

## Antitrust Agencies Issue Guidance on Accountable Care Organizations

The Shared Savings program, established by The Patient Protection and Affordable Care Act,<sup>1</sup> incentivizes providers—including providers that previously competed to serve Medicare and non-Medicare patients—to collaborate to achieve savings for Medicare. 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. 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 Accountable Care Organizations (ACOs) to participate in the Medicare Shared Savings program.

In response to requests for more guidance, the Antitrust Agencies issued a proposed policy statement that establishes a procedure for mandatory antitrust review for ACOs with market shares that exceed 50 percent.<sup>2</sup> The Proposed Statement, issued on the same day that The Centers for Medicare & Medicaid Services (CMS) issued its proposed rules for the structure and regulation of ACOs,<sup>3</sup> also establishes a “safety zone” for ACOs with market shares below 30 percent and an optional review process for ACOs with market shares between 30-50 percent. The requirements of the Proposed Statement—including the analysis to determine whether the ACO must obtain pre-approval from the Antitrust Agencies, gathering information necessary for applying for such approval, and the timing of the application—are important gating items for successfully obtaining CMS approval.

- 1 The Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119-1025 (2010) (to be codified at scattered sections of 42 U.S.C.), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1020.
- 2 See, Federal Trade Commission/Antitrust Division of the Department of Justice, Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating In the Medicare Shared Savings Program [hereinafter Proposed Statement], *available at*: <http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf>.
- 3 Arnold & Porter’s Advisory on the proposed rule and other policy statements relating to ACOs issued on March 31, 2011 is *available at*: [http://www.arnoldporter.com/resources/documents/Advisory%20ACO\\_Alert\\_Emerging\\_Key\\_Provisions\\_Federal\\_Agencies\\_ACO\\_Guidance.pdf](http://www.arnoldporter.com/resources/documents/Advisory%20ACO_Alert_Emerging_Key_Provisions_Federal_Agencies_ACO_Guidance.pdf).

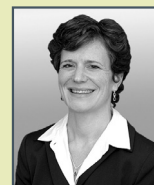
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Healthcare Reform Chart

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Indeed, the Antitrust Agencies estimate that between one-quarter and one-half of all ACOs will either require mandatory review or seek voluntary review. Parties who wish to comment on the Proposed Statement must do so by May 31, 2011.

The Proposed Statement confirms that the Antitrust Agencies intend to apply existing antitrust laws to healthcare providers, including ACOs formed for the Shared Success program. Indeed, Providence Health & Services—a network of hospitals, non-acute facilities, and physician clinics with a presence in Spokane, Washington—recently abandoned its plans to acquire two cardiology clinics in Spokane when the FTC’s Bureau of Competition raised concerns about potential anti-competitive effects of the transactions. Apparently in recognition of the regulatory tone that this result would set for providers seeking to form ACOs, the Bureau’s director, Richard Feinstein, issued a statement on April 8, 2011 that summarized the FTC’s continued enforcement of the antitrust laws with respect to ACOs:

The Bureau of Competition recognizes that physicians across the country are exploring a variety of new business arrangements as part of an effort to achieve cost containment and quality objectives. Some of the new business arrangements include consolidating with other same specialty or multi-specialty physician groups, entering into employment arrangements with hospitals, and forming other affiliations. Such arrangements have the potential to generate cost savings and quality benefits for patients. However, in some cases, such arrangements can create highly concentrated markets that may harm consumers through higher prices or lower quality of care. As is reflected by this investigation and its resolution, the Commission will aggressively enforce the antitrust laws to ensure that consolidation among health care providers will not increase health care costs in local communities across the United States.<sup>4</sup>

<sup>4</sup> See, Federal Trade Commission, Statement of Bureau of Competition Director Richard Feinstein on the Abandonment by Providence Health & Services of its Plan to Acquire Spokane Cardiology and Heart Clinics Northwest in Spokane, Washington, Apr. 8, 2011, *available at*: <http://www.ftc.gov/os/closings/110321providencstatement.pdf>.

### Antitrust Framework

Arrangements that facilitate joint price negotiation by competing providers are generally condemned as per se violations of the antitrust laws, i.e., there can be no justification for such conduct. Collectively negotiating fees with private payers is not 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 clinical 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.”<sup>5</sup> This analysis traditionally begins with a market-share test. Generally, market shares below 30 percent indicate that the collaboration is unlikely to have substantial anti-competitive effects.

Importantly, the Antitrust Agencies have determined that bona fide ACOs—those that meet CMS criteria for ACO formation—are sufficiently clinically integrated to warrant examination under the rule of reason. Accordingly, once an ACO has been approved by CMS, the ACO can offer the same ACO services to private payers, and negotiating the terms of those services will not be viewed by the Antitrust Agencies as a per se violation of the antitrust laws. The Proposed Statement explains how the rule of reason will be applied to ACOs, short of a full merger, formed after March 23, 2010.

### All ACO Applicants Must Undertake a Market-Share Analysis

The Proposed Statement requires every ACO to undertake a market-share analysis to determine whether it must file an application for Antitrust Agency review prior to CMS approval, no matter the intentions of the ACO with respect to serving non-Medicare patients and negotiating with private payers. The Proposed Statement sets forth the process for

<sup>5</sup> Proposed Statement at 4.

computing market shares based on the ACO's combined share of "Common Services" in each participant's Primary Service Area (PSA). ACOs that seek an antitrust review will be required to submit information sufficient to show its PSA share calculations for Medicare, as well as for each Common Service provided to commercial customers where those shares "differ significantly" from PSA share calculations derived from Medicare data.<sup>6</sup>

The process for calculating share involves three steps:<sup>7</sup>

1. Identification of Common Services: Parties must identify Common Services, that is, services provided by at least two independent ACO participants. The definition of "services" varies depending on the ACO participant and is defined in each case by CMS. For 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 (ASC), a service is an outpatient category as defined by CMS.
2. Identification of the PSA for Each Common Service: Parties must next identify the PSA for each Common Service for each ACO participant, defined as "the lowest number of contiguous postal zip codes from which the participant draws at least 75 percent of its patients for that service."
3. Calculation of Share for Each Common Service in Each PSA: Proposed methods for share

calculations are defined separately 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 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 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 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.
- (c) For inpatient services, the ACO's share is calculated as its combined share of inpatient discharges, using state-level all-payer hospital discharge data where available for the most recent calendar year. For example, if an ACO will include two hospitals providing inpatient cardiac care (MDC 05) for cardiac patients located in each hospital's PSA, 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

<sup>6</sup> Proposed Statement at 9.

<sup>7</sup> The Proposed Statement acknowledges that a PSA may "not necessarily constitute a relevant antitrust geographic market" but nonetheless they provide "a useful tool for evaluating potential anticompetitive effects." Proposed Statement at 6 n. 22.

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

### Antitrust “Safety Zone” for ACOs

Qualifying ACOs need not seek prior antitrust review and the “Agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances.”<sup>8</sup>

To qualify for the safety zone:

- All of the ACO’s Common Service PSA shares must be 30 percent or below.
- All hospitals or ASCs participating in the ACO must be non-exclusive to the ACO.
- Any “Dominant Provider” must be non-exclusive to the ACO. A Dominant Provider is an ACO participant providing a service no other ACO participant provides and with a market share greater than 50 percent share in its PSA of that service.
- An ACO with a Dominant Provider cannot contractually restrict a commercial payer’s ability to contract or deal with other ACOs or provider networks.

The proposed policy includes more lenient treatment for ACOs in rural areas. Notwithstanding the market-share limitations described above, an ACO may include one hospital and one physician per specialty from each rural county (defined by the Census Bureau) on a non-exclusive basis and be in the “safety zone.”<sup>9</sup>

### Mandatory Filing Review for ACOs with 50 Percent Share

Every ACO that includes two or more participants who, combined, have a 50 percent share or more in *any* Common Service within a PSA *must* obtain a letter from the FTC or DOJ stating it has no present intent to challenge the ACO *before* CMS review. The Antitrust Agencies require 90 days to review the submission, so the application must be completed and submitted with sufficient time for the

Antitrust Agencies’ review.<sup>10</sup> ACOs should build in sufficient lead time for preparing for such a filing into its regulatory approval strategy.

### Practical Considerations for ACO Formation

ACOs that are not within the safety zone but do not meet the mandatory filing thresholds for prior review will operate with some uncertainty regarding the prospect of an antitrust investigation. The Proposed Statement permits these ACOs to voluntarily submit an application to the Antitrust Agencies using the same mandatory approval protocol. Moreover, the Proposed Statement identifies five types of conduct that may expose ACOs outside the safety zone to increased risk of an enforcement action by the Antitrust Agencies and, presumably, will be considered for those seeking approval, which include:

- using contractual terms that have the effect of discouraging commercial payers from directing or incentivizing patients to choose certain providers, such as “anti-steering,” “guaranteed inclusion,” “product participation,” “price parity,” most favored nations clauses, or similar;
- conditioning (either explicitly or through pricing) the ACO’s services on a commercial payer’s purchase of other services from providers outside the ACO and vice versa;
- making any of the ACO’s participants, (including hospitals, ASCs, and specialists) *except for primary care physicians*, exclusive to the ACO;

<sup>8</sup> Proposed Statement at 6.

<sup>9</sup> Proposed Statement at 7 (citing: <http://www.census.gov/geo/www/ua/2010Urbanruralclass.html>).

<sup>10</sup> The Proposed Statement describes the information required in the submission: (1) the ACO’s application to CMS and all supporting documents; (2) documents relating to the ability of the ACO participants to compete with the ACO or incentives for participants to contract with payers through the proposed ACO; (3) documents discussing the ACO’s business plans or strategies to compete in the Medicare and commercial markets; (4) documents showing that the ACO was formed after March 23, 2010; (5) the ACO’s share calculations; (6) documents reflecting restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract through the ACO; (7) a list of the five largest commercial health plans or other payers for the ACO’s services; and (8) the identity of other known ACOs in the filing ACO’s PSAs.

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- restricting a commercial payer’s ability to make available to enrollees information similar to the Shared Success performance measures; and
- sharing among the ACO’s provider participants competitively sensitive data such as pricing outside the ACO.

Indeed, it is advisable that every ACO devise procedures to prevent the exchange of competitively sensitive information relating to services rendered outside of the ACO among participants to minimize the possibility of improper price coordination for services outside the ACO. ACOs that are not within the safety zone that wish to engage in any of the other conduct listed above should be prepared to explain (as part of the mandatory approval process, a voluntary submission, or in the context of an investigation by the Antitrust Agencies) why such conduct would not have anti-competitive effects (i.e., the conduct would not increase commercial payers’ costs or eliminate consumer choices) and that any anti-competitive effects are outweighed by the quality improvements and cost savings the ACO is designed to achieve.

*We hope that you have found this Advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:*

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ACO PSA Share	Review Process
≤ 30 percent (with a rural exception)	<i>Safety Zone</i> -- No antitrust review necessary by the Antitrust Agencies
>30 percent and ≤50 percent	<i>Expedited review, compliance with list of conduct restrictions, or proceed without antitrust assurances</i> – ACOs may: <ol style="list-style-type: none"> <li>1. Request an expedited review by the Antitrust Agencies and submit letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO,</li> <li>2. Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or</li> <li>3. Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.</li> </ol>
>50 percent	<i>Required expedited review</i> -- ACO must seek review by the Antitrust Agencies to assess likelihood of procompetitive and anticompetitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO's submission of a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

Source: CMS Proposed ACO Rule p. 333

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