BNA's

ANTITRUST & TRADE REGULATION

REPORT

Reproduced with permission from Antitrust & Trade Regulation Report, 100 ATRR 441, 04/22/2011. Copyright © 2011 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

HEALTH CARE

Analysis of DOJ/FTC Proposed Policy on Accountable Care Organizations

BY ROBERT E. BLOCH AND SCOTT P. PERLMAN

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 Accountable Care Organizations (''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 ensured patients as well.

The Federal Trade Commission (''FTC'') and Department of Justice (''DOJ,'' collectively the ''Agencies'') 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 March 31, 2011 (100 ATRR 347), the same date CMS issued proposed rules regarding the formation of ACOs, the FTC and DOJ issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the ''Policy 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 Agencies also requested comments be submitted regarding this proposal no later than May 31, 2011.

The Policy 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, and other joint activity, without being liable for *per se* violations of the Sherman Act. In addition, the Policy 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 Policy Statement will give providers greater leeway than the 1996 FTC/DOJ *Statements of Antitrust Enforcement Policy in Health Care* ("1996 Health Care Statements" or "Statements"), to form consolidated networks with the potential to exercise market power in negotiating with health plans.

Applicability:

The Policy Statement applies to ACOs formed after March 23, 2010, that seek to participate or have been approved by CMS to participate in the Shared Savings Program.

While the Policy 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* ("Merger Guidelines"). See 99 ATRR 231. In order to qualify for the Shared Savings Program, ACOs must sign up with CMS to participate for at least three years beginning January 1, 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 Statements also acknowledged that other types of financial integration might be sufficient. The Statements also 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 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 Policy 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.[1] 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 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 Policy Statement also provides that if a CMS-approved ACO uses the same governance and leadership structure, and provides the same or essentially the same services, 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 Policy 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 three 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) mandatory agency review for ACOs that exceed 50 percent of any PSA share threshold; and (3) optional review and guidance for ACOs that are outside of the safe harbor but do not exceed the 50 percent threshold.[2]

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.[3] For physicians, this threshold applies regardless of whether they

---

[1] See Policy Statement at 5 (CMS proposed eligibility criteria are "broadly consistent" with the indicia of clinical integration in the 1996 Health Care Statements).

[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 smallest contiguous area from which the provider obtains 75% of its patients. Services are defined for physicians based on Medical Services Codes, 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.

[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 in both A's and B's PSA. Unless the share in each

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 0003-6021

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 per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis, and can include rural hospitals (defined by CMS as a ''Sole Community Hospital'' or ''Critical Access Hospital'') on a non-exclusive basis, and qualify for the safety zone even if the inclusion of such a physician 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 commercial payer to contract with the ACO exclusively or otherwise restrict a commercial payer's ability to contract with other ACOs or provider networks.

2. Mandatory Agency Review of ACOs Exceeding the 50 Percent PSA Threshold

An ACO that includes two or more providers with a combined share of more than 50 percent for any common service in any PSA, and that does not qualify for the rural exception, will not be approved to participate in the Shared Savings Program unless, as part of the CMS application process, the ACO provides CMS with a letter from the FTC or DOJ stating that the reviewing Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws.

In order to obtain the required Agency review, the ACO must submit the following information: (1) the ACO's application and supporting materials that is has submitted or plans to submit to CMS for the Shared Savings Program; (2) documents relating to the ACO participants' ability to compete with the ACO, or to any incentives to encourage ACO participants to contract with CMA or commercial payers through the ACO; (3) 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; (4) documents showing the formation of the ACO or any ACO participant formed or affiliated with the ACO after March 23, 2010; (5) information sufficient to show 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 commercial payers for the ACO's services, and the identity of existing or proposed ACOs that will operate in any PSA where the ACO provides services. This information must be submitted to the Agencies at least 90 days before the CMS deadline for applications to the Shared Savings Program. The FTC and DOJ then will decide which Agency will review the information.

The Agencies commit in the Policy Statement that within 90 days of the ACO submitting the required information, the reviewing Agency will advise the ACO that it has no present intent to challenge the ACO, or that it is likely to recommend a challenge.[4] CMS will not approve an ACO that receives a letter indicating the reviewing Agency is likely to challenge the ACO.

3. ACOs Below the 50 Percent Mandatory Review Threshold and Outside the Safety Zone

The Policy Statement acknowledges that an ACO that is outside the safety zone but below the 50 percent mandatory review threshold frequently may be procompetitive, but also has the potential to have anticompetitive effects. Therefore, while such ACOs are not subject to mandatory review, the Policy Statement offers guidance by describing five types of conduct such an ACO should avoid to reduce the likelihood that it will be investigated and found to be anticompetitive:

- Including ''anti-steering'' type clauses that discourage payers from incentivizing insureds to use certain providers, including providers that do not participate in the ACO;
- Tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO (e.g., requiring a payer to contract with a non-ACO hospital affiliated with an ACO hospital);
- With the exception of primary care physicians, contracting with ACO providers (*e.g.*, physician specialists, hospitals, ASCs) on an exclusive basis;
- Restricting a commercial payer's ability to share cost, quality, efficiency and performance information with its enrollees to aid them in selecting providers in the health plan; and
- Sharing competitively sensitive data, including pricing information, among ACO participating providers that could be used to set prices or other terms for their non-ACO business.

An ACO seeking additional guidance can seek expedited review from the Agencies regarding the ACO's formation and planned operation by providing the same information required for a mandatory review. As with a mandatory review, the reviewing Agency will complete its review within 90 days of receiving all required information. CMS will not approve an ACO for the Shared Savings Program if the reviewing Agency provides the ACO with a letter stating it is likely to challenge the ACO if it proceeds.

Impact:

As noted above, the Policy Statement represents what in some respects is a significant departure from the guidance the FTC and DOJ provided in the 1996

PSA is 30% or below, the ACO cannot qualify for the safety zone.

[4] Based on past experience with the 1996 Health Care Statements that promised a similar deadline for reviewing proposed conduct, this time frame seems 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 approval.

Health Care Statements, Statement No. 8 (Physician Network Joint Ventures) and Statement No. 9 (Multi-provider Networks).

Key differences are summarized in the table below:

Comparison of 1996 Health Care Statements and Proposed ACO Policy Statement

Guideline Features	1996 Health Care Statements	ACO Policy Statement
Safety Zone Thresholds	Exclusive physician network — 20% or less of providers in a given specialty in a local geographic market Non-exclusive physician network – 30% or less of providers in a given specialty in a local geographic market No safety zone for multispecialty networks including both physicians and hospitals	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
Exception for Areas with Few Physicians/Rural Exception	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	ACO can include one physician per specialty in each rural county on a non-exclusive basis
Dominant Provider Limitation	Subject to 20%/30% thresholds	Can include a participant with 50% or greater 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
Safety Zone Integration Requirement	Participating providers must share substantial financial risk	Clinical integration as defined by CMS
Geographic Market Definition	Threshold percentages measured in geographic market – generally will be local	Provider PSA
Analysis of Networks Outside the Safety Zone	Rule of reason analysis, including defining relevant markets, evaluating potential anticompetitive effects and efficiencies	Similar rule of reason analysis, but additional guidance is provided regarding steps ACOs can take to avoid challenge
Mandatory Review	None	For ACOs exceeding 50% threshold for any common service in any PSA
Voluntary Review	For any network – commitment to respond within 90 days after submission of all necessary information	For any ACO outside of the safety zone and not requiring mandatory review – commitment to respond within 90 days after specified information is provided

As this table shows, the Policy 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 Policy Statement extends safety zone treatment for the first time to multi-provider networks that include hospitals. Further, while mandatory review for ACOs with PSA shares that exceed 50 percent may discourage the formation of certain ACOs that would result in excessive market concentration, the fact ACOs can hold up to 50 percent of common services without such review may encourage providers to form ACOs that approach that threshold.

On the other side of the ledger, 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

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 0003-6021

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 Policy 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 Policy Statement in its present form appears to allow additional provider consolidation while at the same time relaxing integration requirements, creating a serious risk that it will encourage and condone the formation of ACOs with a greater ability to exercise market power against health plans than would ACOs formed under the principles in the 1996 Health Care Statements.

The Agencies and commentators therefore should consider whether the proposed safety zone thresholds are adequate to protect competition, or whether thresholds closer to those required for the safety zones in the 1996 Health Care Statements should be maintained.

Similarly, consideration should be given to whether, to qualify for the ACO safety zone, ACOs should be required to engage in financial integration, or at least clinical integration consistent with the 1996 Statements.

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 0003-6021