate the antitrust implications of their activities under the rule of reason and not the per se standard of illegality. The Policy Statement also reaffirms the Agencies' commitment to ensuring that ACOs do not raise competitive concerns through the aggregation of competing providers.

The Policy Statement applies to ACOs formed after March 23, 2010. The Agencies are soliciting public comment on the proposed Policy Statement through May 31, 2011.

[1] http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm.

SUFFICIENT INTEGRATION

The Agencies determined that CMS's proposed ACO eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in guidance documents. Further, if a CMS-approved ACO provides the same or essentially the same services to commercial payors, the Agencies will treat joint negotiations with those payors as subordinate and reasonably related to the ACO's primary purpose of improving health care services. Accordingly, the Policy Statement provides that the Agencies will afford rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes that it uses to qualify for and participate in the Medicare Shared Savings Program.

ANTITRUST ANALYSIS OF ACOS THAT MEET CMS ELIGIBILITY

Depending upon the shares of each common service of an ACO comprised of independent competing providers in relevant PSAs, an ACO may qualify for an antitrust safety zone, have the option to seek Agency review, or be required to seek Agency review.

SAFETY ZONE

In the *1996 Statements of Antitrust Enforcement Policy in Health Care*, the Agencies set forth an antitrust safety zone for physician contracting networks, but did not extend the antitrust safety zone to multi-provider networks. Following passage of the Accountable Care Act, many advocated that the Agencies should extend the antitrust safety zone to multi-provider networks such as ACOs. The Agencies responded by creating an antitrust safety zone in the Policy Statement. An ACO qualifies for the safety zone if independent ACO participants that provide the same service have a combined share of 30 percent or less of each common service in each ACO participant's PSA.

Any hospital or ambulatory surgery center (ASC) participating in an ACO must be non-exclusive to the ACO to qualify for the safety zone, irrespective of its PSA share. Physicians and other providers may be non-exclusive or exclusive to the ACO, unless they fall within the rural exception or the dominant provider limitation.

RURAL PROVIDER EXCEPTION

The rural provider exception provides that an ACO may include one physician per specialty from each rural county—even if inclusion of that physician causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service—and still qualify for the safety zone so long as the physician from the rural county participates in the ACO on a non-exclusive basis. An ACO may also include rural hospitals, even if inclusion of a rural hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service, so long as the rural participant participates on a non-exclusive basis. Rural counties are defined by the U.S. Census Bureau. A rural hospital is a "critical access hospital" or a "sole community hospital," both within the meaning of Medicare program requirements.

DOMINANT PROVIDER LIMITATION

To fall within the safety zone, any ACO that includes a participant with greater than a 50 percent share (dominant provider) in its PSA of any service that no other ACO participant provides must be non-exclusive to the ACO. In addition, an ACO with a dominant provider cannot require a payor to contract exclusively with the ACO or otherwise restrict the payor's ability to contract with other ACOs or provider networks.

MANDATORY AGENCY REVIEW

Unless the rural exception applies, CMS will not approve for the Shared Savings Program any ACO with a PSA share in excess of 50 percent in 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 to challenge or recommend challenging the ACO under the antitrust laws. The Policy Statement requires the ACO to submit enumerated documents and information to the reviewing Agency at least 90 days before CMS's deadline for Medicare Shared Savings Program applications for the relevant calendar year. Specifically, the ACO must submit: (i) its CMS Shared Savings Program application and supporting documentation; (ii) documents or agreements relating to the ability of the ACO participants to compete with the ACO; (iii) documents discussing the ACO's business strategies to compete and the ACO's likely impact on quality, cost and price; (iv) formation documents; (v) PSA share calculations; (vi) restrictions on the ability of ACO participants

to obtain pricing information from other ACO participants who contract outside of the ACO; (vii) contact information for the ACO's top five commercial payors; and (viii) the identity of any other known ACO in any PSA in which the ACO will provide services. The Agencies have committed to completing the necessary review within 90 days of receipt of the required documents and information. Within that period, the reviewing Agency will advise the ACO that the Agency either has no present intent to challenge or recommend challenging the ACO (which could be conditional on the ACO taking certain action), or is likely to challenge or recommend challenging the ACO if it proceeds.

OPTIONAL AGENCY REVIEW

ACOs that are outside the safety zone and below the mandatory review threshold may, but are not required to, seek Agency review. Further, the Agencies identify five types of conduct that the ACO can avoid to reduce significantly the likelihood of an antitrust investigation:

- Preventing or discouraging commercial payors from steering patients to other providers
- Tying sales of the ACO's services to the payor's purchase of other services from providers outside the ACO
- Contracting with specialists and other providers on an exclusive basis (except for primary care physicians)
- Restricting a payor's ability to disclose to its beneficiaries cost and quality data
- Sharing among ACO participants competitively sensitive information that could give rise to an unlawful agreement

CALCULATING SHARES

The Policy Statement outlines a three-step process for calculating PSA shares. First, the ACO must identify each service provided by at least two independent ACO participants. Second, the ACO must identify the PSA for each common service for each participant in the ACO. The Agencies define the PSA as "the lowest number of contiguous zip codes from which" the ACO participant "draws at least 75 percent of its" patients, which is a concept they borrow from the Stark Law definition of the "geographic area served by the hospital," for purposes of determining application of the recruitment exception under that law.[2] Third, the ACO must calculate the ACO's PSA share for each common service in each PSA from which at least two ACO participants serve patients for that service.

For physicians, a "service" is the physician's primary specialty, as designated on the physician's Medicare Enrollment Application and identified by Medicare Specialty Code, and the ACO must calculate its shares of Medicare fee-for-service allowed charges. For hospitals, a "service" is a major diagnostic category (MDC) and the ACO must calculate its shares of inpatient discharges using state-level all-payor hospital discharge data where available. For outpatient facilities, a "service" is an outpatient category, as defined by CMS, and an ACO must calculate its shares of Medicare fee-for-service payments. All calculations should be based on the most recent calendar year for which data are available.

Implications for ACO Participants

RULE OF REASON TREATMENT

Application of the rule of reason treatment to an ACO which uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Medicare Shared Savings Program is a welcome relief to many ACOs, which otherwise would be subject to having their activities evaluated on a case-by-case basis to determine whether their provider participants are sufficiently integrated through the ACO to avoid per se condemnation. ACOs should know that rule of reason treatment only applies to an ACO for the duration of its participation in the Medicare Shared Savings Program; if an ACO drops out of the Medicare Shared Savings program but continues to contract with commercial payors jointly on behalf of competing providers, the ACO would not have assurance that the Agencies would view its activities in the commercial marketplace under the rule of reason (although arguably, if the ACO continues to use the same governance and leadership structure and the same clinical and administrative processes as it used to qualify for and participate in the Medicare

[2] 42 C.F.R 411.357(e)(2)(i).

Shared Savings Program, the Agencies should apply rule of reason treatment to it). Similarly, an ACO that never qualified for and participated in the Medicare Shared Savings program would not have this assurance.

SAFETY ZONE TREATMENT

ACO participants are well advised to seek to structure their formation and operation within the safety zone because of the protection from Agency scrutiny (absent extraordinary circumstances). However, many ACOs, particularly those outside of urban metropolitan areas, will not be able to qualify for safe harbor protection. Many ACOs will simply conclude that they need scale above the PSA share limits in order to spread risk and realize cost and quality efficiencies.

ACO participants seeking safety zone treatment should also understand the important limitations of the safety zone. First, it appears to apply to ACOs comprised of independent providers who provide different services so long as there is no dominant provider who is exclusive to the ACO. In other words, even if there is no horizontal combination of providers providing the same service through the ACO, the ACO participants will not qualify for safety zone treatment if any one of those ACO participants is a dominant provider and the dominant provider contracts with the ACO on an exclusive basis. If the dominant provider contracts with the ACO on a non-exclusive basis, then the safety zone should apply. Presumably, the Agencies are concerned that payors would be forced to contract with the ACO if the dominant provider was a "must have" and the ACO contracted with the dominant provider on an exclusive basis or the ACO required the payor to contract with the ACO exclusively.

Second, the safety zone protects the ACO participants from scrutiny by the Agencies only. The safety zone does not insulate the ACO participants from scrutiny from either state antitrust enforcement officials or private litigants with antitrust standing, such as commercial payors. In other words, it is not antitrust immunity. In addition, safety zone treatment applies only as long as the ACO participates in the Medicare Shared Savings program.

Finally, safety zone treatment no longer applies if the ACO's provider composition changes significantly. While the Agencies did not define a significant change, they did state that an ACO that is not within the rural exception and later exceeds the 30 percent share limitation solely because it attracts more patients will not lose its safety zone status.

MANDATORY AGENCY REVIEW

ACOs seeking qualification in the Medicare Shared Savings Program who must undergo mandatory Agency review should begin planning for it now. The Policy Statement requires an ACO that must undergo mandatory Agency review to submit its application to the Agencies at least 90 days before CMS' deadline for Medicare Shared Savings Program applications for the relevant calendar year. By way of example, the Policy Statement provides that if CMS sets November 1, 2011, as the last date for accepting applications to begin participation in the Medicare Shared Savings Program, then the ACO must submit its application to the Agencies no later than August 3, 2011. Since it will take ACOs some time to gather and analyze data to determine whether they must file an application with the Agencies, ACOs who seek to participate in the Medicare Shared Savings Program in the first year of the program should immediately begin to assess available data sources and application of the Policy Statement to the composition of their proposed ACOs.

Several alternatives are available to ACOs that do not want to spend the time or resources undergoing mandatory Agency review, when required. The Agencies state that the Policy Statement applies to collaborations among other competing providers and provider groups. They define a collaboration as a set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity. Therefore, it appears that an ACO comprised solely of an integrated health system and its employed physicians that is viewed as a single economic entity under the antitrust laws would not have to submit an application to the Agencies even if the ACO holds a PSA share in excess of 50 percent. The formation and operation of an ACO comprised solely of that integrated health system would not be a horizontal combination of two or more ACO participants under the antitrust laws. Therefore, an integrated health system whose physician employees hold a PSA share in excess of 50 percent in any relevant physician specialty would not be required to submit an application to the Agencies and receive clearance prior to submitting an application to CMS to participate in the Medicare Shared Savings Program. Of course, outside of the mandatory review process outlined in the Policy Statement, the Agencies could challenge an integrated health system's acquisition of physician practices if the Agencies conclude that the effect of such transaction may be substantially to lessen competition or tends to create a monopoly in violation of Clayton Act Section 7. But unless that acquisition was reportable under the Hart-Scott-Rodino Act, no mandatory Agency review would be required.

An ACO that seeks to contract with commercial payors only, and not with CMS for the Medicare Shared Savings Program, is not required to submit any application to the Agencies.

DOCUMENT CREATION AND MANAGEMENT

The mandatory review procedures under the Policy Statement emphasize the importance of document creation and management. An ACO required to undergo Agency review must submit to the Agencies documents discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets and the ACO's likely impact on the prices, cost or quality of any services the ACO will provide to any payor, among other documents. The Agencies also note that they may request additional documents and information where necessary to evaluate the ACO. ACOs that have generated reports concluding that a purpose of the ACO is to leverage rates with payors, or that the combination of providers through the ACO will enable the providers to raise rates above a competitive level, can be assured that the Agencies will view those documents as establishing unlawful intent and effect, respectively.

NON-EXCLUSIVITY AND FREE-RIDING

In several contexts, the Policy Statement requires non-exclusivity; that is, the ability of an ACO provider to contract with payors independently of the ACO. Specifically, all hospitals and ambulatory surgery centers must be non-exclusive to the ACO. Rural providers with relevant PSA shares over 30 percent and dominant providers must also be non-exclusive to the ACO. Non-exclusivity raises the free-riding issue of whether payors can realize the benefits of ACO activities by contracting with an ACO participant independently of the ACO at a rate that does not take into account the ACO's investment of resources in those ACO activities. The requirement for non-exclusivity in these contexts could have the chilling effect of forestalling the formation of ACOs, as ACOs struggle with the business rationale for investing significant capital, time and other resources in ACO formation when payors can reap the benefits of ACO activities without contracting with the ACO.

JOINT STATEMENT, BUT NOT REVIEW

The Agencies issued the Policy Statement jointly and both Agencies will review mandatory ACO applications, although only one of the Agencies will review each ACO application. It is not clear how the Agencies will assign cases between them. This raises the issue of whether the Agencies will apply the same or consistent review criteria to applications they receive. The Agencies will establish a FTC/DOJ ACO Working Group to collaborate and discuss issues arising out of the ACO reviews, so hopefully the Working Group will serve to minimize any inconsistencies. However, given the divergent views of the Agencies regarding antitrust enforcement generally,[3] the outcome of an ACO submission may depend in part on which Agency reviews the submission.

If you have questions regarding the joint FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, or have questions about accountable care organizations, please contact your regular McDermott lawyer or:

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[3] See "This Takeover Battle Pits Bureaucrat vs. Bureaucrat," by Thomas Catan, *Wall Street Journal*, April 12, 2011.

APPLICATION OF POLICY STATEMENT TO TYPES OF ACOs