Introduction:

The following is an update of our article published in the April 22, 2011 issue of Antitrust & Trade Regulation Report (100 ATRR 441) regarding the Federal Trade Commission ("FTC") and Department of Justice ("DOJ," collectively the "Agencies"), Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "Policy Statement").

The April article described the Agencies' Proposed Policy Statement, which was issued March 31, 2011, and included a request for comments to be submitted no later than May 31, 2011. In total, 127 comments were submitted during that time period. The Agencies also held a workshop on May 9, 2011 in which panels including representatives of health care providers, payers, and academics stated their views regarding the Proposed Policy Statement. In many cases, providers expressed concerns that the provisions of the Proposed Policy Statement were too burdensome, including the requirement that any proposed Accountable Care Organization ("ACO") with a share of more than 50 percent for any service provided by two or more participating providers in their primary service areas (defined below) undergo mandatory review by one of the Agencies as a condition of participating in the Shared Services Program. On the other hand, payers expressed concerns that the Proposed Policy Statement represented an unwarranted relaxation of antitrust enforcement relating to provider networks that increased the likelihood ACOs with market power would form and operate.

On October 20, 2011, the Agencies issued their Final Policy Statement ("Final Statement" or "Statement"). The Final Statement differs from the proposed version in two material respects:

- The Final Statement applies to all provider collaborations that are eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program. The Proposed Policy Statement was limited to ACOs formed after March 23, 2010.

The Final Statement no longer requires that any ACO undergo mandatory antitrust review by the Agencies.²

The following is a summary of the key terms of the Final Statement as well as an analysis of the likely impact of the Final Statement on competition among providers and the terms on which they contract with health plans.

Background:

Section 2706 of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (“PPACA” or the “Act”) authorizes physicians, hospitals and other health care providers to form ACOs to work together to manage and coordinate care for Medicare beneficiaries for purposes of the Act’s Medicare Shared Savings Program.

Under that program, participating providers meeting certain criteria defined by the Centers for Medicare and Medicaid Services (“CMS”) may qualify to share savings they create under the Medicare program. Given the time and resources required to form and operate ACOs, however, it is anticipated that participating providers will use the same ACOs for commercially insured patients as well.

The FTC and DOJ recognize that ACOs may result in innovations and other benefits for both Medicare and commercially insured patients, but also that the increased provider consolidation resulting from the formation of ACOs may have anticompetitive effects. To balance these concerns, on October 20, 2011, the same date on which CMS issued final rules regarding the formation of ACOs, the Agencies issued the Final Statement “to ensure that health care providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets.”

The Final Statement addresses the criteria ACOs qualifying for the Shared Savings Program must meet to be considered sufficiently integrated by the Agencies to engage in joint price negotiations with commercial health plans (referred to in the Statement as “private payers”), and other joint activity, without being liable for per se violations of the Sherman Act. In addition, the Statement sets out criteria for how ACOs representing various shares of services in participating providers’ “primary services areas” will be evaluated by the Agencies under the rule of reason. This includes defining a new safety zone for networks that do not represent more than 30 percent of any health care service, even if the network is exclusive as to physician services.

On the whole, the Final Statement will give providers greater leeway than the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care (http://www.justice.gov/atr/public/guidelines/1791.htm) ("1996 Health Care Statements") and Advisory Opinions (http://www/ftc.gov/bc/healthcare/industryguide/advisory.htm#2010), to form consolidated networks with the potential to exercise market power in negotiating with health plans. Further, elimination of the mandatory review requirement from the Statement will require health plans to be proactive in alerting the Agencies to newly forming ACOs that are potentially anticompetitive as well as existing ACOs that are engaging in anticompetitive behavior.

Applicability:

The Final Statement applies to ACOs that are eligible and intend, or have been approved by CMS to participate in the Shared Savings Program.

While the Statement applies to a variety of forms of collaboration between otherwise independent providers used to form an ACO (e.g., a joint venture), it does not apply to mergers, which will continue to be evaluated under the DOJ and FTC Horizontal Merger Guidelines (99 ATRR 231) ("Merger Guidelines"). In order to qualify for the Shared Savings Program, ACOs must sign up with CMS to participate for at least three years beginning in 2012.

Summary of Policy Statement Provisions:

A. Integration

In general, joint pricing agreements among competitors are treated as per se illegal under Section 1 of the Sherman Act. However, a joint pricing agreement among competing health care providers is evaluated under the rule of reason — under which the potential procompetitive benefits of the agreement are weighed against its potential anticompetitive effects — if the providers are financially or clinically integrated, and the agreement is reasonably necessary to accomplish the procompetitive benefits of that integration.

Under the 1996 Health Care Statements, the Agencies defined specific types of financial integration, or risk sharing, such as entering into capitated contracts or withholding a substantial portion of provider compensation (e.g., 20 percent), that would be paid only if the participating providers as a group met certain cost containment goals; the Health Care Statements also acknowledged that other types of financial integration might be sufficient. In addition, the Health Care Statements described general criteria for sufficient clinical integration, including that the providers implement an ongoing program to evaluate and monitor practice patterns and to create a high degree of interdependence among the providers to control costs and quality, but the Health Care Statements did not provide specific criteria for clinical integration; rather, FTC staff advisory opinions discussed evidence sufficient to meet these requirements in specific circumstances. See FTC advisory opinions at http://www/ftc.gov/bc/healthcare/industryguide/advisory.htm#2010.

In the Final Statement, the Agencies have taken a different approach by agreeing to accept CMS eligibility criteria for the Shared Savings Program as sufficient to demonstrate initially that ACOs are clinically integrated for purposes of qualifying for rule of reason treatment.³ PPACA Section 3022 provides that CMS may approve ACOs that meet certain eligibility criteria, including (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

² Final Statement at 1. Other relevant differences between the Proposed and Final Statements are noted below.

³ See Final Statement at 5 (CMS proposed eligibility criteria are “broadly consistent” with the indicia of clinical integration in the 1996 Health Care Statements and advisory opinions regarding specific proposed networks).
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 Statement also provides that if a CMS-approved ACO uses the same governance and leadership structure and the same clinical and administrative processes it uses in the Shared Savings Program in the commercial market, these integration criteria are sufficient to support rule of reason treatment for ACO agreements with commercial payers as well. Factors (1) and (2) do not have any apparent competitive characteristics of antitrust significance; factors (3)-(5), however, appear to be a proxy (albeit a regulatory one) for the more traditional antitrust analysis that would determine whether a joint venture is financially or clinically integrated.

B. Rule of Reason Treatment for ACOs Meeting CMS Eligibility Criteria

Under the Final Statement, the FTC and DOJ have divided ACOs that meet CMS eligibility requirements for the Shared Savings Program, and therefore are treated as clinically integrated, into two categories for purposes of rule of reason treatment based on the share of services the ACO has in the primary service areas or "PSAs" of participating providers.

These include (1) an antitrust safety zone for ACOs that do not exceed 30 percent of any PSA share threshold; (2) and additional guidance and voluntary Agency review for ACOs that exceed this 30 percent threshold or are otherwise outside of the safety zone.

1. Antitrust Safety Zone

For an ACO to fall within the safety zone, participating providers that provide a "common service" must have a combined share of 30 percent or less of each common service in each participant's PSA. For physicians, this threshold applies regardless of whether they participate in the ACO on an exclusive or non-exclusive basis. (In contrast, in Statement No. 8 of the 1996 Health Care Statements (Physician Joint Ventures), the antitrust safety zone for physician networks applied a 20 percent threshold to exclusive networks, and a 30 percent threshold to non-exclusive networks.) In addition, any participating hospital or ambulatory surgery center ("ASC") must contract with the ACO on a non-exclusive basis, regardless of whether the PSA shares of competing hospitals or ASCs for any common service are 30 percent or below. There are two exceptions to these criteria:

- **Rural Exception:** An ACO can include one physician or physician group practice per specialty from each rural area² on a non-exclusive basis, and can include Rural Hospitals³ on a non-exclusive basis, and qualify for the safety zone even if the inclusion of such a physician, physician practice or hospital causes the ACO to exceed the 30 percent threshold for any common service in any ACO participant's PSA for that service; and

- **Dominant Provider Limitation:** The ACO can include a provider with a greater than 50 percent share in its PSA of any service that is not provided by any other ACO participant in that PSA so long as (a) that "dominant" provider participates in the ACO on a non-exclusive basis, and (b) the ACO does not require a private payer to contract with the ACO exclusively or otherwise restrict a private payer's ability to contract with other ACOs or provider networks.

2. ACOs Outside the Safety Zone

The Proposed Policy Statement provided for mandatory review by the Agencies of an ACO with a PSA share of more than 50 percent for any common service before the ACO could participate in the Shared Savings Program, and guidance and voluntary review for ACOs with shares of 30-50 percent.

The Final Statement does not include a mandatory review requirement. The Statement acknowledges that an ACO that is outside the safety zone frequently may be procompetitive, but also has the potential to have anticompetitive effects. Therefore, it describes certain types of conduct such an ACO should avoid to reduce the likelihood that it will be investigated and found to be anticompetitive. The Final Statement also describes how an ACO can obtain additional guidance from the Agencies, as well as how the Agencies will monitor the competitive performance of ACOs in the Shared Savings Program.

a. Conduct to Avoid

i. Improper Sharing of Competitively Sensitive Information

² To calculate these shares, the ACO first must identify any service provided by two or more participating providers or groups of providers ("common service"). For each such service, the ACO then must calculate the share all ACO providers have in each PSA in which two or more ACO participating providers provide the service. "PSA" is defined as the lowest number of postal zip codes from which the provider obtains at least 75 percent of its patients. Services are defined for physicians based on Medicare Specialty Codes as defined by CMS, and shares are calculated based on total Medicare allowed charges for claims billed; services are defined for inpatient services by Medical Diagnostic Categories and calculated based on patient discharge data; for outpatient services provided by hospitals or ambulatory surgery centers, shares are based on Medicare fee-for-service payment data for the common services categories. Similarly, for services rarely used by Medicare recipients (e.g., pediatrics, OB/GYN), the ACO should use fee-for-service payment data or, if such data are not available, for example, data on the number of active physicians within the specialty located within the PSA.

³ For example, if an ACO includes two cardiologist practice groups, A and B, cardiology would be a common service, and the ACO would need to calculate the combined share of cardiology services based on total Medicare allowed charges for claims billed by the ACO's cardiologists in both A's and B's PSA. Unless the share for each common service in each PSA is 30 percent or below, the ACO cannot qualify for the safety zone.

⁴ Unlike the Proposed Policy Statement, which used U.S. Census Bureau definitions of "rural counties," the Final Statement defines "rural area" as any county containing at least one zip code that has been classified as "isolated rural" or "other small rural" according to the WWAMI Rural Health Research Center of the University of Washington, [http://depts.washington.edu/uwruca/rucha-rural-rural.html](http://depts.washington.edu/uwruca/rucha-rural-rural.html)

⁵ A "Rural Hospital" is defined as a "Solo Community Hospital" or "Critical Access Hospital" as defined for purposes of the Social Security Act and Medicare regulations, or any other hospital located in a rural area that has no more than 50 acute care inpatient hospital beds and is located at least 35 miles from any other inpatient acute care hospital.
Regardless of whether an ACO has a high market share or other indicia of market power, significant competitive concerns can arise if the ACO’s operations lead to price fixing or other collusion among ACO participants in their sale of services outside the ACO. For example, sharing competitively sensitive data, including pricing information, among ACO participating providers could facilitate collusion on prices other terms for their non-ACO business. To avoid these concerns, the Final Statement recommends that the ACO implement appropriate firewalls or other safeguards against such collusion.

ii. Conduct by ACOs with High PSA Shares or Other Possible Indicia of Market Power That May Raise Competitive Concerns

For ACOs with high PSA shares or other indicia of market power, the Agencies identify four types of conduct that may raise competitive concerns. The Final Statement notes that whether these activities actually raise concerns will depend on each ACO’s circumstances, including whether the ACO has market power (i.e., concerns will be greater the fewer the number of competing ACOs and/or the number of physicians available to participate in competing ACOs). The four types of conduct are:

- Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers, including providers who do not participate in the ACO, through “anti-steering,” “anti-tiering,” “most favored nations” or similar contractual clauses or provisions;
- Tying sales of the ACO’s services to the private payer’s purchase of other services from providers outside the ACO (e.g., an ACO should not require a payer to contract with all of the hospitals under common ownership with a hospital that participates in the ACO);
- Contracting with ACO physicians, hospitals, ASCs or other providers on an exclusive basis that prevents or discourages them from contracting with private payers outside the ACO (including through a competing ACO); and
- Restricting a private payer’s ability to share cost, quality, efficiency and performance information with its enrollees to aid them in selecting providers in the health plan.

b. Availability of Expedited Voluntary Agency Review

A newly formed ACO (i.e., an ACO formed after March 23, 2010) that wants additional guidance can seek expedited 90-day review from the Agencies regarding whether the ACO’s formation and planned operation is likely to harm competition. The ACO should submit its request for review to both Agencies prior to entering into the Shared Savings Program, after which the ACO will be told which of the Agencies will conduct the review. To start the 90-day review period, the reviewing Agency must receive certain the documents and information. In addition, to the extent possible during the 90-day review period, the reviewing Agency will consider factors in the rule of reason analysis contained in the 2000 FTC and DOJ Antitrust Guidelines for Collaborations Among Competitors (www.ftc.gov/os/2000/04/ftcdojguidelines.pdf) and the 1996 Health Care Statements, Statement No. 8 (Physician Network Joint Ventures) and No. 9 (Multiprovder Networks).

As noted above, the Final Statement represents what in some respects is a significant departure from the guidance the FTC and DOJ provided in the 1996 Health Care Statements, Statement No. 8 (Physician Network Joint Ventures) and No. 9 (Multiprovder Networks). A number of the key differences are summarized in the table below:

8 The Final Statement does not define “high market share.” Based on the 50 percent mandatory review threshold that was in the Proposed Policy Statement, however, it seems likely that ACOs with a PSA share approaching or exceeding 50 percent for one or more common services will attract closer scrutiny.

9 The Final Statement also notes that the 1996 Health Care Statement Nos. 4, 5 and 6 provide guidance for how pricing, cost and other data may be shared among competitors, including safety zones for fee and non-fee related data.

10 The required information includes: (1) the ACO’s application and supporting materials that it has submitted or plans to submit to CMS for the Shared Savings Program; (2) documents regarding the ACO’s plans to compete in the Medicare or commercial markets and the ACO’s likely impact on prices, costs and quality; (3) the level and nature of competition among ACO participants and the competitive significance of the ACO and its participants in the markets in which they provide services; and (4) information sufficient to show the common services provided by ACO participants, the PSA for each ACO participant, the ACO’s PSA shares for each common service, restrictions that prevent ACO participants from obtaining competitor price information, the identity of the five largest actual or projected private payers for the ACO’s services, and the identity of existing or proposed ACOs that will operate in any PSA where the ACO will provide services. The ACO also may provide other information that may be useful to the review, including evidence the ACO does not have market power, substantial procompetitive justifications for the ACO’s composition, and if relevant, why the ACO is engaging in any of the four types of conduct the Final Statement says should be avoided.

11 Based on past experience with the 1996 Health Care Statements that promised a similar deadline for reviewing proposed conduct, this time frame is unrealistic given all of the information the Agencies are seeking and the follow up that will be required to analyze it. 90 to 180 days is more realistic, especially if the reviewing Agency is besieged with requests for the Agencies’ enforcement intentions.
<table>
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<tr>
<th>Guideline Features</th>
<th>1996 Health Care Statements</th>
<th>ACO Policy Statement</th>
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<tr>
<td>Safety Zone Thresholds</td>
<td>Exclusive physician network — 20% or less of providers in a given specialty in a local geographic market. Nonexclusive physician network – 30% or less of providers in a given specialty in a local geographic market. No safety zone for multi-specialty networks including both physicians and hospitals.</td>
<td>30% or less of a given common service for both exclusive and non-exclusive ACOs regarding physicians in the PSAs of the physicians providing the common service. Same threshold as physicians for hospitals and ASCs provided they are non-exclusive.</td>
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<tr>
<td>Exception for Areas with Few Physicians/Rural Exception</td>
<td>Exclusive network – areas with fewer than 5 physicians in a specialty – can include 1 physician on a non-exclusive basis. Non-exclusive network – areas with fewer than 4 physicians in a specialty – can include 1 physician.</td>
<td>ACO can include one physician or physician group per specialty in each rural county and Rural Hospitals on a non-exclusive basis.</td>
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<tr>
<td>Dominant Provider Limitation</td>
<td>Subject to 20%/30% thresholds.</td>
<td>Can include a participant with a greater than 50% share of a service in its PSA on a non-exclusive basis so long as no other ACO participant provides the same service in that PSA.</td>
</tr>
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<td>Safety Zone Integration Requirement</td>
<td>Participating providers must share substantial financial risk.</td>
<td>Clinical integration as defined by CMS.</td>
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<td>Geographic Market Definition</td>
<td>Threshold percentages measured in geographic market – generally will be local Provider PSA.</td>
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<tr>
<td>Analysis of Networks Outside the Safety Zone</td>
<td>Rule of reason analysis, including defining relevant markets, evaluating potential anticompetitive effects and efficiencies.</td>
<td>Similar rule of reason analysis, but additional guidance is provided regarding steps ACOs can take to avoid challenge.</td>
</tr>
<tr>
<td>Mandatory Review</td>
<td>None.</td>
<td>Proposed Policy Statement: For ACOs exceeding 50% threshold for any common service in any PSA. Final Statement: None.</td>
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<tr>
<td>Voluntary Review</td>
<td>For any network – commitment to respond within 90 days after submission of all necessary information.</td>
<td>For any ACO outside of the safety zone – commitment to respond within 90 days after specified information is provided.</td>
</tr>
<tr>
<td>Agency Monitoring</td>
<td>Respond to complaints re anticompetitive behavior.</td>
<td>Proposed Policy Statement: Respond to complaints re anticompetitive behavior. Final Statement: Will use CMS data to monitor ACO competitive effects and respond to complaints re anticompetitive behavior.</td>
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As this table shows, the Final Statement relaxes a number of key provisions of the 1996 Health Care Statements regarding safety zones, including not requiring financial integration for safety zone treatment, deferring to CMS on what constitutes sufficient clinical integration, permitting exclusive networks with up to 30 percent of the share of services in a geographic area, and permitting ACOs with providers with more than 50 percent of the services in one area, to qualify for safety zone treatment. In addition, the Statement extends safety zone treatment for the first time to multi-provider networks that include hospitals. On the other side of the ledger, Agency monitoring of ACOs in the Shared Savings Program may result in more active Agency enforcement or have the effect of discouraging anticompetitive behavior even by ACOs with market power. However, because the data for such monitoring will be limited to data from the Medicare program, in which the government sets prices and has greater control over the terms of service than a private...
payers, it may have limited impact on whether an ACO engages in anticompetitive behavior towards private payers.

Further, the use of PSAs as a surrogate for geographic markets is likely to result in ACOs being evaluated in narrower geographic areas than under the 1996 Health Care Statements. PSAs are based solely on the areas in which providers historically have obtained patients while geographic market analysis under the 1996 Health Care Statements employed the geographic market definition principles in the Merger Guidelines, which consider the alternatives in other geographic areas to which existing patients could turn in response to a price increase. (See 1996 Health Care Statement No. 8, Section B.2 (Applying the Rule of Reason)). In many cases, a PSA may result in a narrower geographic area, and higher shares, than would a geographic market as described by the Merger Guidelines. On the whole, however, there is a substantial likelihood that the Final Statement will permit ACOs to form that represent a higher degree of market concentration, and less stringent integration requirements, than would have been permitted under the 1996 Health Care Statements.

Conclusion:

The Final Statement appears to allow additional provider consolidation while at the same time relaxing, to a certain extent, integration requirements.

This may allow the formation of ACOs with a greater ability to exercise market power against health plans than ACOs formed under the 1996 Health Care Statements. Given the elimination of mandatory review under the Final Statement, it will be critical for ACOs to carefully consider whether their formation or operation raises competitive concerns and, if so, to take appropriate steps to ensure they operate in compliance with the antitrust laws, including seeking voluntary review where appropriate.

In addition, health plans need to be vigilant about ACOs that they believe raise competitive concerns, or that may be operating in an anticompetitive manner. This may include being much more proactive in contract negotiations and, where appropriate, bringing those concerns to the attention of the Agencies.