BNA's
Health Law Reporter™

FTC/DOJ Final Policy Statement on Accountable Care Organizations: Important Antitrust Issues Remain Unanswered




By Stephen Paul Mahinka, John Clayton Everett Jr., Albert W. Shay, and David Brenneman

The Federal Trade Commission and the Department of Justice (''agencies'') issued their final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (''policy statement'') on Oct. 20, the same day that the Centers for Medicare and Medicaid Services (CMS) issued extensive regulations governing the formation, registration and operation of ACOs.

The Patient Protection and Affordable Care Act (PPACA), enacted in March 2010 as part of the Obama Administration's health care reform law, established the Medicare Shared Services Program (''shared services program'') to encourage the formation of ACO. ACOs are groups of health care providers (e.g., physicians or physician/hospital joint ventures) that are clinically integrated and jointly offer services to patients across a variety of specialties and in a variety of institutional settings.[1] CMS has responsibility for implementing the shared services program. In March, CMS issued a proposed rule detailing eligibility criteria for ACOs, and the agencies issued a proposed joint policy statement (''proposed statement'') detailing the enforcement of antitrust laws regarding ACOs; both proposals were made available for, and generated a significant number of, public comments. On Oct. 20, CMS issued its final rule, concurrent with the agencies' release of the policy statement.

The policy statement outlines in general terms the standards the agencies will apply in analyzing the legality of ACO formation and conduct under the antitrust laws. ACOs formed pursuant to the CMS regulations are not subject to mandatory antitrust review by the agencies, but the agencies have committed to an expedited review process for any ACO that voluntarily requests agency reviews. The policy statement also (1) outlines the standard that will be applied by the agencies in their reviews (the ''rule of reason''), (2) defines a ''safe harbor'' for ACOs that are below certain market share thresholds, and (3) outlines some conduct by ACOs that would be problematic from the agencies' perspective. The final policy statement eliminated a proposed mandatory review mechanism, which had been widely criticized in the public comments, and also

Stephen Paul Mahinka is the chair of Morgan Lewis's Life Sciences and Healthcare Interdisciplinary Group. He also is a member of both the Antitrust Practice and the FDA and Healthcare Practice. John Clayton Everett, Jr. is a partner in the firm's Antitrust Practice. Albert W. Shay is a partner in the FDA & Healthcare Practice, and David Brenneman is an associate in the Antitrust Practice. All are resident in the firm's Washington office.

[1] Pursuant to CMS regulations, in order to participate in the shared services program, ACOs must meet several eligibility requirements, including operating through a formal legal structure, having a mechanism for shared governance, and having at least 5,000 Medicare beneficiaries. As an incentive to form ACOs under the shared services program, ACOs are eligible to share in the Medicare savings by receiving shared-savings payments from CMS, as long as certain quality measures and cost savings thresholds are met.

 ISSN 1064-2137

broadened the scope of its application to all ACOs that are eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program. The final policy statement otherwise does not substantially differ from the proposed statement, which was widely criticized for being insufficiently receptive to the focus of PPACA on encouraging formation and operation of ACOs as a potential cost-containment mechanism.

Notably, the policy statement leaves many important questions unanswered, including (1) how the agencies will apply the rule of reason standard to ACOs; (2) how aggressively the agencies will pursue post-formation challenges to ACOs (and other health care collaboration); and (3) what role the state attorneys' general will play. Given this uncertainty, in order to reduce antitrust risk, ACO applicants should implement internal controls, including firewalls; avoid certain anticompetitive practices; consider the role of state attorneys' general; and, for many ACOs not subject to the antitrust safety zone, participate in the agencies' voluntary review process.

(1) How will the agencies apply the rule of reason standard to ACOs, and what level of detail will they require from ACOs to establish the existence of efficiencies from economic or clinical integration and the ''reasonable necessity'' of integration to achieve those efficiencies?

The activities and formation of ACOs generally will be evaluated by the agencies under the rule of reason. That standard weighs the potential anticompetitive effects of collaboration, such as enhanced pricing power, against its potential procompetitive effects, such as enhancing efficiency. This aspect of the policy statement is indicative of the agencies' evolving, although still skeptical, acceptance of some arrangements providing for clinical and/or quality integration, but which might not be financially integrated.[2]

The policy statement notes that the rule of reason will be applied by the agencies ''if providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the procompetitive benefits of the integration.'' The policy statement acknowledges, moreover, that CMS's ACO eligibility requirements generally are consistent with the type of clinical integration the agencies have accepted in the past. However, the failure of the policy statement to affirmatively endorse those attributes as sufficient indicia of procompetitive integration meeting the agencies' standards (or to explain situations in which ACOs approved by CMS might nonetheless have their agreements challenged as not ''reasonably necessary'' for integration) leaves open the possibility that some ACO actions or agreements might be challenged as *per se* unlawful antitrust violations.

The policy statement also leaves unanswered many questions about how the rule of reason might be applied in the context of ACOs. The policy statement points to the agencies' previously issued health care guidelines and statements for a description of their policies in the area, but notes that the agencies will rely on future data provided by CMS to ''determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements'' to meet the agencies' standards (and the rule of reason). Thus, it remains uncertain how the antitrust laws will be applied by the agencies to collaborations among health care providers to form ACOs.

The agencies historically have been skeptical of collaborations among health care professionals and organizations.

The agencies historically have been skeptical of collaborations among health care professionals and organizations and have brought numerous challenges to physician organizations and other collaborations. The agencies are most skeptical of collaborations that merely negotiate collectively on behalf of health care providers without providing evidence of other procompetitive efficiencies. For example, in 2003, the FTC challenged an entity comprised of competing health care providers that collectively negotiated with health care providers, but showed minimal procompetitive efficiencies. In doing so, the FTC used an ''inherently suspect'' analysis, akin to a ''quick-look'' analysis, instead of a full rule of reason analysis.[3]

More recently, in October, the FTC responded to a New York senator's request to review a New York Senate bill (S. 3186-A (N.Y. Healthcare Act)) that would permit health care providers to negotiate certain fee-related contract provisions with health plans that have a significant market share. Under the bill, the New York attorney general would have 60 days to conduct a substantive investigation of the competitive impact of the proposed agreement.

Yet when there is significant clinical and/or quality integration in addition to collective negotiation that results in efficiencies, the agencies' review of ACOs will focus on (i) the degree of such efficiencies and (ii) whether collective negotiation is ancillary to those procompetitive efficiencies. This is a fact-specific analysis. For example, in 2002, the FTC issued its first staff advisory letter to a physician group (MedSouth) with no financial risk sharing, instead relying solely on clinical integration.[4] There, the FTC staff supported the physician group's operations, which employed both the use of an electronic clinical data record system and implemented clinical practice guidelines and measureable performance goals related to quality for physicians, in

[2] *See, e.g.*, J. Thomas Rosch, Comm'r, Federal Trade Comm'n, Clinical Integration in Antitrust Prospects for the Future, remarks at the Antitrust in Health Care Conference of the American Bar Association/American Health Lawyers Association (Sept. 27, 2007), *available at* http://www.ftc.gov/speeches/rosch/070917clinic.pdf.

[3] In re North Texas Specialty Physicians, 140 FTC 715 (2005), *aff'd in part and rev'd in part*, 528 F. 3d 346 (5th Cir. 2008). *See also* In re Independent Physicians Associates Medical Group Inc. d/b/a AllCare IPA, FTC Dkt. No. C-4245 (decision and order entered Feb. 2, 2009), available at http://www2.ftc.gov/os/caselist/0610258/index.shtm.

[4] *See* advisory opinion letter from Jeffrey W. Brennan, FTC, to John J. Miles, Ober Kaler (Feb. 19, 2002), *available at* http://www.ftc.gov/bc/adops/medsouth.htm.

  HLR ISSN 1064-2137

addition to collective negotiation. The FTC noted, however, that ''mere adoption of a common clinical information system by itself . . . would not suffice to establish [clinical integration] . . . to an extent that joint negotiation of prices would be deemed ancillary to an efficiency-enhancing joint venture.''[5] The FTC again reviewed and approved MedSouth's operations in an advisory opinion issued in 2008.[6]

There have been numerous FTC advisory opinions analyzing a myriad of different health care group formations, and the agencies' analysis of each has necessarily been fact-specific. For this reason, it is unsurprising that the policy statement does not provide any bright-line rules as to which types of collaborations will result in efficiencies that outweigh any anticompetitive effects.[7]

(2) How aggressively will the agencies pursue post-formation challenges to ACOs (and other health care collaborations)?

It is not clear how aggressively the agencies will pursue post-formation challenges, particularly for those ACOs with high primary service area (PSA)[8] shares. Initially, the agencies had proposed a mandatory pre-formation review for any ACO applicant having a 50 percent or greater share of any common service that two or more independent ACO participants provide to patients in the same PSA. The proposed mandatory review process was widely criticized by various health care organizations, claiming that ACO applicants would be subject to undue costs and burdens and that the agencies would exceed their traditional roles as enforcers and become regulators.

The agencies cautioned that they still will ''vigorously monitor complaints'' about an ACO's formation and will take enforcement actions wherever appropriate.

Despite eliminating a mandatory pre-formation antitrust review, the agencies cautioned that they still will ''vigorously monitor complaints'' about an ACO's formation and will take enforcement actions wherever appropriate, ''aided by data and information from CMS that will assist the Agencies in monitoring the competitive effects of an ACO.'' Although ACOs that would have been subject to a mandatory review under the proposed statement no longer have a legal obligation to notify the agencies of their formation, such ACOs still are at risk of post-formation investigations and enforcement actions.

Given that the agencies' proposed statement stated that ''50 percent share threshold for mandatory review provides a valuable indication of the potential for competitive harm from ACOs with high PSA shares,'' it is likely that such ACOs—although no longer subject to a mandatory pre-formation review—will nevertheless receive heightened antitrust scrutiny post-formation.[9] Interestingly, the agencies' reliance on market (PSA) shares in their analysis of ACOs, including using these shares as a screening mechanism for an antitrust safe harbor, seems to conflict with the recently revised DOJ/FTC Horizontal Merger Guidelines, which de-emphasized the use of market shares.[10] It is likely, notwithstanding the elimination of the mandatory review for ACOs with PSA shares above 50 percent, that ACOs that have a greater than 50 percent share of any service in a PSA will present an heightened risk of antitrust scrutiny before and after consummation.

Although the policy statement provides some direction to ACOs seeking to avoid antitrust scrutiny, including a safe harbor provision for certain ACOs with low PSAs and guidance as to what types of conduct to avoid, its utility is limited for those ACOs with high PSA shares. Instead, for those ACO applicants seeking antitrust certainty from the agencies, the policy statement offers a voluntary pre-formation review mechanism.

- **Antitrust Safety Zone**: Absent extraordinary circumstances, such as evidence of collusion, the agencies will not challenge ACOs that meet CMS eligibility criteria as long as they meet certain share thresholds within an antitrust ''safety zone.'' With certain exceptions,[11] the antitrust safety zone applies to ACO participants that provide the same service (a ''common service'') and have a combined share of 30 percent or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA. Higher shares of physi-

[5] Id.

[6] Letter from Markus H. Meier, FTC, to John J. Miles, Ober Kaler (June 18, 2007), *available at* http://www.ftc.gov/bc/adops/070618medsouth.pdf.

[7] Pamela Jones Habour, Comm'r, Federal Trade Comm'n, Clinical Integration: The Changing Policy Climate and What it Means for Care Coordination, remarks before the American Hospital Association, Washington, D.C., Pages 16-17 (April 27, 2009), *available at* http://www.ftc.gov/speeches/harbour/090427ahaclinicalintegration.pdf (''The federal antitrust agencies have been criticized for not providing sufficient guidance to providers, who are struggling to craft and implement clinical integration programs whose joint pricing components will pass antitrust muster . . . Our concern is that any bright-line guidance on clinical integration is likely to stifle the innovation and creativity that are true hallmarks of the ever-evolving American health care system.'')

[8] The boundaries of a PSA are determined by the geographically contiguous ZIP codes that represent 75 percent of the ACO participant's Medicare allowed charges.

[9] Indeed, the FTC's statement in opposition to the N.Y. Healthcare Act cited to its proposed statement as an example of antitrust guidance for health care collaborators.

[10] DOJ and FTC, Horizontal Merger Guidelines (rev. ed. 2010), available at http://www.justice.gov/atr/public/guidelines/hmg-2010.pdf.

[11] Hospitals and ambulatory surgery centers participating in an ACO must be nonexclusive to the ACO in order for a safety zone to apply to that ACO, regardless of PSA share. The policy statement further broadens the antitrust safety zone to include certain ACOs that exist in rural areas by allowing such ACOs to include one physician group or physician group practice per specialty from each rural area on a nonexclusive basis, even if the inclusion of such physicians causes the ACO's share to exceed 30 percent for a common service in any ACO participant's PSA. Similarly, an ACO may include certain rural hospitals on a nonexclusive basis and qualify for the safety zone even if the inclusion causes the ACO's share in a common service to exceed 30 percent in any ACO participant's PSA.

cian practices still may fall within the safety zone if they are in rural areas. This safety zone generally accords with the share thresholds recognized in the courts as sufficient to create ''market power''—a necessary predicate to any antitrust challenge under the rule of reason. ACOs that fall within this safety zone can be reasonably confident that their formation will not be challenged by the agencies, though it is not clear how state AGs will treat such ACOs, as discussed below.

- **Conduct to Avoid:** The policy statement warns ACO participants, regardless of PSA shares or market power, not to share competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO. ACO participants therefore should implement firewalls in order to prevent the dissemination of competitively sensitive information.
  The policy statement also details conduct that ACOs with high PSA shares should avoid in order to reduce the potential for antitrust scrutiny:
  (1) use of certain ''anti-steering,'' ''anti-tiering,'' ''guaranteed inclusion,'' ''most-favored-nation,'' or similar contract provisions;
  (2) tying sales of the ACO's services to the private payer's purchase of other services from providers outside of the ACO, including those providers affiliated with an ACO participant;
  (3) contracting on an exclusive basis with ACO physicians, hospitals, ambulatory surgical centers, or other providers that may prevent or discourage those providers from contracting with private payers outside of the ACO, either individually or through other ACOs or analogous collaborations; and
  (4) restricting a private payer's ability to make available to its enrollees certain information about the ACO's cost, quality and efficiency.
  Notably, these types of conduct also were listed in the proposed statement for those ACOs outside of the safety zone, but below the mandatory review threshold. Accordingly, it is unclear to what degree avoiding this conduct will protect ACOs with PSA shares above 50 percent from antitrust scrutiny.
- **Voluntary Review:** The policy statement makes available a voluntary 90-day expedited antitrust review to all ACOs formed after March 23, 2010. Given the threat of post-formation antitrust scrutiny, and the ambiguity of the statement as to how economic and/or clinical integration will be evaluated, it reasonably can be expected that many ACO applicants with high PSA shares will seek a voluntary review in order to avoid more costly and burdensome potential post-formation scrutiny from the agencies. If the agencies provide negative feedback to an ACO, that ACO can adjust its structure or dissolve. A positive response from the agencies in response to a voluntary review, which appears similar to the DOJ's existing business review letter process, could help reduce the likelihood of a successful antitrust challenge by private parties post-formation.
  Prior to entering the shared savings program, the ACO applicant may submit a request for review to the agencies, and the agencies promptly will notify the applicant whether the FTC or DOJ will conduct the review. In order to begin the 90-day review period, the ACO applicant then must submit to the reviewing agency a variety of documentation, including (1) the ACO application and all supporting documents, (2) documents discussing business strategies and competition, (3) certain competitive and market information, and (4) information related to restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge to private payers which do not contract through the ACO.
  In addition, the ACO applicant may submit additional information and documents to the reviewing agency pertaining to market power (or lack thereof), procompetitive justifications, and an explanation as to why the ACO would not be anticompetitive or might be procompetitive. Within 90 days after receiving all documents and information, the reviewing agency will advise the ACO that it either (1) does not likely raise competitive concerns or does not do so conditioned on the ACO's written agreement to take specific steps to alleviate the agency's concerns, (2) potentially raises concerns, or (3) likely raises competitive concerns.

ACOs that intend to operate in commercial or Medicaid markets, in addition to Medicare, also must consider state law and enforcement in addition to the federal antitrust laws and agencies.

(3) What role will the state attorneys' general play?

The policy statement addresses only the enforcement policies of the federal antitrust authorities—the FTC and DOJ. All but one of the states and the District of Columbia have separate antitrust laws enforced by their state attorneys general. ACOs that intend to operate in commercial or Medicaid markets, in addition to Medicare, thus also must consider state law and enforcement in addition to the federal antitrust laws and agencies. Many state AGs have been particularly active in health care markets.

For instance, Pennsylvania's attorney general recently filed a complaint against the Urology of Central Pennsylvania Inc. (UCPA), an entity formed six years ago when five independent urology practices in Harrisburg merged into a single entity. The merger was not reportable to the FTC and DOJ pursuant to the Hart-Scott-Rodino Act. The attorney general's action alleged that the merger was anticompetitive in that it gave UCPA an increased ability and incentive to raise prices, and it permitted UCPA ''to collectively bargain with area health plans to obtain increases in reimbursement rates for urology services and ancillary services.'' The parties entered into a settlement whereby UCPA agreed to a series of conduct remedies and fines.

This case highlights the potential for state antitrust scrutiny of ACOs. Given there is no preemption provision in the PPACA that relates specifically to antitrust, there is a clear potential that the states will apply their

  HLR ISSN 1064-2137

own antitrust laws, possibly with different or more severe antitrust scrutiny than that set out in the policy statement.

Antitrust Certainty for ACO Applicants

Because the antitrust guidance set out in the policy statement is limited, those ACO applicants that are not subject to the antitrust safety zone should consider a voluntary review. An expedited voluntary review will be cheaper, less burdensome, and any agency concerns identified in the review will be easier to remedy than a post-consummation investigation. Given the agencies' expressed skepticism about ACOs with shares in any PSA in excess of 50 percent, such ACO applicants should strongly consider taking advantage of the voluntary expedited review process. Additionally, other ACO applicants not within the antitrust safety zone should also consider a voluntary review, depending on PSA shares and other competitive considerations, and all such ACO applicants should avoid potentially anticompetitive practices such as those described in the policy statement.

Further, all ACOs, regardless of PSA shares, should consider the following prior to ACO formation:

- *Implementation of Firewalls*—All ACOs, regardless of PSA shares, should implement firewalls to prevent the dissemination of competitively sensitive information between competitors. Even those ACOs within the antitrust safety zone are not exempt from antitrust scrutiny if there is evidence of collusion.
- *Consider State Laws and AGs*—As illustrated by the action brought by Pennsylvania against UCPA, state AGs can be expected to investigate and seek action against health care collaborations in certain instances.
- *Implementation of Internal Controls*—The implementation of certain internal controls, in addition to firewalls, may reduce antitrust risk.
- *Provider Collaboration for Collective Bargaining*—The FTC has expressed hostility toward providers collectively bargaining with competing health care providers. Prior to implementing a collaborative collective bargaining effort, providers should consult with antitrust counsel.