

Antitrust Issues For Accountable Care Organizations: Revised Agency Guidance Spotlights Possible Concerns

Antitrust risk presents challenging issues for healthcare providers structuring an Accountable Care Organization (ACO) under the Medicare Shared Savings Program (MSSP).¹ The MSSP includes incentives to providers to collaborate to achieve savings for Medicare beneficiaries. Collaborations among competitors, however, can raise risks under the antitrust laws if they result in increased prices, fewer choices for consumers and payers, or a decrease in quality. Indeed, the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) (collectively the “Antitrust Agencies”) have been active in their enforcement of the antitrust laws against healthcare providers, prompting calls from the industry for further guidance on the formation and operation of ACOs. Accordingly, ACOs must consider whether the structure of their ACO and its actions with respect to commercial payers may run afoul of the antitrust laws.

The Antitrust Agencies recently jointly issued a “Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participation in the Medicare Shared Savings Program” (Policy Statement).² This statement finalizes a proposed statement issued for comment in April 2011. The most important elements of the Policy Statement are as follows, with major differences from the proposed Policy Statement noted:

- The Policy Statement, except for the expedited voluntary review, applies to all ACOs that are collaborations (short of a merger) among independent providers and provider groups. (The proposed Policy Statement would not have applied to collaborations in existence prior to the enactment of the Patient Protection and Affordable Care Act (PPACA)).
- Advanced approval by the Antitrust Agencies is not mandatory. (It would have been required for many ACOs by the Center for Medicare & Medicaid Services’ (CMS) proposed rule and the Antitrust Agencies’ proposed Policy Statement.) A newly-formed ACO may voluntarily request a review by the Antitrust Agencies and will receive a response within 90 days with an opinion on whether the ACO raises competitive concerns.

¹ The Medicare Shared Savings Program was established by the Patient Protection and Affordable Care Act (PPACA) and further defined by rules recently promulgated by the Centers for Medicare & Medicaid Services (CMS). Our Advisories on the CMS’s final rule are available at http://www.arnoldporter.com/public_document.cfm?u=CMSRuleImprovesBusinessCaseforACOsbutChallengesRemain&id=18045&key=13F1 and http://www.arnoldporter.com/public_document.cfm?u=AccountableCareOrganizationFinalRuleandGuidanceIncludesSubstantialChangesToEncourageParticipation&id=18032&key=22C0.

² 76 Fed. Reg. 67026 (Oct. 28, 2011).

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- ACOs with combined market shares of 30 percent or less for each of the participants' common services may qualify for a "safety zone" (i.e., safe from challenge by the Antitrust Agencies absent extraordinary circumstances). To qualify, hospitals, ambulatory surgical centers (ASCs), and "dominant providers" (discussed below) must be non-exclusive to the ACO. Special safety zone rules apply to ACOs in rural areas.
- The Policy Statement acknowledges that ACOs not within the safety zone may still be procompetitive. For these ACOs, the Policy Statement identifies conduct to avoid in order to mitigate risk of an enforcement action.

I. Applicability

The Policy Statement is broadly applicable to potential MSSP participants. The Proposed Statement would have been limited to ACOs formed after the PPACA became law. Industry participants urged the Agencies to apply the same Policy regardless of when the ACO was formed. In response, the final Policy Statement, except for the voluntary expedited review procedure, applies to all collaborations, short of a merger, among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the MSSP.

II. "Rule of Reason" Treatment For ACOs

The Policy Statement confirms that, in the Antitrust Agencies' view, collective price negotiations in the private market by ACOs that meet the eligibility requirements for the MSSP should be analyzed not as illegal *per se* horizontal price fixing, but rather under the more lenient "rule of reason." Arrangements that facilitate joint price negotiation by unintegrated, competing providers are generally condemned as *per se* violations of the antitrust laws, i.e., such conduct cannot be justified. However, collectively negotiating fees with private payers will not be deemed illegal *per se* when such negotiations are ancillary and reasonably necessary to achieve clinical integration that delivers services at a lower cost consistent with medical management protocols and guidelines. Such clinically integrated collaborations are analyzed under the "rule of reason" to evaluate "whether

the collaboration is likely to have substantial anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects."³

Accordingly, so long as ACO participants are not engaged in practices that facilitate price fixing – such as the exchange of competitively sensitive price information that relates to commercial business that is not within the ACO's scope of integrated services – *bona fide* ACOs will not be condemned as *per se* illegal price fixing agreements by the Agencies.

III. Antitrust Risk Analysis For ACOs

The Antitrust Agencies' attempt to answer in deciding whether to challenge the actions of an ACO focuses on whether the ACO possesses "market power," which is the ability to raise its prices to commercial payers above a competitive level or reduce quality or output of services below what would otherwise prevail absent the formation of the ACO. Because high market shares can be indicative of market power, the Antitrust Agencies scrutinize participants' market shares. The Policy Statement describes how the Agencies will calculate ACO market shares, at least initially, and establishes a "safety zone" for ACOs with shares of 30 percent or less that also meet other criteria. The market share calculation and the safety zone are described below.

A. Calculating Primary Service Area (PSA) Shares

While each ACO is not required to perform a market share analysis, any ACO that combines providers that offer the same services is advised to do so to assess the risk of an antitrust challenge related to the ACO's activities in the commercial market. The process for calculating shares involves three steps:

1. Identification of Common Services: Common Services are identified as those services provided by at least two independent ACO participants. The definition of "services" varies depending on the type of ACO participant and is defined for each type by CMS. For

³ *Id.* at 67027.

physician participants, a service is the physician's primary specialty as determined by the physician's primary Medicare Specialty Code (MSC) designated in the physician's Medicare Enrollment Application. For hospitals and other inpatient facility participants, a service is defined as a major diagnostic category (MDC). For outpatient facility participants, including hospitals and ambulatory surgery centers (ASCs), a service is an outpatient category as defined by CMS.

2. Identification of the PSA for each Common Service: The PSA for each Common Service for each ACO participant is identified as the lowest number of postal ZIP codes from which the participant draws at least 75 percent of its patients for that service. Each independent physician solo practice, each fully integrated physician group practice, each hospital facility, and each outpatient facility will have its own PSA.
3. Calculation of Share for Each Common Service in Each PSA: Methods for calculating PSA share vary based on the type of participant.
 - a. For physician services, share is calculated as the ACO's share of Medicare fee-for-service allowed charges in the PSA during the most recent calendar year for which data are available. For example, the PSA share for a Common Service of orthopedic surgery would be the total Medicare-allowed charges billed by all of the ACO's orthopedic surgeons divided by the total allowed charges for orthopedic surgery for all Medicare beneficiaries within the PSA.
 - b. For inpatient services, the ACO's share is calculated as its combined share of inpatient discharges, using state-level, all-payer hospital discharge data for the most recent calendar year. For example, if an ACO will include two hospitals providing inpatient cardiac care (MDC 05), the ACO's share for the Common Service would be calculated, separately for each hospital's PSA, as the total number of inpatient discharges for MDC 05 within that PSA for both

participating hospitals, divided by the total number of inpatient discharges for MDC 05 for that PSA.

- c. For outpatient services, share is calculated as the ACO's share of Medicare fee-for-service payments during the most recent calendar year for which data are available. For example, if a participating hospital and an ASC each provide cardiovascular tests/procedures on an outpatient basis, a PSA share for the Common Service would be calculated as the participating hospital's and ASC's combined total payments for cardiovascular tests/procedures for Medicare beneficiaries divided by total payments for cardiovascular test/procedures for all Medicare beneficiaries within that PSA.

B. "Safety Zone" Requirements

The agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances, such as the improper exchange of price information regarding the sale of competing services outside the ACO. In summary, the safety zone eligibility requirements are:

- Independent ACO participants that provide a common service have a combined share of 30 percent or less of each common service in each participant's PSA.
- Hospitals and ASCs must be non-exclusive to the ACO (i.e., the hospital or ASC is free to contract with private payers through other ACOs or individually).
- If the ACO has a "dominant participant," defined as a participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA, the "dominant participant" must be non-exclusive to the ACO. Also, an ACO with a "dominant participant" cannot require a private payer to contract exclusively with the ACO or otherwise restrict a private payer's ability to contract or deal with other ACOs or provider networks.

Because ACOs that operate in rural areas may exceed the 30 percent market share cap for the "safety zone," the Policy Statement includes a safety zone exception for rural areas. An ACO may include one physician or physician

group practice per specialty from each rural area on a non-exclusive basis and still fall within the safety zone if the physician's or group's primary office is in a ZIP code that is classified as "isolated rural" or "other small rural" according to the WWAMI Rural Health Research Center of the University of Washington's seven category classification.⁴ An ACO may also include a rural hospital on a non-exclusive basis and stay within the safety zone.

C. Behavior to Avoid

The Policy Statement stresses that all ACOs should implement controls to prohibit the improper sharing of competitively sensitive information relating to the provision of participants' services that compete outside the ACO. This caution applies regardless of whether the ACO is within the safety zone.

- ACOs with high PSA shares or other indicia of market power can mitigate antitrust risk, according to the Policy Statement, by avoiding the following conduct:
- Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "anti-tiering," "guaranteed inclusion," "most-favored-nation," or similar contractual clauses or provisions.
- Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the private payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant.
- Contracting on an exclusive basis with ACO physicians, hospitals, ASCs, or other providers.
- Restricting a private payer's ability to make available to its health plan enrollees information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency, and performance measures used in the MSSP.

⁴ Policy Statement, 76 Fed. Reg. at 67029 (citing <http://depts.washington.edu/uwruca/ruca-maps.php>).

The Policy Statement, however, acknowledges that some of the conduct listed above may be competitively neutral or even procompetitive, depending on the circumstances. Indeed, the Antitrust Agencies have acknowledged in guidance for multiprovider networks that, "an exclusive arrangement may help ensure the multiprovider network's ability to serve its subscribers and increase its providers' incentives to further the interests of the network."⁵ With the benefit of legal counsel, the ACO will need to balance antitrust risk with other business considerations when deciding how to structure itself and how it will operate with commercial payers.

IV. Expedited Voluntary Review

A newly-formed ACO that desires further antitrust guidance regarding its formation and planned operation may seek expedited review before entering the MSSP.⁶ The Antitrust Agencies have committed to providing a response within 90 days after the ACO provides all of the information they require for this purpose. The reviewing Agency will advise the ACO that the ACO's formation and operation, as described in the information provided to the Agency, either (i) does not likely raise competitive concerns or does not likely raise competitive concerns conditioned on the ACO's written agreement to take specific steps to remedy concerns raised by the Agency; (ii) potentially raises competitive concerns; or (iii) likely raises competitive concerns.

Although there is no mandatory advanced antitrust approval process by the Antitrust Agencies, providers seeking to form ACOs should carefully assess antitrust risk. Determining whether the ACO will fall into the safety zone will require a detailed analysis of provider PSA shares. For ACOs

⁵ FTC & DOJ, Statements of Antitrust Enforcement Policy in Health Care, Statement 9, p. 118 n.62 (1996) [hereinafter "Health Care Statements"] available at: <http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm>.

⁶ According to the Policy Statement, "newly-formed ACOs" are those ACOs that, as of March 23, 2010 had not yet signed or jointly negotiated any contracts with private payers, and have not yet participated in the MSSP. An ACO is not newly-formed if it comprises only the same, or a subset of the same, providers that signed or jointly negotiated contracts with private payers on or before March 23, 2010.

that are not within the safety zone, the participants will need to consider the risk of a challenge by the Antitrust Agencies. Moreover, the participants may want to consider whether they would benefit from the voluntary antitrust review procedure described in the Policy Statement. Many participants will want to consult with experienced antitrust counsel for guidance on these issues.

If you have any questions about any of the topics discussed in this Advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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