ACO Antitrust Guidelines: Coordination Among Federal Agencies

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Section 3022 of the Patient Protection and Affordable Care Act\(^1\) (Affordable Care Act) establishes a “Shared Savings Program” intended to improve health care delivery and lower costs by promoting accountability for patient populations, fostering better coordination of Medicare services, and “encourag[ing] investment in infrastructure and redesigned care processes for high quality and efficient service delivery.”\(^2\) To achieve these goals, Section 3022 encourages groups of health care providers that meet certain criteria to work together through an accountable care organization (ACO), which can share in any savings it creates if it meets certain quality criteria.\(^3\)

ACOs generally “consist of providers who are jointly held accountable for achieving measured quality improvements and reductions in the rate of spending growth.”\(^4\) Under Section 3022, an ACO must have a shared governance mechanism and may involve a variety of provider configurations, such as physician practices, networks of physicians working together, and integrated health care delivery systems.\(^5\)

Implementation of the statute prompted an unusual degree of coordination among various federal agencies. This coordination responded to concerns expressed to federal officials by a variety of health care experts, providers, provider groups, and others. These stakeholders cautioned that, absent careful crafting, the substantive rules and policies of these agencies could deter the formation and participation of ACOs in the Shared Savings Program. Their concern was not only with the likely substance of the guidance, but also with the potential for agencies’ rules and policies to conflict with each other.

To address the need for agency coordination, the Office of Management and Budget set up a series of staff meetings among the relevant federal agencies. These agencies included (1) the Centers for Medicare and Medicaid Services (CMS), which has responsibility for drafting the rules implementing Section 3022; (2) the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS), and the Civil Division of the Department of Justice, which, along with CMS, share responsibilities under the federal physician self-referral and anti-kickback statutes and civil monetary penalty provisions addressing inducements to beneficiaries and hos-

\(^2\) Id.
\(^3\) Id.
\(^4\) Mark McClellan, Aaron N. McKethan, Julie L. Lewis, Joachim Roski & Elliott S. Fisher, A National Strategy to Put Accountable Care into Practice, 29 Health Aff. 982 (May 6, 2010) [hereinafter National Strategy].
\(^5\) Affordable Care Act, supra note 1, § 3022.
pital payments to physicians;6 (3) the Treasury Department and Internal Revenue Service, which provide tax guidance to non-profits, including non-profit health care facilities; and (4) the Federal Trade Commission and the Antitrust Division of the Department of Justice, which enforce the antitrust laws relevant to the formation and conduct of ACOs.

Early coordination among federal agencies on potentially overlapping rules and policies is not typical, but it proved useful in this case. The inter-agency meetings enabled staff from each agency to understand other agencies’ laws and policies relevant to ACOs and how the concepts underlying those laws and policies might overlap with the concepts underlying their own laws and policies. In particular, the meetings served to identify at an early stage any issues that held the potential for inconsistencies between or among agencies.

This article discusses how the FTC and the DOJ (the “antitrust agencies”) worked with CMS as it developed its rules for ACOs and as the antitrust agencies developed their Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.7

Consumers should benefit from the collaboration between the antitrust agencies and CMS. As discussed in more detail below, CMS will assist the antitrust agencies in monitoring the competitive effects of ACOs by providing aggregated data and information that may help the agencies identify ACOs that could pose competitive concerns.

Providers should benefit as well. The antitrust agencies have agreed to evaluate an ACO’s price negotiations with commercial payers under the rule of reason, if the ACO participates in the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in commercial markets. Both consumers and businesses can benefit when agencies work together to streamline and ensure consistency among their rules and guidance documents.

Seeking Stakeholder Input

Before developing their rules and policy guidance, CMS, the HHS OIG, and the FTC worked together to organize a workshop at CMS headquarters to seek input from stakeholders—such as providers already operating integrated health care delivery systems, provider groups, payers, academics, and economists—about the types of guidance they believed would be necessary or useful to foster the development of ACOs.8 Among other things, this workshop helped identify issues that providers and payers hoped would be addressed in an antitrust policy statement.

Providers asked for additional guidance on how to avoid charges of per se illegality for joint price negotiations with payers in the private market. They explained that ACOs in the Shared Savings Program would likely want to serve not only Medicare beneficiaries, but also patients insured through private insurance. Thus, an ACO would likely negotiate prices on behalf of its participants with payers in the private market. Providers sought further guidance on the circum-

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stances under which the agencies would evaluate such joint price negotiations under the rule of reason instead of finding them per se illegal.9

Payers and other stakeholders at the workshop, on the other hand, emphasized that the antitrust agencies and others should take steps to prevent the formation of ACOs with market power and to address the types of ACO conduct that could prevent private payers from obtaining lower prices or better quality service from ACOs. These stakeholders raised concerns that if the Shared Savings Program inadvertently encouraged collaborations that created market power, the program could lead to higher prices and lower quality care—the opposite of Congress’s goals.

Per Se Illegality and CMS’s Eligibility Criteria for ACOs

One goal of Section 3022 is to encourage greater clinical integration among providers. Analogously, with respect to antitrust analysis, clinical integration among providers is one factor that, if combined with other factors, can enable a physician network to avoid charges of per se illegal joint pricing, if the integration appears likely to improve care and reduce costs.

Section 3022, in part, responds to critics who have pointed out that “[t]he current [health care payment] system, based on volume and intensity, does not disincentivize, but rather pays more for, overuse and fragmentation.”10 For example, doctors’ failures to coordinate treatment plans for the same patient may result in orders for duplicative tests or prescriptions of medications that, together, can harm the patient. To address these and other problems, Section 3022 encourages health care providers to coordinate their work more closely through ACOs in order to reduce costs and achieve better quality health care for their patients. To accomplish those goals, the statute requires that ACOs, among other things, (1) promote evidence-based medicine; (2) promote patient engagement; (3) report on cost and quality measures; and (4) coordinate care.11

The antitrust agencies likewise consider clinical integration, among other factors, in evaluating whether joint price negotiations are per se illegal. The FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care (Health Care Statements) explain that if “competitors economically integrate in a joint venture,” then joint price agreements, “if reasonably necessary to accomplish the procompetitive benefits of the integration, are analyzed under the rule of reason.”12 Rule of reason analysis considers likely procompetitive, as well as anticompetitive, effects. The goal of an evaluation under this standard is to “distinguish between price fixing by health care providers, which is likely to increase health care costs, and effective clinical integration among health care providers[, which] has the potential to achieve cost savings and improve health outcomes.”13 The Health Care Statements explain that clinical integration may be demonstrated by a network of

9 Because Medicare reimbursements generally are set by regulation, the same issue generally does not arise in Medicare markets.
10 See, e.g., McClellan et al., National Strategy, supra note 4, at 982.
11 Affordable Care Act, supra note 1, § 3022, 124 Stat. 119, 395–99.
13 Prepared Statement of the Fed. Trade Comm’n Before the H. Comm. on the Judiciary, Subcomm. on Courts and Competition Policy, Antitrust Enforcement in the Health Care Industry 6 (Dec. 1, 2010), available at http://www.ftc.gov/os/testimony/101201antitrusthealthcare.pdf. Under the Health Care Statements, if the participants in a physician network share substantial financial risk, joint price negotiations by participants in the physician network also will be evaluated under the rule of reason. Health Care Statements, supra note 12, Statement 8, at 72. Section A.4. of Statement 8 provides examples of how providers can share substantial financial risk. Id. at 67–70.
physicians “implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”

FTC staff advisory opinions also discuss evidence that appears sufficient to demonstrate clinical integration in specific factual circumstances. For example, in a 2007 opinion, FTC staff noted that planned clinical activities, such as the use of evidence-based practice guidelines, sharing clinical information related to patients among physicians, and the use of electronic health records, along with other factors, indicated that the proposed collaboration “would involve substantial integration among its physician participants that has the potential to produce significant efficiencies in the provision of medical services, including both improved quality and more efficient and appropriate provision of those services by the [participating] physicians.”

With passage of Section 3022, however, it was inevitable that CMS would articulate at least some rules that overlapped with the antitrust agencies’ assessment of clinical integration. Ideally, the clinical integration criteria in the CMS rules and the antitrust analysis of clinical integration would be consistent, so that providers did not confront conflicting requirements. The agencies also considered whether more could be achieved: could rules be devised so that an ACO could meet CMS’s eligibility standards and also satisfy the antitrust agencies that it would be clinically integrated and that any joint price negotiations were reasonably necessary to achieve the benefits of that integration?

14 Id. at 72.
15 See, e.g., FTC Staff Advisory Opinion to TriState Health Partners, Inc. (Apr. 13, 2009), available at http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf; Follow-Up to MedSouth, Inc. 2002 Staff Advisory Opinion (June 18, 2007) (offering, as illustrative list of typical aspects of clinical integration program, some or all of the following: “development or adoption of appropriate performance standards and goals, referral guidelines or requirements, or other performance criteria and measures for the participants, both individually and as a group; establishment of mechanisms, including information systems that permit collection and analysis of relevant data to monitor and evaluate both individual and group performance relative to the established standards, goals, and measures; and provision for appropriate educational, behavior modification, and remedial action, where warranted, to improve both individual and overall group performance”), available at http://www.ftc.gov/bc/adops/070618medsouth.pdf. The FTC’s health care advisory opinions are available generally at http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm.
16 FTC Staff Advisory Opinion to Greater Rochester Independent Practice Association, Inc. (Sept. 17, 2007), available at http://www.ftc.gov/bc/adops/gripa.pdf. FTC staff also concluded “it appears that joint contracting with payers on behalf of [the collaboration’s] physician members is subordinate and reasonably related to [the collaboration’s] plan to integrate the provision of medical care by its members, and is reasonably necessary to implement the proposed program and achieve its efficiency benefits.” Id.
17 Final ACO Antitrust Policy Statement, supra note 7, at 67,027.
18 Id.
In order to develop proposed CMS eligibility criteria for ACOs that would also be relevant to antitrust analysis, staff from the antitrust agencies and CMS compared the statutory criteria set forth in the Affordable Care Act, the antitrust agencies’ existing guidance on and experience with clinical integration assessments, and CMS’s experience with the Physician Group Practice (PGP) Demonstration, a predecessor to ACOs. That demonstration created incentives for physician groups to coordinate the delivery of care to Medicare patients, rewarded the groups for improving the quality and cost efficiency of health care services, and created a framework for collaboration among providers to the advantage of Medicare beneficiaries.

The results of the agencies’ efforts to coordinate CMS proposed rules with the antitrust analysis of clinical integration were announced in CMS’s proposed rule and the proposed antitrust policy statement for ACOs. In its proposed rule, CMS recognized the alignment between antitrust analysis and the goals of the Shared Savings Program, noting the antitrust agencies’ conclusion that “successfully achieving clinical integration requires the establishment and operation of active and ongoing processes and mechanisms to facilitate, encourage, and assure the necessary cooperative interaction.”

CMS explained that those criteria “also provide insight into the leadership and management structures, including clinical and administrative systems, necessary for ACOs to achieve” the goals of the Shared Savings Program, and “are very similar to the factors identified previously by participants in the PGP demonstration as critical to improving quality and controlling the cost of health care . . . .” After discussing other similarities, CMS’s proposed rule concluded that “[i]t is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration.” CMS noted that “the certainty created by harmonizing our eligibility criteria with antitrust requirements will help to ensure that an ACO organization participating in the Shared Savings Program will not subsequently face an antitrust challenge that its conduct is per se illegal, which could prevent the ACO from fulfilling the 3-year term of its agreement under the Shared Savings Program.”

The antitrust agencies’ proposed policy statement likewise stated:

The Agencies have determined that CMS’s proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers. The Agencies also have determined that organizations meeting the CMS criteria for approval as an ACO are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants’ joint efforts. Further, if a CMS-approved ACO provides the same or essentially the same services in the commercial market, the Agencies have determined that the integration criteria are sufficiently rigorous that joint

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20 id.
22 id. at 61, 76 Fed. Reg. at 19,542.
23 id.
negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO’s primary purpose of improving health care services.25

When the proposed ACO policy statement was issued in April 2011, many providers applauded its coordination of antitrust analysis with CMS’s proposed rule for ACOs.26 They appreciated that ACOs would be held to only one standard for purposes of (1) evaluating their eligibility for the Medicare Shared Savings Program, and (2) avoiding antitrust treatment of the ACO’s joint price negotiations as per se illegal, if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Medicare Shared Savings Program.27

Nonetheless, a number of providers complained that some of CMS’s proposed eligibility rules were too prescriptive and burdensome.28 The CMS final rule for ACOs is responsive to many of the providers’ concerns. Among other things, CMS clarified its requirement that ACOs demonstrate sufficient “clinical and administrative processes” by specifying that the “processes” should align with those required by the statute: (1) promote evidence-based medicine; (2) promote patient engagement; (3) report on cost and quality measures; and (4) coordinate care.29

CMS’s rules do not define how ACOs should accomplish these processes; rather, an ACO applicant “must define, establish, implement, evaluate, and periodically update processes to accomplish” those goals, and “[e]xplain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process.”30 For example, to meet the eligibility requirement of care coordination, an applicant must, among other things, “[d]efine its methods and processes established to coordinate care throughout an episode of care,” and “[s]ubmit a description of its individualized care program, along with a sample individual care plan.”31

Staff from the antitrust agencies worked with CMS staff to develop these and other changes to the proposed rule. Consistent with the antitrust agencies’ approach of avoiding specified checklists for how to establish clinical integration, the CMS final rule allows ACO applicants some degree of flexibility in choosing how they will meet the statutory standards.

27 Id.
30 Id. § 425.112(a)(3)(i).
31 Id. § 425.112(b)(4)(i)–(ii).
The antitrust agencies’ Final ACO Antitrust Policy Statement continues to coordinate with CMS eligibility requirements, stating:

In light of CMS’s eligibility criteria, and its monitoring of each ACO’s results, the Agencies will treat joint negotiations with private payers as reasonably necessary to an ACO’s primary purpose of improving health care delivery, and will afford rule of reason treatment to an ACO that meets CMS’s eligibility requirements for, and participates in, the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in commercial markets. 33

The Potential for ACOs with Market Power
Both the antitrust agencies and CMS have expressed a desire to avoid having the Shared Savings Program lead to the formation of ACOs with market power that might engage in anticompetitive conduct. CMS first proposed to require mandatory antitrust review for certain large ACOs. The proposed rule required that:

Except for an ACO that qualifies for the rural exception articulated in the [Antitrust] Policy Statement, an ACO with a PSA [Primary Service Area] share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA must submit to us, as part of its Shared Savings Program application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging, the proposed ACO. Absent such a letter, the proposed ACO will not be eligible to participate in the Shared Savings Program. 34

CMS proposed that this requirement would apply only to ACOs formed after March 23, 2010, the date on which the Affordable Care Act was passed. 35

CMS described the purpose of this requirement as two-fold: (1) to ensure that ACOs in the Shared Savings Program would not be subject to antitrust challenges that could prevent them from fulfilling their three-year agreement with CMS, and (2) to maintain competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. 36

32 The Final ACO Antitrust Policy Statement emphasizes that

[ ] to assess whether an ACO has improved quality and reduced costs to Medicare, CMS will collect and evaluate cost, utilization, and quality metrics relating to each ACO’s performance in the Shared Savings Program. The results of this monitoring will help the Agencies determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements, and may help inform the Agencies’ future analysis of ACOs and other provider organizations.

Final ACO Antitrust Policy Statement, supra note 7, at 67,028.

33 Id.

34 CMS Proposed Rule, supra note 21, at 19,629. The Final ACO Antitrust Policy Statement defines a PSA as “the lowest number of postal zip codes from which the ACO participant draws at least 75 percent of its [patients], separately for all physician, inpatient, or outpatient services.” Final ACO Antitrust Policy Statement, supra note 7, at 67,028 (citing Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Program; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004)).

35 CMS Proposed Rule, supra note 21, at 19,628.

36 Id. at 19,630. In its final rule, CMS explains that:

In this context market power refers to the ability of an ACO to reduce the quality of care furnished to Medicare beneficiaries and/or to raise prices or reduce the quality for commercial health plans and enrollees, thereby potentially increasing providers’ incentives to provide care for private enrollees of higher-paying health plans rather than for Medicare beneficiaries.

CMS Final Rule, supra note 29, at 67,841.
The agency explained that competition in the marketplace would promote the quality of care for Medicare beneficiaries and protect their access to a variety of providers. CMS pointed out that economic theory and competition policy suggest that, in the absence of price competition, providers in Medicare markets “will compete to serve Medicare beneficiaries on the basis of non-price dimensions such as quality of care, innovations that improve care, and choice in treatment options.” The agency cited “[e]mpirical studies of the Medicare program [that] confirm this theory and demonstrate that, where prices are fixed, competition among health care providers produces higher quality for consumers.” CMS described a variety of means by which competition could foster improvements in quality, innovation, and choice for Medicare patients, including through “[m]otivat[ing] innovation in the use of existing treatment and care protocols and the development of new protocols,” and “[r]ais[ing] the likelihood of preserving alternatives in the market, ultimately leading to the emergence of better procedures and treatments.”

Moreover, CMS explained, ACOs in the Shared Savings Program that have market power may also, if allowed, operate in commercial markets, and could raise prices charged to private payers in those markets. To explain how those prices could affect services to Medicare beneficiaries, CMS noted a study by staff of the Medicare Payment Advisory Commission reporting that hospitals with high payments from private payers had high levels of profitability, and expressed concern that “ACOs may wish to increase the profitable private patients they serve and, as a result, reduce the number of Medicare beneficiaries they serve.” CMS concluded that, “[i]n this way, commercial price increases resulting from newly created ACOs with market power could limit access to care for Medicare beneficiaries.”

In response to CMS’s initiative, the antitrust agencies initially agreed to provide expedited, ninety-day review for ACOs that were required to obtain mandatory review because they met the PSA share thresholds and were formed after March 23, 2010. The proposed ACO policy statement noted that although “[t]he 50 percent share threshold for mandatory review provides a valuable indication of the potential for competitive harm from ACOs with high PSA shares,” the agencies would consider during the ninety-day review “any information or alternative data suggesting that the PSA shares may not reflect the ACO’s likely market power, and also will consider any substantial procompetitive justification for why the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market.” The antitrust agencies also specified documents and information that an ACO applicant would need to provide to trigger the start of the ninety-day review.

37 CMS Proposed Rule, supra note 21, at 19,630.

38 Id.

39 Id. (citing Daniel P. Kessler & Mark B. McClellan, Is Hospital Competition Socially Wasteful?, 115 Q.J. ECON. 577 (2000), and Daniel P. Kessler & Jeffrey J. Geppert, The Effects of Competition on Variation in the Quality and Cost of Medical Care, 14 J. ECON. & MGMT. STRATEGY, 575 (2005)); see also Abigail Tay, Assessing Competition in Hospital Care Markets: The Importance of Accounting for Quality Differentiation, 34 RAND J. ECON. 786 (2003).

40 CMS Proposed Rule, supra note 21, at 19,630.


42 CMS Proposed Rule, supra note 21, at 19,630.

43 Id. at 19,631.


45 Id. at 21,897–98.
Payers generally applauded CMS’s requirement of mandatory review for providers with high PSA shares.\textsuperscript{46} Indeed, many recommended that CMS and the antitrust agencies expand the mandatory review requirement to apply to any ACO with PSA shares above 50 percent, not just ACOs formed after March 23, 2010.\textsuperscript{47} Providers, on the other hand, strenuously objected to CMS’s mandatory review requirements.\textsuperscript{48} Some questioned whether CMS had authority to impose such a requirement,\textsuperscript{49} and they complained that the antitrust agencies’ proposed guidance on how it would accomplish mandatory review imposed too many burdens on ACOs.\textsuperscript{50}

CMS reconsidered its position on mandatory review and concluded that it could achieve the objectives identified in its proposed rule—maintaining competition for the benefit of Medicare beneficiaries and ensuring ACOs could fulfill their agreement with CMS without an antitrust challenge—through “a less burdensome approach that is consistent with antitrust law enforcement norms and does not raise” concerns that CMS lacks the authority to impose the mandatory review requirement.\textsuperscript{51}

CMS’s new approach “relies on three prongs to maintain competition among ACOs.”\textsuperscript{52} In the first prong, CMS “strongly encourage[s] newly formed ACOs that may present competitive issues or are uncertain about their legality under the antitrust laws” to take advantage of the offer of expedited, ninety-day voluntary antitrust review contained in the Final ACO Antitrust Policy Statement.\textsuperscript{53} Second, CMS will provide the antitrust agencies “with aggregate claims data regarding allowable charges and fee-for-service payments, which will assist the Antitrust Agencies in calculating PSA shares for ACOs participating in the Shared Savings Program.”\textsuperscript{54} CMS will also require ACOs formed after March 23, 2010, to agree that CMS may share their applications with the antitrust agencies.\textsuperscript{55} Based on its consultations with the antitrust agencies, CMS believes that “both the aggregate data and the information contained in these applications will help the Antitrust Agencies to assess and monitor ACOs’ effects on competition and take enforcement action, if appropriate.”\textsuperscript{56}

\textsuperscript{51} CMS Final Rule, supra note 29, at 67,842. The concerns involved arguments that CMS lacked authority to “subdelegate” its decision-making power about an ACO’s eligibility to participate in the Shared Savings Program to an antitrust agency’s decision that it would likely challenge the ACO on antitrust grounds.
\textsuperscript{52} Id.
\textsuperscript{53} Id.
\textsuperscript{54} CMS states that it will share those data with the antitrust agencies as soon as the data become available. Id.
\textsuperscript{55} Id.
\textsuperscript{56} Id.
Finally, CMS will rely on the antitrust agencies to use “their existing enforcement processes for evaluating concerns raised about an ACO’s formation or conduct and [to file] antitrust complaints when appropriate.” CMS can exclude any ACO that violates the antitrust laws from the Shared Savings Program. Moreover, CMS reaffirms its intent “to coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program to ensure that the implementation of the program does not have a detrimental impact upon competition.”

For their part, the antitrust agencies have pledged to “vigilantly monitor complaints about an ACO’s formation or conduct and take whatever enforcement action may be appropriate.” In addition, the FTC, which has the authority to conduct studies under Section 6(b) of the FTC Act, has taken under consideration a CMS request for “a study examining how ACOs participating in the Shared Savings Program have affected the quality and price of health care in private markets.” CMS states that “[w]e anticipate using the results of this study to evaluate whether we should, in the future, expand our eligibility criteria so that we consider competition concerns more explicitly in the Shared Savings Program application review process.”

Conclusion

Both the final CMS rules and the Final ACO Antitrust Policy Statement reflect common goals of maintaining competition and encouraging true clinical integration that is likely to improve health care and lower costs. The coordination between CMS and the antitrust agencies will continue as the Medicare Shared Savings Program goes into effect. Staff of all three agencies have developed collaborative working relationships that will facilitate coordination in the future on other issues as well. Both consumers and other health care marketplace participants stand to benefit from such continued collaboration to achieve mutual goals.

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57 Id.
58 CMS Final Rule, supra note 29, at 67,980.
59 Id. at 67,842.
60 Final ACO Antitrust Policy Statement, supra note 7, at 67,026.
63 Id.
Accountable Care Organizations: Antitrust Business as Usual?

Ken Glazer and Catherine A. LaRose

The Patient Protection and Affordable Care Act of 2010 (ACA) seeks to improve the quality and reduce the cost of health care services, in part through the reform of delivery systems. One reform promoted by the ACA is the formation of Accountable Care Organizations (ACOs), which take responsibility for populations of Medicare beneficiaries in return for the opportunity to participate in the Medicare Shared Savings Program. In October 2011, the Federal Trade Commission and the Antitrust Division of the Justice Department (Agencies) announced the issuance of the Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. The Final Statement was released in conjunction with the final regulations for ACOs issued by the Centers for Medicare and Medicaid Services (CMS).

The Final Statement differs from the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program issued on March 31, 2011 in several important respects, while preserving key elements. For example, mandatory antitrust review for ACOs that account for a high share in a primary service area (PSA) is no longer required, consistent with the elimination of this requirement under the final CMS regulations. The Final Statement is applicable to all ACOs regardless of formation date; the Proposed Statement only applied to ACOs formed after March 23, 2010. As in the Proposed Statement, the Final Statement maintains the rule of reason analysis for qualifying ACOs and provides a safe harbor for ACOs that meet certain thresholds.

The Final Statement is broadly consistent with earlier guidance from the antitrust agencies regarding competitor collaborations and joint ventures in the health care arena. It reiterates the same basic principles of preserving competitive markets, and uses familiar mechanisms of analysis and review. Like the Health Care Statements, the Final Statement also provides stricter safe harbor thresholds for ACOs that require exclusivity from their providers/participants. It also maintains some of the emphasis on market share.

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Despite this general consistency with the antitrust agencies’ prior guidance, the Final Statement raises two interesting issues. First, because the CMS rules require participants to meet strict performance requirements and because CMS will collect substantial data regarding quality of care, antitrust challenges to ACOs may give rise to some unusually detailed rule of reason analyses of the kind rarely, if ever, seen in antitrust cases. Second, although Medicare reimbursements are subject to set fees for services, which eliminates the possibility that an ACO might conspire to fix prices for various services it provides to beneficiaries, the government will still be alert to anti-competitive schemes regarding non-price elements of competition.

**Business as Usual?**

In a speech at a 2010 conference on antitrust in health care, then Assistant Attorney General Christine Varney explained the DOJ’s view of the role of antitrust in health care:

> The ultimate goal of health care reform is to harness the power of competition, together with regulation, to expand coverage, improve quality, and control the cost of health care for all Americans. The role of antitrust is to ensure that competition is preserved and protected, so that it is there to be harnessed.6

This emphasis on competition is underscored by the Agencies’ previous guidance on antitrust and health care and its new guidance on ACOs. As with other types of health care collaborations,7 the threshold antitrust question for an ACO will be whether or not it impedes the functioning of a competitive market.8 The Final Statement focuses on standard antitrust concepts, including measurement of market share, and cautions against the most common forms of anticompetitive conduct. It provides safe harbors for ACOs that are unlikely to have market power, and a mechanism for business review. The guidance provided by the Final Statement suggests that it is unlikely that ACOs will be treated much differently from pre-ACO physician network joint ventures or multiprovider networks.

**Clinical Integration.** The Final Statement reflects the Agencies’ view that ACOs admitted to the Shared Savings Program will be considered sufficiently clinically integrated to qualify for rule of reason treatment. Pursuant to the Final Statement, if an ACO qualifies for the Shared Savings Program, the Agencies will treat joint negotiations with private payers as “reasonably necessary to an ACO’s primary purpose of improving health care delivery.”9 The Agencies will afford the ACO rule of reason treatment if it meets the CMS eligibility requirements, participates in the Shared Savings Program, and uses the same governance and leadership structures and clinical and administrative processes it uses for the Shared Savings Program to serve patients in commercial markets.10

The automatic rule of reason treatment for qualifying ACOs should eliminate one of the bigger sources of uncertainty regarding this type of provider collaboration in the health care industry. The

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8 See Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

9 Id.

10 Id.
Agencies’ prior guidance on integration was set forth in various policy statements, such as the Health Care Statements, but the Agencies refrained from providing specific criteria required for integration in their ACO guidance. The Health Care Statements provided broad guidelines for financial integration, such as capital investment and risk sharing, and for clinical integration, such as data gathering and quality measurement, implementation of care guidelines and protocols, and consequences for participants who failed to meet those goals.

As FTC Commissioner Rosch recently noted, however, the guidance provided in the Health Care Statements was not very precise. Provider networks and joint ventures wishing for more clarity were forced to seek review by the Agencies. But subsequent guidance in the form of Advisory Opinions was not necessarily any clearer for providers seeking guidance. As such, the clarity of automatic rule of reason treatment should be a welcome relief for providers seeking to form ACOs under the Shared Savings Program.

The CMS clinical integration requirements are consistent with the guidance set forth in the Health Care Statements and, to a lesser extent, the Competitor Collaboration Guidelines. CMS requires that ACOs “maintain an identifiable governing body” and that the governing body define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care. It also requires that ACOs coordinate care for beneficiaries and have a formal legal structure for the receipt and distribution of payments under the Shared Savings Program. Although the Final Statement indicates the Agencies’ willingness to accord rule of reason treatment to ACOs that qualify for the Shared Savings Program and use the same structures and processes in the commercial market, it is likely that such an ACO would have been accorded rule of reason treatment under the existing antitrust guidance.

**Mandatory Review.** The Proposed Statement provided for mandatory review by one of the Agencies if participants in an ACO provided the same service in the same PSA and their combined PSA share for that service exceeded a 50 percent threshold. The most important change between the Proposed and Final Statements is the elimination of this mandatory antitrust review for ACOs with participants having PSA shares exceeding 50 percent. The Final Statement defines the PSA share for each service as “the lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients] separately for all physician, inpatient or outpatient services.”

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12 Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

13 Health Care Statements, supra note 5, at 8 and 9.


16 Rosch, supra note 14, at 8. Commissioner Rosch described the Advisory Opinions on the issue of clinical integration as “clear as mud.”

17 CMS Rules, supra note 3, at 67,819.

18 Final ACO Antitrust Policy Statement, supra note 2, at 67,027.

19 Id. at 67,030.

20 Id. at 67,029. The Proposed Statement had defined a PSA slightly differently as “the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]” for that service.
Prior to the issuance of the Final Statement, many industry participants had objected to the mandatory review. Some objected on legal grounds, namely that mandatory review by the Agencies might be an impermissible subdelegation of CMS’s statutory decision-making authority. Others were concerned that the mandatory review process would be too cumbersome and expensive, particularly for independent providers that might not have the tools to calculate PSA shares or easily gather other requested information. Primarily due to subdelegation concerns, the CMS Rules eliminate the gatekeeping function ascribed to the Agencies under the Proposed Statement. Instead, the CMS rules rely on three prongs of antitrust scrutiny to maintain competition among ACOs: (1) voluntary, expedited review of newly formed ACOs by the Agencies; (2) information sharing between CMS and the Agencies; and (3) existing antitrust enforcement mechanisms. Since the Agencies always offered review, and the existing enforcement processes remain in effect, the only real change is the information-sharing requirement.

**Use of Market Shares.** The focus on market share as an indicator of potential market power is another area in which the Final Statement is generally consistent with prior guidance and enforcement, but with some increased clarity and additional benefits for ACOs. For example, the Health Care Statements provide safety zones for exclusive and non-exclusive physician network joint ventures. Exclusive physician network joint ventures restrict participants’ ability to contract or affiliate individually with similar joint ventures or health plans; physician participants in non-exclusive joint ventures can, and often do, contract individually with health insurers or affiliate with other physician network joint ventures. Exclusive joint ventures qualify for the safety zone if the participants constitute 20 percent of the physicians or less in a given specialty with hospital privileges, practicing in the relevant geographic market. The threshold is 30 percent for non-exclusive physician network joint ventures. However, this safety zone is only applicable to financially integrated joint ventures, in which the participants share substantial financial risk.

The Final Statement provides a safety zone for clinically integrated ACOs if independent participants providing the same service in the same PSA have a combined share of 30 percent or less of that service in that PSA. The Agencies will use PSAs for physician specialties, major diagnostic categories (for inpatient facilities), and CMS-defined outpatient categories (for outpatient facilities), to determine whether ACOs meet safety zone thresholds or are likely to be able to exercise market power. Any hospital or ambulatory surgical center participant, regardless of PSA share, must be non-exclusive to the ACO for the ACO to fall within the safety zone. To be considered “non-exclusive,” an ACO participant “must be allowed to contract with private payers through entities other than the ACO, including contracting individually or through other ACOs or analogous collaborations.”

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23 Rosch, supra note 14, at 9–10.

24 CMS Rules, supra note 3, at 67,842.


26 Id.

27 Id.

28 Id.

29 Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

30 Id.
The Final Statement acknowledges that PSAs do not necessarily coincide with any geographic market and that the services analyzed do not necessarily constitute relevant product markets.\textsuperscript{31} However, it contains additional requirements and warnings for ACOs that include participants with high PSA shares, maintaining the focus on the potential for market power. Under the dominant participant limitation, for example, if an ACO has an individual participant with a PSA share that is greater than 50 percent of any service that no other ACO participant provides to patients in that PSA, that provider must be non-exclusive to the ACO for the ACO to qualify for the safety zone.\textsuperscript{32}

**Potentially Problematic Conduct.** The Final Statement’s focus on exclusivity is another way in which it is consistent with the Health Care Statements. As mentioned above, the safety zones for both ACOs and physician network joint ventures are dependent on whether certain participants are exclusive or non-exclusive to the ACO. For ACOs, hospital and ambulatory surgical center participants must be non-exclusive (able to contract with other payers independently or through similar collectives), as must physicians that fall under the dominant participant limitation.\textsuperscript{33} Exclusive physician network joint ventures must have lower market shares to qualify for the safety zone than non-exclusive joint ventures.\textsuperscript{34} The Final Statement recognizes that exclusivity may be both contractual or de facto through pressures exerted by the ACO, and notes that the Agencies consider indicia of non-exclusivity provided in the Health Care Statements in determining whether ACOs are exclusive.\textsuperscript{35} These indicia of non-exclusivity include: the presence of viable competing networks or health plans in the market, evidence that participants actually participate in (or have the incentive to participate in) those other plans and networks, evidence that participants earn revenue through other plans and networks, the absence of indications of significant withdrawals of participants from other plans and networks, and the absence of indications of coordination by participants concerning price or other “competitively significant terms of participation” in other plans and networks.\textsuperscript{36}

The Final Statement also makes clear that the Agencies will still scrutinize conduct that has been traditionally found to be anticompetitive, particularly for those ACOs with high PSA shares. The statement lists certain types of conduct that all ACOs should avoid, including improper sharing of competitively sensitive information. For ACOs with high PSA shares or “other possible indicia of market power,” conduct such as tying arrangements, exclusive contracting with providers, anti-steering provisions, most-favored-nations clauses, and similarly restrictive contracting provisions, and restrictions on commercial payers’ ability to share performance data, will still be considered anticompetitive.\textsuperscript{37}

Even for ACOs that meet the safety zone thresholds, the Agencies will still challenge conduct in “extraordinary circumstances,” such as collusive behavior or exchanges of pricing or other competitively sensitive information with respect to the sale of competing services outside the ACO.\textsuperscript{38} These are the same types of conduct that the Agencies have cautioned against in prior guidance, such as the Health Care Statements and the Competitor Collaboration Guidelines.\textsuperscript{39}

\begin{itemize}
\item[] \textsuperscript{31} Id.
\item[] \textsuperscript{32} Id. at 67,029.
\item[] \textsuperscript{33} Id. at 67,028–29.
\item[] \textsuperscript{34} Health Care Statements, supra note 5, Statement 8.
\item[] \textsuperscript{35} Final ACO Antitrust Policy Statement, supra note 2, at 67,028 n.30.
\item[] \textsuperscript{36} Health Care Statements, supra note 5, Statement 8.
\item[] \textsuperscript{37} Final ACO Antitrust Policy Statement, supra note 2, at 67,029–30.
\item[] \textsuperscript{38} Id. at 67,028 n.24.
\item[] \textsuperscript{39} Health Care Statements, supra note 5, Statements 8 and 9; Competitor Collaboration Guidelines, supra note 11, at 3, 6.
\end{itemize}
Enforcement. CMS and the Agencies are relying on existing antitrust enforcement mechanisms to maintain competition in the era of ACOs. There have not yet been any challenges or consent decrees involving ACOs formed pursuant to the ACA, but the business review process is still essentially the same. Although ACOs admitted into the Shared Savings Program will not have to seek business review letters to determine whether they meet the threshold for integration, the Agencies have committed to providing expedited (ninety-day) review for newly formed ACOs (formed after March 23, 2010) seeking additional guidance. The ACOs must not yet have signed or jointly negotiated with private payers, or participated in the Shared Savings Program. The most likely candidates for this type of review are those ACOs that include providers who do not meet the thresholds for the safety zone.

The review will be conducted on a voluntary basis, and the Agencies will share the reviewing responsibilities. Like other agency review processes, the voluntary review for ACOs will require the submission of fairly substantial amounts of data, including the CMS Shared Savings Program application, sample agreements, business plans and strategies, information about market competition, and information on PSA shares of participants. The Agencies also seek procompetitive justifications for potential conduct that would fall under the Final Statement’s “Conduct to Avoid” heading. This is the type of information collected generally by the Agencies during an investigation and underscores the continued focus on market power and the preservation of competition.

The Fullest Monty Ever?

Rule of reason analysis in antitrust cases often, if not typically, turns on sparse empirical records. Courts often struggle to balance the pro- and anticompetitive effects in a rule of reason analysis, in part because of the lack of quantitative data on both sides of the ledger.\(^{40}\) ACO cases, if or when they ever materialize, may be unlike any prior rule of reason cases because of the detailed data reporting required by the CMS rules. CMS will provide the Agencies with “aggregate claims data regarding allowable charges and fee-for-service payments, which will assist the . . . Agencies in calculating PSA shares for ACOs participating in the Shared Savings Program.”\(^{41}\) CMS will also gather and evaluate information regarding cost, utilization, and quality metrics from Shared Savings Program Participants. The Agencies will continually evaluate this information to inform their future analysis of ACOs, and the Statement indicates that the information might also be applicable to “other provider organizations.”\(^{42}\)

CMS requires participants in the Shared Savings Program to report on thirty-three quality control measures in four domains: Patient/Caregiver Experience, Care Coordination/Patient Safety, Preventive Health, and At Risk Populations. The ACOs must collect data on specific performance metrics, such as timely care, appointments, communication, hospital readmissions, vaccinations, screening for certain cancers, and management of chronic conditions, such as diabetes, hypertension, and coronary artery disease.\(^{43}\)

An ACO that is challenged under the rule of reason can point to its performance in these areas in the context of the Shared Savings Program. An efficiency-enhancing ACO may be able to point to its Medicare performance scores for patient satisfaction and quality and cost savings under the

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\(^{40}\) See, e.g., New York ex rel. Abrams v. Anheuser Busch, Inc., 811 F. Supp. 848, 872 (E.D.N.Y. 1993) (noting that the rule of reason balancing is “extremely awkward to apply” and that “[c]ompetitive effects are not susceptible to any kind of numerical valuation . . . .”).

\(^{41}\) CMS Rules, supra note 3, at 67,842.

\(^{42}\) Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

\(^{43}\) CMS Rules, supra note 3, at 67,889 (Table 1).
Shared Savings Program. If the ACO uses the same processes and structure to achieve similar results on the commercial side, the data collected through the Shared Savings Program may provide a pro-competitive justification for a rule of reason analysis in a case challenging the ACOs activities in the commercial market. Having access to this data could enable the Agencies to quickly determine which ACOs have procompetitive benefits that will outweigh anticompetitive effects. It may also allow the Agencies to determine which ACO structures and processes are the most likely to produce sufficient procompetitive benefits to justify any potential competitive harm.

This approach could provide greater certainty for the entire industry. Courts and the agencies base rule of reason analysis on the specific facts of any given case, and it can take years to get any type of consistent guidance on the likely treatment of various procompetitive justifications. ACOs will begin reporting data during the first year of their participation in the Shared Savings Program. So long as CMS shares data with the Agencies, it should be comparatively simple to develop a rule of reason framework incorporating this data that is applied consistently. As the program matures, the availability of this data will give ACOs some level of comfort if they are performing well in quality measures while obtaining payments representing cost savings from the Shared Savings Program. If an ACO is not performing well, its participation in the Shared Savings Program could be terminated, but it is unlikely that the procompetitive benefits of an unsuccessful ACO would outweigh the anticompetitive effects of any bad conduct.

Non-Price Elements of Competition
ACOs have the potential to injure commercial payers with higher prices. This is not true under Medicare because Medicare fees are set by the government and cannot be affected by price collusion. That does not mean, however, that ACOs are necessarily incapable of hurting Medicare through collusion. As is well recognized in antitrust law, price is not the only element of competition. Many types of output restrictions that could be relevant to ACOs have been found unlawful, even under the rule of reason, because the economic impact is similar to that of agreements to fix prices. For example, some courts have applied the per se rule to agreements to limit business hours or restrict access to certain services, and courts have also found such agreements to be unlawful under the rule of reason. Even the government could be hurt by collusion on these types of non-price elements in the Medicare field.

CMS recognizes that “[p]rograms that include incentives to reduce costs for care may result in unintended consequences, such as avoidance of at-risk patients, ‘stinting’ on care, fraud and abuse, overutilization, deliberate delay in claims submission, and other such activities.” Some strategies that providers could use to artificially reduce costs and increase payments under the Shared Savings Program could wind up looking like unlawful output restrictions. As an example, providers within an ACO could try to restrict clinic hours, or they could reduce the level of care provided. They could also engage in strategies to try to drive potentially expensive “at-risk” patients to other providers, as patients have the freedom to seek care from Medicare providers.

44 See, e.g., Detroit Auto Dealers Ass’n, 955 F.2d 457 (6th Cir. 1992) (upholding FTC consent order applying rule of reason to agreements among auto dealers to restrict the hours of operation); Tennessee ex rel. Leech v. Highland Mem’l Cemetery, 489 F. Supp. 65, 68 (E.D. Tenn. 1980) (agreement by cemeteries not to conduct burials on Sundays violated Sherman Act); see also Port Washington Real Estate Board, 120 F.T.C. 882 (1995) (consent order preventing real estate board from restricting ability of its members or brokers to hold open houses).

45 See CMS Rules, supra note 3, at 67,945. “At risk” patients are those whose conditions are likely to be very expensive to treat and maintain. These can include non-compliant patients, those with disabilities or histories of frequent emergency room visits, or patients with mental health or substance abuse disorders. Id. at 67,950.
outside their assigned ACO. Although the CMS rules seem to prohibit this type of conduct, antitrust enforcers could also have a role to play, and it is conceivable that the antitrust authorities would have an interest in non-price coordination that is also the subject of CMS rules. Such an interest, however, would be subject to the Supreme Court’s ruling in Credit Suisse, which taught that antitrust law can be precluded by another body of law—securities law there, CMS law here—even where the antitrust concerns are generally consonant with those of the other area of law.47

Conclusion
After more than a year of workshops, proposals, comments, and revisions, the Final Statement does little to alter the fundamental application of the antitrust laws to ACOs. It does, however, provide some additional clarity by confirming rule of reason treatment for ACOs participating in the Shared Savings Program, and it gives greater leeway for collaborations among providers who are clinically integrated, but would not necessarily have met the financial risk-sharing requirements under earlier guidance. A potentially significant consequence is that data that must be collected under the Shared Savings Program may give rise to more-detailed rule of reason analyses than ever seen before. The ACO cases may also give rise to a relatively novel focus on non-price competition in the Medicare context, given the inability of providers to collectively impact reimbursement rates. It remains to be seen how such non-price competition may play out in that setting.

46 Id.
47 Credit Suisse (USA) LLC v. Billing, 551 U.S. 264, 278–79 (2007) (rejecting the plaintiffs’ argument that “there is no possible ‘conflict’ since both securities law and antitrust law aim to prohibit the same undesirable activity.”).
The ACO Antitrust Policy Statement: Antitrust Enforcement Meets Regulatory Rulemaking

Robert F. Leibenluft

As the Obama Administration began to draft regulations governing Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP), the federal antitrust agencies faced a significant challenge. Critics of health care reform had charged that the Affordable Care Act\(^1\) contained little to control health care costs. The Administration’s response was that ACOs and similar initiatives would transform how care is delivered and, in the long run, result in both lower cost and higher quality care. ACOs were therefore a critical component of the Administration’s health care reform agenda.

But ACOs are founded on the premise that the best way to reduce costs and improve quality is to encourage greater collaboration among health care providers. Such an infrastructure, however, would inevitably result in greater consolidation and coordination in the health care sector. The Department of Justice and the Federal Trade Commission therefore needed to develop rules that would address concerns that ACOs would improperly collude or exercise market power when dealing with commercial health plans, but at the same time would not create undue roadblocks to the formation and operation of ACOs that were being touted as key to Medicare payment reform.

The FTC/DOJ statement on ACOs\(^2\) reflects how the antitrust agencies addressed these conflicting demands. It also illustrates fundamental differences in the approach and tools available to antitrust enforcers wary of prescribing detailed rules of conduct, as compared to Medicare officials who operate an agency that is both a regulator and by far the dominant purchaser of health care services.

The Path to the ACO Statement: Agency Consideration of Clinical Integration

To put the ACO Antitrust Policy Statement in context, it is essential to review the antitrust agencies’ consideration of provider collaborations, particularly those involving recent “clinical integration” initiatives. Both the FTC and the DOJ have a long history of actively prosecuting physicians and other health care providers who lack economic integration but who jointly negotiate with health plans.\(^3\) In response to providers who asserted that they needed more guidance regarding how the

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antitrust laws apply in the health care setting, the antitrust enforcement agencies in 1993⁴ issued the first—and still only—statements of antitrust enforcement policy aimed at a single industry sector (Guidelines). The Guidelines explained that the antitrust agencies would apply the rule of reason to physician networks that took on substantial financial risk, e.g., through capitation or substantial withhold to be paid based on achieving certain cost or quality goals. The Guidelines also established “safety zones” for physician networks that did not exceed 30 percent of the physicians (20 percent in the case of non-exclusive networks) in any specialty with hospital privileges in the relevant geographic market.

In 1996 the DOJ and FTC issued revised guidelines that, among other things, provided that the antitrust agencies would apply rule of reason treatment to physician networks that are “clinically integrated,” even if they lacked financial risk sharing.⁵ This change came about in response to providers who urged that reliance only on financial risk sharing was too restrictive, and that physicians who were working together to achieve substantial cost and quality efficiencies should not be viewed as engaging in price fixing if their efforts required joint negotiations with health plans. These Health Care Statements, however, described clinical integration in only very broad, conceptual terms. They stated that:

Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.⁶

The FTC and DOJ explained that they did not wish to offer more details regarding what might constitute clinical integration out of concern that more prescriptive language might dampen innovation. Officials of these antitrust agencies feared that providers might feel constrained to using arrangements that closely followed whatever model the guidelines would describe, at the expense of developing their own approaches better suited to meet their particular needs.

Such flexibility is a marked departure for providers accustomed to the approach of the Centers for Medicare and Medicaid Services (CMS), the Health and Human Services Office of Inspector General, the Internal Revenue Service, and other government agencies which oversee the highly regulated health care sector. But the FTC and DOJ guidelines also lack the certainty that a regulatory regime offers. Physician networks, not surprisingly, often asked their counsel (and the antitrust agencies) to tell them “how much clinical integration was enough?” to assure that their joint negotiations were not condemned as per se illegal. For many years, the antitrust agencies declined to respond to those inquiries, continuing merely to point to the general language in the 1996 Health Care Statements.

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⁶ Id. at 72–73.
FTC staff, however, in a series of increasingly lengthy Advisory Opinions beginning in 2002,7 has tried to provide greater insight into how the FTC staff analyzes clinical integration arrangements. These Advisory Opinions have been informative to antitrust counsel, but may have been somewhat opaque to health care providers and lawyers less familiar with antitrust joint venture analysis. As the Advisory Opinions explain, the antitrust analysis of clinical integration arrangements focuses on three key questions: (1) Does the arrangement have the potential to produce substantial cost or quality efficiencies that could not be achieved by the providers acting independently? (2) Are joint negotiations reasonably necessary and related (i.e. ancillary) to achieving those efficiencies? and (3) Will the arrangement have market power and what will be its likely competitive effects?8 Most of the focus in the Advisory Opinions has been on the first issue—i.e., analyzing whether the proposed arrangements appear to hold the promise of substantial efficiencies.

The Advisory Opinions also discuss at some length when joint negotiations might be considered ancillary to the venture’s legitimate goals. They conclude that joint negotiations may be justified to ensure that there is a consistent group of physicians who participate in the clinical integration program across a broad array of payers, but also explicitly reject arguments that joint negotiations are needed to ensure physician participation, or because the network offers a new product.9

The Advisory Opinions have tended to focus relatively little on market power questions. In some cases, the proposal may not have raised serious market power concerns. In others, however, FTC staff relied largely on assurances that the proposed network would be non-exclusive, and cautioned that its favorable opinion was conditioned on whether the network indeed was not coercive.10 Of course, it is not surprising that FTC staff has not undertaken in-depth consideration of market power issues given that staff advisory opinions must be drafted before the proposed conduct has been undertaken and are not based on any extensive investigation of market conditions.

Only a handful of provider networks that rely primarily on clinical integration have been established in the fifteen years since the concept first appeared in the 1996 Health Care Statements. Provider groups have blamed this in part on the lack of better guidance from the antitrust agencies, coupled with concerns about regulatory restrictions governing patient referrals, tax, corporate practice of medicine, and other issues.11 On the other hand, health plans have expressed

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7 The first FTC Advisory Opinion addressing clinical integration involved a proposed agreement in Denver, Colorado. See FTC Staff Advisory Opinion to MedSouth Inc. (Feb. 19, 2002) [hereinafter MedSouth Advisory Opinion], available at http://www.ftc.gov/bc/adops/medsouth.shtm. The most recent FTC Advisory Opinion was 37 single-spaced pages, and was issued more than 21 months after the initial request for the review. See FTC Staff Advisory Opinion to Tristate Health Partners Inc. (Apr. 13, 2009) [hereinafter Tristate Advisory Opinion], available at http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf.

8 See, e.g., Tristate Advisory Opinion, supra note 7, at 14–36.

9 See, e.g., FTC Staff Advisory Opinion to Greater Rochester Independent Practice Association, Inc. 18–24 (Sept. 17, 2007), available at http://www.ftc.gov/bc/adops/gripa.pdf (rejecting that the “new product argument” or transaction efficiencies by themselves would justify joint negotiations).

10 See, e.g., MedSouth Advisory Opinion, supra note 7 (concluding that staff would recommend an enforcement action if MedSouth physicians are able to use collective power to obtain higher prices absent evidence that substantial efficiency benefits outweigh likely anticompetitive effects); Tristate Advisory Opinion, supra note 7, at 37 (same).

skepticism that clinical integration alone, without substantial financial risk, can bring about significant efficiencies, a view also articulated by FTC Commissioner J. Thomas Rosch. Moreover, some clinically integrated groups have reported that local health plans have not been interested in contracting with them and thus whatever investment was made in establishing them may result in little return.

Anticipating ACOs—the Health Care Sector Reaction

Notwithstanding the relatively slow growth of clinically integrated networks designed to deal with commercial health plans, towards the end of the last decade several policymakers focused on the fragmented nature of the U.S. health care system as a major obstacle to the kind of coordinated care needed to improve quality and lower costs. They proposed that if providers in small practices could form “Accountable Care Organizations” or “ACOs” that would be responsible for the quality and cost of care delivered to a defined set of individuals, they might be able to achieve the level of results attained by fully integrated groups, such as the Cleveland Clinic or the Kaiser Permanente Group. This concept found its way into the Affordable Care Act and became the focus of the Administration’s effort to control health care costs, in part because the Act contained few other cost-control or quality improvement provisions.

The ACO concept has not been extensively tested. The closest evaluation of the model was the Medicare Physician Group Practice demonstration, which tested incentives similar to those in the ACO program. It, however, had mixed results, particularly with respect to achieving cost goals. Nevertheless, the provider community viewed with great anticipation the proposed regulations for ACOs in the MSSP as a harbinger of a dramatic shift in how Medicare would ultimately be paying for provider services. Even if the number of providers who actually form ACOs under the MSSP is small, there is a widespread belief that there is a need for more coordinated care, and that over time payment systems will evolve that reward greater integration across providers.

This belief has contributed to a marked trend towards greater consolidation among health care providers. Other factors leading to increased consolidation include the economies of scale that can be achieved by larger hospital and physician practices, the attraction of an employed lifestyle for many younger physicians, and the desire by providers to obtain more leverage in negotiations with health plans. Thus, in recent years, hospitals are increasingly merging, sometimes with hos-
Hospitals in their own geographic markets, but also with hospitals in other geographic markets to form broad systems. Hospitals are employing an increasing number of physicians, and physician groups are merging with each other to form larger single- and multi-specialty group practices. This consolidation has the potential to bring about greater coordination of care, higher quality, and cost savings. But health plans and some academics are concerned that it could also increase market power and drive up prices.\(^{18}\)

It is this last concern that has motivated, in part, the DOJ and the FTC to give so much attention to articulating how they intended to apply antitrust principles to ACOs that wish to participate in the MSSP. At one level, the attention that the antitrust enforcers are giving to ACOs may seem premature. These are organizations being created to participate in the Medicare program where payment levels will be set unilaterally by CMS. There is thus no possibility of a direct impact on prices to Medicare. Furthermore, these organizations only now are being formed, so it is unclear whether, and how much, ACOs will compete with each other on quality dimensions for patient business.\(^{19}\) But the antitrust agencies believe that providers will form ACOs not just to participate in Medicare but also to jointly contract with commercial health plans. Thus, their concern is twofold: (1) to the extent the ACO concept is successful, it will further accelerate the trend toward provider consolidation; and (2) if an ACO receives approval to participate in the MSSP, it may become more difficult at a later date to bring a successful challenge in court if it appears that the ACO is exercising market power in negotiations with health plans or otherwise engaging in anticompetitive practices.

Another motivation for the ACO Antitrust Policy Statement, however, was quite different. As noted above, the antitrust agencies had been criticized, whether fairly or not, on the grounds that the lack of clear antitrust guidance had deterred providers from engaging in clinical integration initiatives. Given the importance that the Administration was placing on ACOs as a fundamental building block for health system delivery reform, it was crucial that providers interested in ACOs not be deterred because of undue fear that they would run afoul of the antitrust laws.

Thus the DOJ and FTC, in developing their ACO Antitrust Policy Statement, had to balance several potentially conflicting objectives:

- Provide clear guidance to those considering forming ACOs so as to not deter collaborations that would be competitively benign or neutral.
- Ensure that such guidance would not be overly prescriptive so as to deter innovative approaches or fail to address unique situations.
- Explain when ACO formation and conduct raised serious antitrust concerns, and lay the foundation for challenging such situations.
- Establish review mechanisms that could be implemented in a timely manner.

**Agency Guidance to Providers**

The ACO Antitrust Policy Statement offers guidance to providers in three significant ways. First, the antitrust agencies will afford rule of reason treatment to ACOs that: (1) meet the CMS eligibility requirements; (2) participate in the MSSP; and (3) use with commercial plans the same
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\(^{19}\) A more likely area for competition among ACOs may be for physician participation.
ernance, leadership structure, and clinical and administrative processes that they use under the MSSP. The antitrust agencies note that the CMS eligibility requirements “are broadly consistent with the indicia of clinical integration” that the agencies had previously set forth in the 1996 Health Care Statements and in advisory opinions.\textsuperscript{20} The CMS eligibility requirements are quite detailed with respect to governance and in demonstrating that they have an array of processes to promote evidence-based medicine, patient engagement, reporting, coordination of care, and patient-centeredness.\textsuperscript{21} Moreover, depending on the particular track that they choose, ACOs under the MSSP program have the potential to earn up to 60 percent of shared savings, up to a certain limit, and are at risk of having to repay up to 60 percent of losses, also not exceeding a certain limit, based on their quality scores.\textsuperscript{22}

CMS estimates that the average ACO will spend $589,000 in start-up investment costs, and $1.27 million annually in operating costs.\textsuperscript{23} Moreover, the antitrust agencies note that CMS will be collecting cost, utilization, and quality data from all participating ACOs, and such data will help the agencies determine whether the CMS eligibility criteria “have required a sufficient level of clinical integration to produce cost savings and quality improvements,” and that CMS will be monitoring each ACO’s results.\textsuperscript{24} Under such circumstances, it is not surprising that the antitrust agencies have concluded that such organizations are “reasonably likely to be bona fide arrangements” intended to improve quality and reduce costs and that they should be afforded rule of reason treatment. Perhaps more noteworthy is the antitrust agencies’ blanket conclusion—without more elaboration—that they will treat “joint negotiations with private health plans as reasonably necessary to an ACO’s primary purpose of improving health care delivery.”\textsuperscript{25} As noted above, the FTC Staff Advisory Opinions on clinically integrated arrangements have devoted much more attention to the specific rationale for concluding why joint negotiations with health plans are ancillary to the network’s legitimate purposes.\textsuperscript{26}

Thus, the antitrust agencies are providing useful guidance without promulgating specific criteria for clinical integration—which is something they have been reluctant to do. Of course, as the antitrust agencies observe, the CMS requirements for ACOs do not reflect the only approach to clinical integration, but do offer providers a concrete example that will pass muster with the antitrust enforcers. An important implication is that as provider groups organize as ACOs (or something similar), the key antitrust uncertainties and issues will likely focus less on whether they are clinically integrated and if their joint negotiations are ancillary, which have been the key issues

\textsuperscript{20} ACO Antitrust Policy Statement, supra note 2, at 67,027.


\textsuperscript{22} Id. at 67,910.

\textsuperscript{23} Id. at 67,969.

\textsuperscript{24} Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

\textsuperscript{25} Id.

\textsuperscript{26} See supra note 7 and accompanying text.
historically, and more on market power concerns which, in many ways, will be even more difficult to assess.

The second way that the ACO Antitrust Policy Statement offers guidance to providers is by establishing a “safety zone” for certain ACOs in the MSSP. To determine whether the safety zone is available, the ACO must first calculate the ACO’s share of services in each participant’s Primary Service Area (PSA), which is the lowest number of zip codes that account for at least 75 percent of the participant’s patients. For every service (based on physician specialties), major diagnostic categories (for hospital services), and outpatient categories (for outpatient facilities) where two or more independent ACO participants provide that service (referred to in the ACO Antitrust Policy Statement as common services), the ACO must have a combined share of 30 percent or less of each ACO participant’s PSA, where two or more ACO participants provide that service to patients from that PSA. Moreover, each hospital and ambulatory service center must be non-exclusive to the ACO, regardless of its PSA share. ACOs may exceed the 30 percent share limit and still qualify for the safety zone if they have only one physician or physician group per specialty in each county that contains at least one rural zip code, provided these physicians’ primary offices are in rural zip codes and they are non-exclusive to the ACO. If the ACO includes a participant with a greater than 50 percent market share, that participant must be non-exclusive, even if no other ACO participant provides the service in that PSA. The Statement contains a lengthy appendix explaining how the PSA share calculations should be made.

The approach taken by the safety zone in the ACO Antitrust Policy Statement differs significantly from that of the safety zone in Statement 8 (on physician network joint ventures) of the 1996 Health Care Statements. The Statement 8 safety zone is laid out in general terms—it applies to financially integrated nonexclusive networks where the physician participants constitute 30 percent or less (or 20 percent or less in the case of exclusive networks) of “each physician specialty with active hospital staff privileges who practice in the relevant geographic market.” Statement 8 provides no guidance on how physician specialties are to be defined, nor does it discuss how the geographic market should be defined, other than in a footnote commenting that “[g]enerally, relevant geographic markets for the delivery of physician services are local.” Thus, physician networks and their counsel who wish to know whether the Statement 8 safety zone applies need to make their own best judgments as to how the relevant product and geographic markets should be defined.

The ACO Antitrust Policy Statement takes a much more mechanistic, almost regulatory, approach. Thus, it defines specific categories of providers or services, each of which must be analyzed, although it acknowledges that such categories “do not necessarily constitute relevant antitrust product markets.” The approach to geographic market is even more prescriptive—based on PSAs that have their origin in the Stark II regulations—and are built around patient flow

28 Id. at 67,031–32.
29 Health Care Statements, supra note 5, at 64–65.
30 Id. at 65 n.26.
31 Final ACO Antitrust Policy Statement, supra note 2, at 67,028.
32 Id. at 60,731.
data that the antitrust agencies, and virtually all economists, have recognized are at best only a useful starting point for defining geographic markets. The advantage of such an approach is that ACO applicants now have a clear recipe for determining whether or not they qualify for the safety zone. The downsides with using PSAs are that they are unlikely to result in an analysis built on relevant antitrust markets and may require a considerable amount of data analysis.

Ultimately, the specific contours of the prescribed safety zone analysis may not matter all that much because it is likely that few ACOs will meet the core PSA 30 percent share requirement. Given the high bar to obtaining safety zone status, it is important that providers remember, as the antitrust agencies note, that ACOs outside the safety zone still may be procompetitive and lawful.34

Thus, the more important take-away from the safety zone provision is the underlying rationale—which unfortunately is not explicitly stated—that the antitrust agencies appear not to have significant competitive concerns about ACOs whose market share in any properly defined relevant market does not exceed 30 percent. Accordingly, ACOs should focus on this ultimate issue and not be sidetracked in the mechanics of defining each PSA for each of their participants or whether there are some overlaps that modestly exceed the safety zone threshold methodology as it has been defined. Indeed, the ACO Antitrust Policy Statement recognizes that an ACO may have reliable evidence other than PSA shares from which the ACO may reasonably conclude that it is unlikely to raise competitive concerns.35 ACOs should keep in mind that even exceeding a 30 percent threshold in a properly defined relevant market does not automatically mean that there are serious antitrust issues. As that share increases, however, more concerns are raised and more in-depth antitrust analysis is required.

The third way that the antitrust agencies offer guidance in the ACO Antitrust Policy Statement is their commitment to expedited, voluntary antitrust review for any ACO formed after March 23, 2010.36 The FTC and DOJ promise they will complete their review within ninety days of receiving certain specified information described in the statement, and that they will indicate whether the ACO: (1) is not likely to raise competitive concerns (perhaps conditioned on the ACO’s written agreement to take certain specific steps); (2) potentially raises anticompetitive concerns; or (3) likely raises competitive concerns.37 The assessment of any particular ACO will be done by either the DOJ or the FTC, but they are establishing a Working Group to collaborate on their reviews.38

This is a salutary and potentially important development, depending on how many ACOs seek opinions, and how the process is implemented. Until now, reviews of clinical integration proposals have been undertaken only by the FTC and have typically taken a long time, often more than a year. The announced approach indicates that both antitrust agencies will be involved in the


34 Final ACO Antitrust Policy Statement, supra note 2, at 67,028.

35 Id. at 67,029.

36 This is the date of the passage of the Affordable Care Act. Presumably the antitrust agencies did not wish to commit to expedited review of entities that were formed without regard to the MSSP ACO program. Also, it is likely that most of such entities are already in operation and therefore would not be eligible for an FTC Advisory Opinion or DOJ Business Review Letter.

37 Id. at 67,031.

38 Id. at 67,030.
process, and this could provide assurances that the two federal antitrust enforcers have a single view on these issues, and also result in additional resources for the task.

The antitrust agencies’ views, as with other Advisory Opinions and Business Review Letters, will be available to the public, and thus—depending on how they are written and how much information is revealed—could provide important additional guidance to the health care sector. The big wild card will be whether many ACOs seek such agency review. The advantage to providers is more certainty regarding agency action; the downside is that the reviewing antitrust agency may disapprove of the arrangement or condition it on certain conduct commitments that the ACO might believe to be unnecessary but would find difficult not to implement once the reviewing agency has gone on record regarding its views.

FTC and DOJ Concerns Regarding Potentially Anticompetitive ACOs

The most controversial part of the proposed CMS ACO regulation and the Proposed ACO Antitrust Statement issued last spring was the requirement that every ACO (except certain rural ACOs) that had a PSA share of 50 percent or greater in any common service offered by two or more independent ACO participants had to undergo a mandatory review by the DOJ or the FTC. 39 Without a letter from the antitrust agencies indicating that they had no present intention to challenge or recommend challenging the ACO, the ACO could not qualify for the MSSP.

The proposed mandatory review was controversial for a number of reasons. It was based on the same type of screens using defined product markets and PSAs that are used in the final Statement for the purpose of defining the safety zone. As discussed above, defining these PSAs not only requires extensive analysis of data (which may not always be available), but also does not necessarily reflect relevant antitrust markets. The rationale for using them is that the antitrust agencies needed to establish a bright-line test that ACO applicants, on their own, could mechanically apply to determine if they were subject to mandatory review; the agencies emphasized that the proposed PSA thresholds were simply screening criteria, not intended to necessarily delineate antitrust markets, and were being used in the absence of any better alternative. Nevertheless, there were concerns that the cost of performing the PSA analysis, particularly where a large number of different provider types and services were involved, would be significant. Moreover, the mandatory review thresholds were set at a level such that it was widely believed that many ACOs would be subjected to review, which would involve additional costs and burden. 40

More fundamentally, the proposed mandatory review process placed the antitrust enforcers in a role that was much more akin to that of a regulatory agency. With the exception of Hart-Scott-Rodino premerger review, entities are not typically required to obtain clearance from the antitrust agencies prior to formation or before they begin operations. While some ACOs might have the potential for anticompetitive effects, the mandatory review process applied to every ACO that trig-

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gered the 50 percent PSA share threshold for just one ACO participant for just one common service, even if the ACO had not done any business (which was likely the case), or lacked plans to jointly negotiate with commercial health insurers. In the preamble to the proposed regulations, CMS asserted that competition was relevant to ACOs in the MSSP, notwithstanding that such ACOs could not negotiate prices with Medicare, because competition fostered higher quality for the services they would render to Medicare beneficiaries.41

CMS also suggested that if ACOs had market power, they might obtain higher commercial rates relative to Medicare and reduce the number of Medicare beneficiaries they serve, thereby threatening access to care by Medicare beneficiaries.

A final CMS concern was that if an ACO was challenged by the antitrust agencies after it had begun participation in MSSP, it could prevent the ACO from completing the term of its agreement with CMS. Notwithstanding these rationales, questions were raised as to whether CMS had the authority under the Affordable Care Act to take into account antitrust considerations in approving ACO applicants, and even if it did, to effectively delegate this responsibility to the antitrust enforcers.42

Under the Proposed Statement, the antitrust agencies had committed to complete their mandatory review within ninety days. But it is unclear whether the antitrust agencies would have had the resources and the time to make well-founded determinations about the potential competitive effects of such entities. The result could have been a large number of false positives (putting a damper on benign innovative initiatives), false negatives (essentially immunizing arrangements that might prove problematic), or both.43

While the mandatory review proposal was subject to the criticisms noted above, it did receive support from health plans and others, who urged that CMS and the antitrust agencies needed to be proactive in reviewing the consolidation and possible anticompetitive conduct that might accompany ACO formation. In the end, CMS dropped the mandatory review requirement. In its place, CMS notes that it will provide the antitrust agencies with copies of certain ACO applications, along with aggregate claims data reflecting allowable charges and fee-for-service payments to the ACO participants. It also encourages ACOs to seek voluntary expedited antitrust review from the DOJ and the FTC if they have any competitive concerns. And the antitrust agencies, for their part, assert that they will “vigilantly monitor complaints about an ACO’s formation or conduct, and take whatever enforcement action may be appropriate.”44 In short, while the antitrust agencies are declaring they will be closely scrutinizing ACO formation and conduct, by dropping mandatory review, they will be relying on the same approaches they use in other sectors of the economy—i.e. reacting to complaints from purchasers, competitors, and other market participants and opening investigations when they believe it is appropriate.

The ACO Antitrust Policy Statement retains provisions in the Proposed Statement that caution ACOs against conduct, such as the improper sharing of competitively sensitive information among competing participants that could facilitate collusion among the ACO participants. It also contains a discussion of four types of conduct that the antitrust agencies believe may raise competitive

41 CMS Proposed Rule, supra note 39, at 19,630.
43 See Comments on the Proposed DOJ/FTC Statement of Antitrust Enforcement Policy, supra note 40, at 7–11.
44 Final ACO Antitrust Policy Statement, supra note 2, at 67,026.
concerns when engaged in by ACOs with high PSA shares or other indicia of market power. They include:

- Preventing or discouraging private payers from steering patients to certain providers, such as through “anti-steering,” “anti-tiering,” “guaranteed inclusion,” “most-favored nation,” or similar clauses.
- Tying sales of the ACO’s services to a private payer’s purchase of other services outside the ACO, e.g., requiring that the purchaser contract with all of the hospitals in a system.
- Contracting on an exclusive basis with ACO providers so that the providers are not available to contract with payers outside the ACO arrangement either individually or through other ACOs or similar arrangements.
- Restricting a private payer’s ability to make available to its enrollees information about cost, quality, efficiency, or performance that could aid enrollees in selecting providers in the health plan.\(^45\)

While observing that in some situations such conduct may be competitively neutral or even pro-competitive, the ACO Antitrust Policy Statement clearly reflects concerns about such practices by ACOs with market power. For example, providers who seek voluntary expedited review are required, if they are engaged in any of the four types of conduct, to provide an explanation as to why such conduct is not problematic.\(^46\)

This list of “suspect” conduct is important because it identifies practices that the antitrust agencies are concerned about but which likely would be difficult to challenge on their own in most circumstances. For example, in recent years health plans have found that because their subscribers want broad provider choice, it may be difficult to market a successful health plan product that excludes more than a few providers, particularly those that are highly regarded and might be viewed as a “must have.” A strategy that might be used to counter this is for a health plan to include most providers in their networks, but to provide financial incentives to its members (such as reduced co-pays) to steer at least some of them to lower cost providers. Information about quality also could be used by plans to steer members towards providers who have better quality metrics.

While steering/tiering and similar tactics have not met with widespread success so far, they are viewed by some health plans as a potentially important tool in the future.\(^47\) The antitrust agencies are concerned, however, that dominant providers may insist that their health plan contracts contain language that would limit a health plan’s ability to use such approaches that rely on competition based on cost and or quality within networks. But insistence on such contract terms, by itself, would be a difficult practice to challenge on antitrust grounds in most circumstances. Had the Final ACO regulations and ACO Antitrust Policy Statement included the mandatory review provision, the antitrust agencies might have used the additional leverage that it gave them to condition their approval on the ACO’s agreement not to engage in any of the four types of specified “suspect” conduct. The antitrust agencies may still employ this tactic with respect to ACOs that seek voluntary review, but for ACOs that do not seek such review, it will be more difficult for the agencies to address such conduct proactively. By identifying the conduct in the ACO Antitrust Policy Statement they have put providers on notice that the antitrust agencies are concerned

\(^{45}\) Id. at 67,030.
\(^{46}\) Id. at 67,030–31.
about such tactics, but short of initiating a challenge to the ACOs, they do not have the type of oversight over ACOs that they would have had under the Proposed Statement through the mandatory review process.

Conclusion
There is no real consensus regarding how ACOs should work, and even less as to whether they will in fact be an important path to the type of health care delivery reform that is needed to make an appreciable impact on reducing health care costs and improving quality. Notwithstanding this, over the past eighteen months the health care sector has experienced ACO fever, with providers and payers (or at least their consultants) expressing tremendous interest in the possible shape of the MSSP ACO program. As a result, the proposed MSSP ACO regulations were received with great anticipation, and CMS in connection with its proposed regulation estimated that 75 to 150 ACOs would participate in the MSSP. Given such projected interest in ACOs, and the important place they were expected to have in the Administration’s health care agenda, the antitrust agencies also had to gear up for a potential ACO onslaught. Their Proposed ACO Antitrust Policy Statement, particularly the mandatory review provisions, not surprisingly attracted a great deal of attention.

Providers, however, were very disappointed with the proposed MSSP regulations, which many found to be far too burdensome and restrictive for a program that appeared to offer too little upside gain and too much downside risk. Many have praised CMS for providing more flexibility and regulatory relief in its final regulations, but it remains to be seen how many ACOs actually will seek to participate in the MSSP, particularly at the outset of the program in 2012. But even if there is less interest in MSSP ACOs than originally anticipated, in the longer run it is likely that there will be growth in the type of integration and delivery system changes that are foreshadowed by the ACO concept. It will just likely take longer, and through a greater variety of arrangements and programs—with both Medicare and private payers—than through MSSP ACOs alone. Thus, while CMS regulations governing the MSSP ACOs are important, their significance lies not so much in the MSSP ACO program itself, but rather as a reflection of the kind of changes in incentives and rules that will affect the health care delivery system in the years ahead in a wide range of both government and private health plan programs.

The same can be said for the final ACO Antitrust Policy Statement—while it contains important provisions, it should be seen not as a significant departure from prior policy, but rather as another step in what is an evolving story of how antitrust enforcement must address changes in the health care delivery system that are reflected in, but go far beyond, MSSP ACOs. Both the provider and the payer community anxiously awaited the Proposed ACO Antitrust Statement—the former hoping it would provide the guidance it felt it needed to assure providers that they could form ACOs and other clinically integrated groups, the latter hoping for assurances that the antitrust agencies would be vigilant with respect to what it saw as increasing concentration among

48 CMS Proposed Rule, supra note 39, at 19,633. In the notice regarding the final rule, CMS estimates that 50 to 270 ACOs might participate in the first four years of the program. CMS Final Rule, supra note 21, at 67,965.

49 There may be more interest in other payment reform initiatives that CMS has proposed, including Pioneer ACOs and bundled payment approaches. See Dep’t of Health and Human Servs., CMS, Bundled Payments for Care Improvement Initiative, available at http://innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html; Dep’t of Health and Human Servs., CMS, Pioneer Accountable Care Organizations (ACO) Model Request for Application, available at http://innovations.cms.gov/wp-content/uploads/2011/05/Pioneer-ACO-RFA.pdf. These initiatives also will entail greater collaboration among providers.
health care providers. The Proposed ACO Antitrust Statement offered some of both. Providers received assurance that if they meet the CMS ACO eligibility requirements they will be analyzed under the rule of reason and their joint negotiations viewed as ancillary to their efforts. They also were offered a mechanism whereby, if they want, they can receive expedited ninety-day review of their ACO arrangements. On the other hand, the Proposed Statement identified four types of conduct about which payers had expressed concern. More significantly, CMS and the antitrust agencies proposed a mandatory review of all ACOs that might have market power in even a relatively narrow array of provider services.

The mandatory review proposal ultimately proved to be too controversial. It would have placed the antitrust agencies in the unusual position of essentially being the gatekeeper for determining which ACOs would be able to participate in the MSSP. The antitrust agencies would have been faced with making determinations for nascent organizations, most of which would have little or no track record, regarding both their potential benefits and possible anticompetitive effects. The likely response for ACOs that fell into the “gray area” where future effects would be difficult to predict would have been some form of conditional approval, for example, being subject to the ACO agreeing to certain conditions on its conduct and continued monitoring by the antitrust agencies of reports on the ACOs’ performance and input from health plans and other market participants. This approach, however, would have placed the antitrust enforcers effectively in the unaccustomed role of regulators, monitoring compliance with conduct orders and scrutinizing performance statistics.

Although the antitrust agencies dropped mandatory review, they have emphasized that they will be vigilant in the area. We will need to see how this is reflected in future advisory opinions and business review letters, and more important, in any enforcement actions that may arise. The analytical task facing the antitrust agencies is likely to become even more challenging in the years ahead. It will require balancing the potential advantages of greater integration and coordination against the potential risks of increased consolidation and anticompetitive practices. Complicating the picture further is the growing disparity between the level of Medicare and Medicaid payments (which account for 40–50 percent or more of most providers’ revenues) with the payment rates of commercial plans, which increasingly are viewed by providers as essential to subsidize the government payment shortfall.50 This disparity likely will increase substantially as deficit-reducing plans target Medicare and Medicaid and other government programs. Medicare and Medicaid rely on provider price competition to only a limited degree, for example through Medicare Advantage and Medicaid Managed Care plans. To a larger extent, the government programs essentially reflect a monopsony buyer with providers being price-takers. For this reason, historically there has been relatively little collaboration between CMS and the antitrust agencies. Medicare costs were not significantly impacted (at least directly) by health care consolidation or anticompetitive practices, and CMS staff could provide little information or market insight to the antitrust enforcers with respect to investigations the latter were undertaking.

50 See James Robinson, Hospitals Respond to Medicare Payment Shortfalls by Both Shifting Costs and Cutting Them, Based on Market Concentration, 30 HEALTH AFF., July 2011, at 1265, available at http://content.healthaffairs.org/content/30/7/1265.full.pdf+html. This is also reflected in the DOJ’s recent challenge to the contracting practices of United Regional Health System. The DOJ alleged that because hospitals in the relevant market received little or no profit margin from government payers, alleged foreclosure from commercial health plans that constituted only 8 percent of a rival hospital’s patients prevented it from competing effectively. Complaint ¶¶ 62, 67, United States v. United Regional Health System, No. 7:11-cv-00030 (N.D. Tex. Feb. 25, 2011), available at http://www.justice.gov/atr/cases/unitedregional.html.
In this respect, the ACO Antitrust Policy Statement represents an important development. CMS could have taken a narrow view and not considered what impact, if any, ACOs in the MSSP might have on private health plan markets. But it did not. Rather, from the outset CMS staff worked closely with the DOJ and the FTC staff, and included competition concerns in crafting the CMS regulations. Staff from the three agencies met routinely for months on the proposed and final regulations, and staff from both antitrust agencies have been detailed to the CMS. As the final CMS regulation and ACO Antitrust Policy Statement make clear, this coordination will continue, as the CMS will share with the antitrust agencies information about ACO applicants and relevant claims data. Such collaboration among those charged with ensuring that health care markets are competitive and those charged with setting payment policies for the dominant health care payer is essential, and this may be the most important legacy of the ACO Antitrust Policy Statement.●
The Final ACO Antitrust Policy Statement: Much Improvement

Jeff Miles

Hooray, hooray, hooray! The Federal Trade Commission and Department of Justice Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,1 issued on October 20, 2011, jettisons the requirement of the previously issued Proposed Statement2 that certain accountable care organizations obtain a favorable antitrust review letter from the FTC or DOJ as a condition to participating in the Medicare Shared Savings Program. Without question, this was the most criticized aspect of the Proposed ACO Antitrust Policy Statement that the federal antitrust agencies issued on March 31 of this year. Many of the 127 public comments filed in response to the proposed Statement3 argued that the requirement turned the agencies into regulators rather than law enforcers and was not needed to ensure detection of ACOs exercising market power.

In addition to this major and welcome change, the Final ACO Antitrust Statement includes subtle changes from the Proposed Statement, most of them for the better and many of which likely resulted from public comments invited by the antitrust agencies. All in all, the antitrust agencies did an excellent job fulfilling a difficult mandate—crafting a “one-size-fits-all” statement that nevertheless provides helpful guidance in varied factual situations.

What Is This All About?

In late March 2010, Congress enacted and the President signed the Affordable Care Act4 to aid in reforming the health-care system in the United States. Section 1899 of the Act establishes a new Medicare Shared Savings Program (SSP). The Act authorizes the establishment of provider-controlled contracting networks, called accountable care organizations (ACOs), to participate in the SSP by contracting with the Centers for Medicare & Medicaid Services (CMS) to care for Medicare fee-for-service beneficiaries in a coordinated manner. The dual intention of the program is to improve health-care quality by requiring ACOs to meet quality-of-care benchmarks and to incentivize participants to reduce health-care costs below those that would otherwise prevail by their sharing in savings they generate for Medicare.

An ACO may consist of a single entity that provides the requisite services or a “collaboration” of otherwise independent providers who join together to provide an array of services. Collaborative ACOs will likely include competing providers. Because collaborative ACOs are not single

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3 The comments are available at http://www.ftc.gov/os/comments/aco-comments.
entities for antitrust purposes and include otherwise competing providers that control the ACO's activities, the actions of those ACOs will result from agreements subject to Section 1 of the Sherman Act. 5

The ACOs will contract on behalf of their participants with CMS to participate in the SSP at the usual reimbursement rates established by the Medicare program. At the same time, most, if not all, ACOs will also contract with commercial health plans to care for their members at prices negotiated between the ACOs and the plans. Therein is the major potential antitrust rub: Joint negotiations of prices by an “agent” on behalf of competitors result in horizontal price-fixing agreements, and horizontal price-fixing agreements are typically per se violations of Section 1 of the Sherman Act. 6

Statements 8 and 9 of the antitrust agencies’ 1996 Statements of Antitrust Enforcement Policy in Health Care, 7 however, provide guidance on two forms of provider integration that can justify rule-of-reason analysis of the networks’ jointly negotiating contracts for their participants, turning naked price-fixing agreements into ancillary price-fixing agreements analyzed under the rule of reason: (1) the participants’ sharing substantial risk through the network, sometimes referred to as financial integration, and (2) clinical integration. As Statement 8 explains, participants in provider-controlled contracting networks can share financial risk through a number of different mechanisms, including the network’s accepting capitated rates 8 or the participants’ accepting “financial rewards or penalties based on group performance.” 9

Achieving sufficient clinical integration so a network’s joint negotiations are an ancillary restraint—and ACOs, in essence, are clinically integrated networks—is a more amorphous issue. Statement 8 defines the concept of clinical integration but provides no in-depth guidance. Four FTC Staff Advisory Opinions do provide substantially more analysis and detail. 10 But many providers contemplating the formation of ACOs wondered whether ACOs would exhibit sufficient clinical integration so that their negotiation of prices with commercial health plans would circumvent summary condemnation. The Final ACO Antitrust Policy Statement answers that question very clearly: Yes—if the network meets CMS’s ACO eligibility requirements and participates in the SSP.

But even if the per se rule is inapplicable, a second question is whether the network—whether an ACO or not—will have the power to raise prices to commercial health plans anticompetitively. If so, its joint negotiations may be unlawful under rule-of-reason analysis. The ACO Antitrust Policy

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5 15 U.S.C. § 1. See, e.g., N. Tex. Specialty Physicians v. FTC, 528 F.3d 346, 356 (5th Cir. 2008) (explaining that “[v]hen an organization is controlled by a group of competitors, it is considered to be a conspiracy of its members”).

6 15 U.S.C. § 1; see, e.g., United States v. Masonite Corp., 316 U.S. 265, 276 (1942) (explaining that “the fixing of prices by one member of a group pursuant to express delegation, acquiescence, or understanding is just as illegal as the fixing of prices by direct, joint action”).


8 “A ‘capitated’ rate is a fixed, predetermined payment per covered life (the ‘capitation’) from a health plan to the [network] in exchange for the [network’s] (not merely an individual physician’s) providing and guaranteeing the provision of a defined set of services to covered individuals for a specified period of time, regardless of the amount of services actually rendered.” Id. Statement 8.A.4 (1).


Statement provides less guidance here, likely because that analysis considers many variables and is quite fact-specific. The Statement however, does: provide a concrete rule-of-reason antitrust safety zone for ACOs meeting certain maximum market-share requirements; list particular types of conduct that may spell antitrust trouble for ACOs with apparent market power; and provide an expedited voluntary antitrust review letter process for ACOs “that desire further guidance.”

What Subjects Does the Final ACO Antitrust Policy Statement Address?
Broadly speaking, the Statement discusses six subjects: (1) which provider-controlled contracting networks are subject to the Statement; (2) the circumstances under which the rule of reason applies to ACO joint negotiation of prices with commercial health plans; (3) an antitrust safety zone for certain ACOs; (4) a discussion of rule-of-reason treatment of ACOs outside the safety zone; related to that, (5) the agencies’ expedited voluntary antitrust review letter process; and (6) in an appendix, how to calculate ACO market shares.

To What Networks Does the Final ACO Antitrust Policy Statement Apply?
Not surprisingly, the ACO Antitrust Policy Statement applies only to “ACOs,” which are limited to networks formed through “collaborations” that “are eligible and intend, or have been approved, to participate in the [Medicare] Shared Savings Program.” “Collaborations” are agreements among otherwise independent and often competing providers who join to form the network. The Statement does not apply to other networks that contract only with commercial health plans.

Unlike the Proposed ACO Statement, the Final Statement applies to ACOs regardless of when the network that becomes an ACO was created. The Proposed Statement applied only to those formed after March 23, 2010, the enactment date of the Patient Protection and Affordable Care Act. The antitrust agencies apparently thought that if a network were formed before that date, the agencies would have learned of any antitrust concerns it raised. Many of the public comments on the Proposed Statement criticized this “exemption” from the Statement, and the agencies reversed their position in the final Statement.

As in the Proposed Statement, however, the Final Statement does not apply to ACOs that constitute a single entity for antitrust purposes under the Copperweld doctrine. Thus, the Final Statement would not apply to a hospital and its employed physicians if they are the only participants in an ACO. Apparently, the agencies believe it sufficient that Section 7 of the Clayton Act is available to challenge any single-entity ACOs formed through mergers that may result in ACO market power.

Under the Final Statement, the “otherwise independent providers and provider groups that constitute the ACO” are “ACO participants.” There was some confusion in the Proposed Statement about the types of providers that would qualify as ACO participants. The definition of “participant” was important because “participant” market shares had to be calculated to determine whether the

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12 Id. at 67,027.
13 Id. at n.9.
14 Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752 (1984) (seminal decision for the principle that the constituent parts of a fully integrated entity are a single entity for purposes of Sherman Act § 1 and thus incapable of conspiring with one another).
15 15 U.S.C. § 18. Section 7 prohibits all forms of acquisitions that “may . . . substantially lessen competition.”
16 Final ACO Antitrust Policy Statement, supra note 1, at 67,027.
ACO fit within the antitrust safety zone (which is still true under the Final Statement) and whether
the ACO had to obtain a mandatory antitrust review letter from one of the agencies.

The Final Statement alleviates, but does not obviate, the confusion. It provides that ACO partic-
pants “can be” a physician or physician practice, an inpatient hospital, or an outpatient facili-
ty,17 but it does not indicate that “ACO participants” are limited to these types of providers. Later,
the Statement, while noting that it “focuses” on physician specialties, inpatient facilities, and out-
patient categories, states that it does “not apply” to other types of providers, such as clinical labs
or nursing homes.18 But it is not clear, for example, to what types of outpatient facilities the State-
dment does and does not apply: just ambulatory surgery centers, or, for example, imaging centers
as well? To confuse matters further, the Statement makes clear that its definition of “ACO partici-
pant” may differ from CMS's definition found in the final CMS ACO regulation.19

Under What Circumstances Does the Rule of Reason Apply to ACO Joint Negotiation of
Prices with Commercial Health Plans?

CMS, by regulation, has prescribed a large number of eligibility criteria that a collaborative net-
work must meet to become an ACO and participate in the SSP. Several of those appear to mirror
the requirements for a network clinical integration program justifying rule-of-reason analysis of joint
negotiations. For example, to participate in the SSP, the CMS ACO regulation mandates that ACO
applicants have a formal legal structure, an operation that includes clinical and administrative
processes, ways to promote evidence-based medicine, reporting by the ACO on quality and cost
measures, and provision of coordinated care for patients.20 Moreover, CMS intends to monitor
closely the actual cost and quality performance of ACOs participating in the SSP and can termi-
nate those that habitually fail to achieve quality improvement and cost savings established by
CMS benchmarks.

According to the Final Statement, CMS’s eligibility requirements are “broadly consistent” with
the antitrust agencies’ own indicia of sufficient clinical integration21 as discussed in FTC Staff
Advisory Opinions. As a result, as was true in the Proposed Statement, the Final Statement pro-
vides, in effect, a conclusive presumption that the agencies will apply the rule of reason in assess-
ing the effect on competition of ACO joint negotiations with commercial insurers if the ACO (which,
by definition, is participating in the SSP) “uses the same governance and leadership structures
and clinical and administrative processes it uses in the [SSP] to serve patients in commercial mar-
kets.”22 Presumably, when contracting with commercial health plans, someone—perhaps the
ACO itself—would need to monitor the ACO’s actual performance with respect to cost and qual-
ity benchmarks set by the ACO or the health plans with which it contracts and take corrective
action where warranted.

CMS will share the results of its monitoring of ACO cost, utilization, and quality
performance with the antitrust agencies. The Statement explains that this will aid the agencies in determining

17 Id. n.10.
18 Id. at 67,028 & n.25.
19 Id. at 67,027 n.10.
20 Dep’t of Health and Human Servs., Centers for Medicare & Medicaid Servs., Medicare Program; Medicare Shared Savings Program:
21 Final ACO Antitrust Policy Statement, supra note 1, at 67,027.
22 Id.
whether the degree of clinical integration required by the CMS eligibility requirements is sufficient to produce actual quality improvements and cost savings, thus justifying rule-of-reason analysis of the ACO’s joint negotiations. The Statement explains that this may “help inform the Agencies’ future analysis of ACOs and other provider organizations.”

23 Thus, if ACOs are unsuccessful in reducing cost and improving quality, this suggests that the antitrust agencies may revisit whether compliance with the CMS eligibility requirements should result in automatic rule-of-reason analysis. And it also may suggest that if ACOs actually do improve performance as intended, the agencies may opine that non-ACO networks contracting with commercial insurers are sufficiently integrated if their clinical integration programs include the same elements.

When Does the Rule-of-Reason Safety Zone Apply to ACOs?

Matters become more complicated when determining whether an ACO falls within the ACO rule-of-reason safety zone—i.e., no ACO market shares exceeding 30 percent—because this requires calculation of each ACO participant’s common-service market share in each primary service area (PSA) from which the participants providing common services draw patients. A “common service” is a service—cardiology, for example—provided by two or more providers (or provider practices) participating in the ACO. 24 A participant’s PSA consists of the smallest number of zip code zones from which the participant draws at least 75 percent of its patients. 25 Under the Final Statement, unlike the Proposed Statement, those zip codes need not be contiguous, which, as a practical matter, makes delineating the ACO participants’ PSAs somewhat simpler.

As surrogates for the relevant product market to use in calculating shares, the Final Statement, as did the Proposed Statement, uses Medical Specialty Codes (MSCs) for physician services, Major Diagnostic Categories (MDCs) for inpatient hospital services, and outpatient categories as defined by CMS. 26 Everyone, including the antitrust agencies, recognizes that these are likely not true antitrust relevant product markets. 27 There are some 55 MSCs for physicians (general practice, family practice, geriatric medicine, and internal medicine are grouped into a single primary-care “market”), but, in practice, there is substantial overlap between the services provided by physicians in different MSCs. As to inpatient hospital services, there are some 25 MDCs, some of which include numerous Diagnostic Related Groups for services that are not substitutable for one another. This means that a “product market” delineated by MDCs can, in actuality, be overinclusive or underinclusive, which can drastically affect the accuracy and value of the hospital’s “market share” in assessing its market power.

Similar problems of accuracy arise from using PSAs as surrogates for relevant geographic markets. 28 PSAs indicate from where the provider draws patients, but provide little indication of where patients or health plans would turn if the provider in question attempted to exercise market power

23 Id. at 67,028.
24 Id.
25 Id.
26 Id.; see also id. at 67,031.
27 Id. at 67,028 (explaining that “[a]lthough these services are useful in evaluating potential anticompetitive effects, they do not necessarily constitute relevant antitrust product markets”).
28 See id. (explaining that “[a]lthough a PSA does not necessarily constitute a relevant antitrust geographic market, it nonetheless serves as a useful screen for evaluating potential anticompetitive effects”).
by raising price. Typically, service areas are not relevant geographic markets; a true relevant geographic market may be larger or smaller than a PSA, or, only by coincidence, the size of the PSA.

In addition, delineation of a PSA based on the area from which a provider draws only 75 percent of its patients will tend to lead to narrower geographic markets than in other antitrust contexts. In hospital-merger decisions, where courts typically must define relevant geographic markets, a majority of courts, if relying on patient-flow information, have applied a 90 percent threshold. In providing a safety zone, however, and thus providing certainty of no challenge absent extraordinary circumstances, the antitrust agencies’ decision to use a more conservative figure is understandable, especially where the goal of the analysis is merely to provide some rough, quick indication whether the ACO is likely to have market power.

To calculate what might be called ACO market shares, first, the “common services” are identified—i.e., each service (MSC, MDC, and outpatient service) provided by two or more ACO participants. Second, the PSA for each ACO participant providing a common service is delineated. Third, with respect to each PSA in which two or more ACO participants provide a common service, the combined share of the ACO participants providing the common service to patients residing in that PSA is calculated. That constitutes the ACO’s “market share” of the common service. In the case of physician services, that share is calculated on the basis of Medicare fee-for-service allowed charges. For hospital services, the shares are calculated on the basis of inpatient hospital discharges. And for outpatient services, Medicare fee-for-services allowed charges is the measure.

The ACO falls within the rule-of-reason safety zone if none of its participants’ combined shares of common services exceeds 30 percent in any PSA in which they provide those services, and if all participating hospitals and ambulatory surgery centers participate in the ACO on a non-exclusive basis—i.e., they remain free to contract with payers directly or through other networks of providers. The Final ACO Statement, as did the Proposed Statement, emphasizes that non-exclusivity must be so “in fact and not just in name” and refers to the factors discussed in the Health Care Statements that the agencies examine to determine if, indeed, the relationship between a participant and its network is truly non-exclusive in fact. The ACO’s physicians, however, may be exclusive to the ACO without destroying the ACO’s safety-zone protection. Thus, the Final Statement’s safety zone varies from the Health Care Statement’s Statement 8 safety zones for physician network joint ventures, which provide different safety-zone requirements depending on whether a network’s providers are exclusive or non-exclusive to the network.

The Final Statement’s safety zone retains both the “rural exception” and “dominant provider limitation” from the Proposed Statement. The rural exception permits ACOs in rural areas to include one physician or physician group in each specialty from a “rural area,” regardless of the resulting common-service PSA share, as long as that physician or group practice participates in the ACO on a non-exclusive basis. “Rural Hospitals” may also participate, regardless of their common-service PSA share, as long as they also participate in the ACO on a non-exclusive basis.

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29 See Herbert Hovenkamp, Federal Antitrust Policy § 3.6d at 130 (4th ed. 2011) (explaining “a seller’s ‘trade area,’ or the area from which it currently draws its customers, is not the same thing as a relevant antitrust market”).


31 Final ACO Antitrust Policy Statement, supra note 1, at 67,028.

32 Health Care Statements, supra note 7, Statement 8.A.3.

33 Id. Statement 8.A.2.

34 For the definitions of “rural area” and Rural Hospitals, see Final ACO Antitrust Policy Statement, supra note 1, at 67,029 nn.32 & 34.
The dominant-provider limitation provides that even if an ACO otherwise meets the safety zone requirement, the safety zone does not apply if any ACO participant has a market share in its PSA above 50 percent and no other participant provides the same service in that PSA unless (1) the dominant provider participates in the ACO on a non-exclusive basis, and (2) the ACO does not “require” health plans to contract with it on an exclusive basis or otherwise restrict their ability to contract with other providers. Therefore, an ACO might include two cardiology groups, both with 90 percent shares in their PSAs, and enjoy safety-zone protection as long as their PSAs do not overlap and each is non-exclusive to the ACO.

The ACO’s safety-zone protection remains in place only for the duration of its SSP agreement with CMS. Thus, if the ACO terminates its SSP arrangement, or if CMS terminates the ACO, the ACO’s safety-zone protection ends as well. More important, an ACO’s safety-zone protection remains in place only so long as it meets the safety zone’s requirement that no common-service PSA share exceed 30 percent. Thus, ACOs desiring to remain in the safety zone when adding new providers of common services will need continually to monitor and recalculate their shares. But the ACO does not lose its safety-zone protection if a common-service PSA share exceeds 30 percent merely because the ACO attracts new patients.

Finally, even if an ACO meets the safety-zone requirements, its protection does not apply in “extraordinary circumstances.” What might constitute extraordinary circumstances is not clear, although the Final ACO Antitrust Policy Statement does explain that collusion among ACO participants regarding the prices they charge outside of the ACO—what Statement 9 of the Health Care Statements refers to as a “collateral agreement”—is a possible example.

If the ACO Is Outside the Safety Zone, Do Its Participants Go to Jail?
The answer is “No”: “The Agencies emphasize that ACOs outside the safety zone may be pro-competitive and legal.” There is no presumption that ACOs failing to meet the safety-zone requirements have market power or will unreasonably restrain competition.

As a practical matter, it seems unlikely that many ACOs will meet the safety-zone requirements; most are likely to have at least one common-service PSA market share above 30 percent. Thus, it would seem particularly important for the Final ACO Antitrust Policy Statement to provide as much guidance as possible about how the agencies will carry out their rule-of-reason analyses and the variables they will examine. Although the Statement discusses few specific relevant variables, the agencies will presumably apply the rule-of-reason principles of Statements 8 and 9 from the Health Care Statements and the agencies’ own general guidelines for collaborations among competitors. The Statement does point out several types of conduct that ACOs “with high PSA shares or other possible indicia of market power” might want to avoid (while recognizing that,

35 Id. at 67,029.
36 Id. (stating that “[a]n ACO will not lose its safety zone status solely because it attracts more patients”).
37 Id. at 67,028.
38 Health Care Statements, supra note 7, Statement B.B.1.
39 Id. n.24.
40 Final ACO Antitrust Policy Statement, supra note 1, at 67,028; see also id. at 67,029 (“ACOs that fall outside the safety zone may be pro-competitive and lawful. An ACO that does not impede the functioning of a competitive market will not raise competitive concerns.”).
depending on the circumstances, that conduct may be procompetitive), offers ACOs the opportunity to request expedited voluntary antitrust review letters.

The Statement warns all ACOs, even those within the safety zone, not to share competitively sensitive information, particularly the prices they charge for their services when contracting with health plans directly or through other networks in which they participate. It warns ACOs with possible market power to be wary of actions impeding the ability of health plans to steer their members to certain providers, including those that are not ACO participants, through using certain tactics such as anti-tiering and most-favored-nations provisions.

The ACO Statement also warns ACOs with possible market power against implementing tying arrangements requiring, as a condition of the ACO’s selling health plans its services, that health plans not purchase services from providers not participating in the ACO, or requiring health plans to purchase services not included in the ACO from ACO participants. An interesting example of the latter cited by the Statement is the ACO’s requiring health plans to purchase hospital services from a hospital not participating in the ACO where another hospital in the same hospital system is an ACO participant.

Provider exclusivity, the Statement notes, is another potential concern for ACOs with market power, particularly where it prevents health plans from obtaining the providers they need for viable provider panels if the health plans choose not to contract with the ACO. Finally, the Statement warns ACOs against tactics to prevent health plans from disseminating information to their members about the performance of different providers—information that helps health-plan members evaluate and select among different providers.

**What Is the Expedited Voluntary Antitrust Review Letter Process?**

The Statement offers “newly formed ACOs”—i.e., those that engaged in no joint negotiations or contracting with health plans before March 23, 2010—the opportunity to “obtain further antitrust guidance regarding [their] formation and planned operation” by requesting an expedited voluntary antitrust review letter. That the ability to obtain a review letter is limited to newly formed ACOs is consistent with the agencies’ rules in providing FTC Advisory Opinions and DOJ Business Review Letters for proposed, rather than implemented, conduct.

The Final Statement requires ACOs seeking a review letter to submit much of the same information that had to be submitted under the Proposed Statement to obtain a mandatory or voluntary review letter: (1) the SSP application to CMS and its supporting documents; (2) documents discussing the ACO’s business strategies and plans, the ACO’s likely impact on prices and quality, and the degree of competition among ACO participants; and (3) information sufficient to show the common services provided by ACO participants, the service areas of participants, any PSA market-share calculations the ACO has or other data relating to the competitive strength of the

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43 *Id.* at 67,029.
44 *Id.* at 67,030.
45 *Id.* (noting that “an ACO should not require a purchaser to contract with all of the hospitals under common ownership with a hospital that participates in the ACO”).
46 *Id.*
47 *Id.*
48 *Id.* at 67,030.
ACO and its participants, safeguards to protect the competitively sensitive information of participants, such as the prices they charge when contracting outside of the ACO, the identity of the five largest payers in the area, and the identity of other existing or proposed ACOs. The best news in all this is that ACOs are not required to calculate PSA market shares. Some, however, may want to, whether they request a review letter or not, to determine if they fit within the safety zone and, more generally, to obtain a general idea of whether they may be vulnerable to an antitrust challenge because of their market power.

In addition, the Statement invites ACOs to submit additional information that they believe will help the reviewing agency reach a decision about the ACO’s likely effect on competition, including any evidence of lack of market power, any substantial procompetitive justification for including a large number of providers, and any information justifying the ACO’s engaging in those practices (e.g., tying and provider exclusivity) that the Statement warns are problematic for ACOs with large common-service PSA market shares.

Again, the agencies provide little specific guidance about the rule-of-reason analysis they will apply but do state generally that they “will consider factors . . . as explained in [their] Antitrust Guidelines for Collaborations Among Competitors and the [Health Care Statements]." As noted before, the required analysis is sufficiently fact-specific that little more than generalizations are possible in a one-size-fits-all document like the Statement.

The antitrust agencies commit to issue their review letter within ninety days of the ACO’s submitting all the required information. The reviewing agency can request additional information, but its doing so does not extend the ninety-day period. The ACO itself can request that the period be extended to allow the agency additional time to respond. In responding, the agency will reach one of three conclusions: that the ACO “does not likely raise competitive concerns” (or will not raise competitive concerns if it remedies particular concerns raised by the agency); that the ACO “potentially raises competitive concerns”; or that the ACO “likely raises competitive concerns.” These responses are somewhat different from those provided in FTC Advisory Opinions and DOJ Business Review Letters, where the agency states whether it intends to challenge or not challenge the proposed conduct.

Under the Proposed Statement, the agency review letter would have stated that it “has no present intent to challenge or recommend challenging the ACO” or that it “is likely to challenge or recommend challenging the ACO if it proceeds.” Regardless of whether the review was mandatory or voluntary, if the agency reached the latter conclusion, CMS would bar the ACO from participating in the SSP. Under the Final Statement, there is no explicit bar from the SSP for ACOs that the agency finds “likely raise[ ] competitive concerns.” This change—that a negative agency review letter does not, itself, prevent a network from becoming an ACO and participating in the SSP—may reflect the concern raised by some that the antitrust agencies’ ability to bar participa-
tion in the SSP through a negative review letter constituted an unlawful subdelegation of power by CMS to the antitrust agencies to determine the eligibility of ACOs receiving negative letters to participate in CMS’s SSP.\footnote{56}

The Final Statement spells out, in much more detail than the Proposed Statement, the process for obtaining a voluntary antitrust review letter. The ACO completes a form cover sheet requesting general information, which can be obtained on line from either agency, and submits it to both the FTC and Antitrust Division. The agencies decide which of them will provide the review letter, and that agency notifies the ACO. At that point, the ACO submits the required information outlined above, and the ninety-day period begins to run.\footnote{57}

As a practical matter, it will be interesting to see how many ACOs request a voluntary review letter. The betting here is “not many,” but that decision depends on a number of legal and practical factors peculiar to the ACO’s particular situation.

\section*{Conclusion}

Almost all the commentators that filed comments about the Proposed Statement, although expressing criticisms and suggestions for improvement, congratulated the antitrust agencies for a job well done given the constraints under which they worked. The same can be said about the Final ACO Antitrust Policy Statement, which improves on the proposed version. The two major changes—deletion of any mandatory antitrust review letter requirement, and extension of the Statement’s coverage to networks formed before March 23, 2010—were badly needed for the reasons expressed in the many comments that suggested these changes. In addition, the Final Statement clarifies several ambiguities in the Proposed Statement.

To a large extent, ACOs are an experiment. No one at present can predict with any accuracy whether they are just another health care fad that will disappear with time like others, whether they indeed will beneficially affect costs and quality, or what their effects on competition will be. The Summary of the Final Statement explains that the agencies, through information and data supplied by CMS, will closely “monitor[] the competitive effects of ACOs” and that “the Agencies will vigilantly monitor complaints about an ACO’s formation and conduct and take whatever enforcement action may be appropriate.”\footnote{58} In five or so years, it will be interesting to begin to assess the effects of ACOs on health-care costs and quality and the extent, if any, to which ACOs are subjected to antitrust enforcement actions or private litigation.


\footnote{57}{Final ACO Antitrust Policy Statement, supra note 1, at 67,030.}

\footnote{58}{Id. at 67,026.}
Rule of Reason Analysis for Accountable Care Organizations

Gregory J. Pelnar and Gretchen M. Weiss

The Centers for Medicare & Medicaid Services (CMS) recently issued its Final Rule\(^1\) for implementing the Shared Savings Program, in which provider organizations will accept “accountability” for the care of their Medicare patients and, in return, may receive a share of any “savings” generated.\(^2\) The program’s three-part aim is to improve the care of individual patients through better coordination of care, improve the health of patient populations, and lower Medicare health care expenditures.

The “accountable care organizations” (ACOs) participating in the Shared Savings Program are also expected to contract with private payers, and this is where the potential for anticompetitive effects is of special concern. While CMS largely dictates to providers the prices that it will pay for each covered service provided to Medicare patients, thereby blunting any ACO market power, a major concern is that ACOs will be able to exercise their market power when contracting with private payers. In addition to market power concerns, there are two other competitive questions raised by ACOs composed of independent provider organizations. Will such “collaborative” ACOs be engaging in illegal price fixing if they jointly negotiate with private payers? And, will ACO participation facilitate collusion among the participants in their services provided outside the ACO context?

To provide guidance to provider organizations considering ACO participation, either on a collaborative or standalone basis, the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice jointly issued the Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Policy Statement).\(^3\) The Policy Statement clarifies that ACOs comprised of independent provider organizations will be considered to be clinically integrated and subject to rule of reason treatment.

The first step in a rule of reason analysis focuses on the anticompetitive risks raised by ACOs. The Policy Statement sets forth a framework for identifying ACOs that raise significant anticompe-
petitive concerns. The second step in a rule of reason analysis focuses on potential offsetting efficiencies. ACOs will provide a net benefit to consumers if their health care costs, on a quality-adjusted basis, do not rise. Since one hope for ACOs is that they will significantly improve quality of care, a simple examination of health care costs may give a false indication of an ACO’s competitive effect. Moreover, assessing an ACO’s effect on quality of care will be more challenging than may be supposed. Simple quality metrics, such as those incorporated in the Final Rule, are not necessarily reliable indicators of quality of care.

Nor would evidence of realized savings necessarily be a reliable indication of more efficient provision of provider services. “Savings” can be illusory. Savings that arise from curbing the incentive for overutilization or overprovision of services, as is widely recognized to occur under fee-for-service (FFS) payment systems, are real and could be evidence of an ACO’s procompetitive benefits. However, “savings” that arise from underprovision of services, as may arise under capitation, bundled payments, and shared savings programs, will not improve the quality of care and thus should not be counted by the antitrust authorities.

One mechanism to curb the incentive for the underprovision of services is to condition the sharing of savings on satisfactory performance on a number of quality metrics. But because such metrics have serious limitations as indicators of quality of care, the antitrust authorities should not accept realized savings as evidence of real savings without closer study.

**Screening ACOs for Significant Anticompetitive Risks**

Even before passage of the Affordable Care Act, there were many complaints by participants in the health care industry that the antitrust laws prevented the formation of physician networks that would benefit patients through improved “coordination of care.” After passage of the Act, some in the health care industry pointed to the potential for the antitrust laws to block health care

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5 When designing the Shared Savings Program, CMS was aware that ACOs could have an incentive to produce “savings” in a variety of ways counterproductive to CMS’s goals, such as avoidance of at-risk populations and restricting (or delaying) care. CMS incorporated several measures into its Final Rule in an attempt to align ACO interests with those of CMS. For example, CMS required ACOs to obtain satisfactory performance scores on a set of quality metrics before they would be eligible to share in the “savings” they produced. CMS also planned to detect and discipline ACOs avoiding at-risk populations. Therefore, the magnitude of the procompetitive benefits of ACOs will depend, at least in part, on how well the Final Rule successfully aligns ACO incentives with CMS’s three-part aim.


7 For example, the American Hospital Association argued in congressional testimony that the success of the Affordable Care Act in encouraging innovative delivery systems like ACOs “depends in no small measure on whether Congress and the Administration are willing to effectively tackle and bring down barriers to needed change, such as those presented by our nation’s antitrust laws and policies.” Antitrust Laws and Their Effects on Healthcare Providers, Insurers and Patients: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. 74 (Dec. 1, 2010) [hereinafter Hearing], available at http://judiciary.house.gov/hearings/printers/111th/111-157_62658.PDF. At the Hearing, Texas Representative Lamar Smith testified: “Several news organizations have reported that physician groups and hospitals are lobbying to obtain antitrust exemptions as part of the ACOs.” Id. at 5. There were also attempts in several states, including Connecticut and Texas, to pass state laws exempting “certified” health care cooperative arrangements from state and federal antitrust laws. See Letter from FTC Directors DeSanti, Farrell, and Feinstein to Representative Elliott Naishtat of the Texas House of Representatives (May 18, 2011), available at http://www.ftc.gov/os/2011/05/1105texashealthcare.pdf; Letter from FTC Directors DeSanti, Farrell, and Feinstein to Senators Eric D. Coleman and John A. Kissel and Representatives Gerald Fox and John W. Hetherington of the Connecticut General Assembly (June 8, 2011), available at http://www.ftc.gov/os/2011/06/110608chc.pdf.
reform, and there was even industry lobbying for an antitrust exemption. Ofﬁcials at the antitrust agencies countered that the antitrust laws do not prevent the formation of procompetitive provider organizations. Nevertheless, the antitrust agencies agreed to provide further “guidance.”

The Policy Statement explains how the agencies will screen for potentially anticompetitive ACOs. Two important features of the Policy Statement are that (1) the agencies recognize that the anticompetitive effects of an ACO may outweigh its procompetitive patient welfare benefits and (2) the agencies will enforce the antitrust laws even at the risk of being accused of thwarting the President’s and Congress’s wishes in passing the Affordable Care Act.

However, the Policy Statement is potentially flawed in several respects. For example, much of the Policy Statement depends on the success of primary service area (PSA) shares in detecting potential anticompetitive effects. The PSA of an ACO participant for a particular service is deﬁned as the fewest number of zip codes from which it draws at least 75 percent of its patients for that service. PSAs are used to deﬁne the safety zone, the “rural exception,” and the “dominant participant limitation,” as well as to determine which ACOs are subject to the “conduct to avoid” provisions.

It is not clear why the antitrust agencies chose to base the safety zone on PSAs rather than antitrust markets given the latter were used, apparently without signiﬁcant problems, in the safety zones set forth in the antitrust agencies’ Statements of Antitrust Enforcement Policy in Health Care and Antitrust Guidelines for Collaborations Among Competitors. If PSA shares turn out to be an unreliable screen for evaluating potential competitive effects, the Policy Statement could lead the antitrust agencies to focus on the wrong ACOs.

Another potential problem with the Policy Statement is that it does not apply to all ACOs. It applies only to ACOs formed by collaboration among otherwise independent provider groups and does not apply to ACOs formed by mergers, which will be evaluated under the Horizontal Merger Guidelines. Nor does the Policy Statement apply to a single integrated provider organization that chooses to operate as an ACO on a standalone basis. Thus, it is unclear to what extent the concerns expressed by the antitrust agencies extend to ACOs falling outside the Policy Statement’s scope. For example, a hospital or ambulatory surgery center exclusive with an ACO automatically falls outside the Policy Statement safety zone. Whether exclusivity issues would ﬁgure into antitrust analyses of merged or standalone ACOs that include a hospital or ambulatory surgery center is unclear. Would, say, a standalone ACO which includes a hospital have a “duty to deal” with other provider organizations?

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8 In his prepared statement before a congressional subcommittee, the FTC Director of the Bureau of Competition, Richard Feinstein, testiﬁed: “Some have suggested that the antitrust laws act as barriers to health care provider collaborations that could lower costs and improve quality. That is simply wrong.” Hearing, supra note 7, at 34. Later in his prepared statement, Feinstein testiﬁed: “We believe antitrust policy can support the improved health care services and lower health care costs that Congress sought through the Shared Savings Program; after all, the antitrust laws do not stand in the way of collaboration among providers that improve health care quality and lower costs.” Id. at 39.


Another example is the Policy Statement’s list of “actions to avoid” by ACOs to reduce the likelihood of raising the antitrust agencies’ concerns. The first—that ACOs should avoid the improper sharing of competitively sensitive information—applies to all ACOs regardless of the magnitude of their PSA shares or other indicia of market power. The other “conduct to avoid” concerns apply to ACOs with high PSA shares or other possible indicia of market power. Such ACOs should avoid anti-steering or similar provisions, tying sales of the ACO’s services to the private payer’s purchase of other services from providers outside the ACO (and vice versa), exclusive contracts with providers, and restrictions on a private payer’s ability to make available to its enrollees cost and quality information on providers.\(^\text{14}\)

The antitrust agencies apparently find the prospect of such conduct so troubling that the Policy Statement advises that “ACOs within the safety zone should also refrain from this conduct.”\(^\text{15}\) Left unsaid is the consequence for failing to heed the agencies’ advice. At a minimum, such conduct appears to raise the possibility of expulsion from the safety zone. Moreover, the antitrust agencies have not indicated whether the same actions undertaken by a standalone or merged, rather than collaborative, ACO would attract the same level of antitrust scrutiny.\(^\text{16}\)

A third problem with the Policy Statement is that it provides details only on how the antitrust agencies will screen those ACOs to which it applies, not how the antitrust agencies will conduct a “full analysis” of ACOs identified as meriting closer evaluation.\(^\text{17}\) Although the rule of reason framework suggests the relevant issues (e.g., anticompetitive effects, offsetting efficiencies), no guidance is offered on key questions. For example, what will the antitrust agencies find as credible evidence of efficiencies (e.g., magnitude of the shared savings generated, performance scores on selected quality metrics)? As discussed in more detail below, there are good reasons to be wary of such evidence and, at a minimum, the antitrust agencies should be skeptical of ACOs’ claimed efficiencies. The generation of shared savings and high quality scores can occur for reasons that do not reflect patient welfare benefits.

Even assuming there are quality of care improvements, the antitrust agencies leave unaddressed how they will be incorporated into the price effect of an ACO under the rule of reason analysis. Evidence of a jump in prices would not necessarily be evidence that the ACO has acquired market power because the quality of the ACO’s product may also have jumped. On a quality-adjusted basis, prices may actually have fallen. The Policy Statement says nothing about quality-adjusted prices.

A fourth concern is that the Policy Statement lacks a “market power presumption” provision. The earlier proposed version of the Policy Statement contained a provision mandating an antitrust review of ACOs with a PSA in excess of 50 percent.\(^\text{18}\) ACOs requiring mandatory review would have needed clearance from the antitrust agencies to participate in the Shared Savings Program. The antitrust agencies would have functioned as regulators, rather than enforcers. The mandatory review provision was dropped from the final version of the Policy Statement but was not

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\(^{14}\) \(\text{Id. at 67,029-30.}\)

\(^{15}\) \(\text{Id. at 67,029.}\)

\(^{16}\) One of the actions to avoid—the sharing of competitively sensitive information among participants in an ACO—would not apply to standalone or merged ACOs since such an ACO cannot “conspire” with itself. The sharing of competitively sensitive information with other ACOs or providers, on the other hand, could create antitrust problems for a standalone ACO.

\(^{17}\) Final ACO Antitrust Policy Statement, supra note 3, at 67,027.

replaced with a provision setting forth conditions under which an ACO would warrant a presumption of enhanced market power, as is provided in the Merger Guidelines.\(^{19}\)

There are a number of ways the Policy Statement might have been better: if it had applied to all ACOs; been based on shares in antitrust markets rather than PSAs; explained at least roughly how the antitrust agencies would conduct a “full analysis;” and identified explicit conditions that, if met by an ACO, would warrant the presumption of an enhancement of market power. Including these elements would have been challenging even without the time constraint imposed by the Affordable Care Act’s goal of launching the CMS Shared Savings Program by the start of 2012. After all, the Merger Guidelines have been evolving over more than two decades; the antitrust agencies had less than two years to produce the Policy Statement. Yet the agencies have succeeded in their most important task: Prior to the issuance of the Policy Statement, the antitrust laws, despite numerous claims to the contrary, did not ban the formation of procompetitive provider networks (but did ban those whose anticompetitive effects were not outweighed by their procompetitive benefits). This remains equally true today.

**Measuring ACOs’ Procompetitive Benefits**

A rule of reason analysis of an ACO will entail a weighing of its anticompetitive and procompetitive effects. If an ACO is challenged by the antitrust agencies after it has been in operation long enough to establish a track record, it may point to several pieces of evidence as support for its procompetitive effects. Two obvious candidates are the magnitude of realized shared savings and improvements on various quality metrics. While both measures may be attributable to better coordination of care, they also may be due to other less desirable factors, such as strategic changes in the ACO’s patient population. The challenge faced by the antitrust agencies is to isolate the portion of performance improvements due to better coordination of care. Otherwise, if the antitrust agencies accept the claimed improvements at face value, they will overweight ACOs’ procompetitive benefits in their rule of reason analyses.

The difficulty of a rule of reason analysis is compounded if an ACO is scrutinized at inception. Without a track record, the antitrust agencies are left with only the ACO’s potential incentives. In the case of ACOs participating in the Shared Savings Program, they may investigate whether the ACO’s incentives are aligned to improve care for individuals, improve health for populations, or lower growth in Medicare expenditures. In the case of ACOs contracting with third-party payers, the antitrust authorities need to examine the incentives created by the specific contract terms. As with the Shared Savings Program, the antitrust authorities need to understand ACOs’ incentives (and disincentives) under their contracts with private payers to provide better quality of care to patients more efficiently and the ways in which measures of quality of care and savings can be misleading or manipulated.

No mechanism is likely to completely align ACO incentives with those of their patients or to be free of the potential for ACOs to game or manipulate the system to their advantage. Requiring complete alignment of interests would be unrealistic and unnecessary. Nevertheless, the antitrust agencies may have a tough task in determining whether sufficient alignment exists to view an ACO’s claimed efficiencies as credible. After ACOs have developed a track record, retrospective studies would allow the agencies to better understand how to identify procompetitive and anticompetitive ACOs.

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\(^{19}\) The Merger Guidelines state that a merger warrants a presumption of enhancement of market power if the post-merger HHI exceeds 2500 and the increase in HHI exceeds 200 points. Horizontal Merger Guidelines, *supra* note 12, § 5.3.
**ACOs May Not Result in Better Care for Individuals.** One motivation for the ACO experiment is to provide better care for individuals through improved coordination of care. However, success in achieving this goal will require that ACOs, and the physicians they employ, have the proper incentives to achieve it. The problem (or challenge) is that, because the ACO model financially rewards provider organizations for achieving cost savings, it creates an inherent incentive to undertreat and underutilize (i.e., delay or withhold care as long as the health consequences for patients are not too severe or will not emerge until much later). Likewise, individual physicians will have an incentive to reduce or delay care so as to contribute to shared savings.

The CMS quality metrics were designed at least partly to prevent ACOs from undertreating patients. However, as discussed in more detail below, quality metric scores may not reflect the quality of health care delivered accurately enough to prevent this unintended consequence. Therefore, ACO incentives are not necessarily aligned with the aim of better care for individuals because restricting or delaying care may generate cost savings without triggering a decline on reported quality measures. The same would be true under a capitation, bundled payment, or shared savings contract between an ACO and a private payer.

One method of achieving high quality metric scores is for an ACO to serve healthy (or at least compliant) patients. Although CMS will assign beneficiaries to ACOs based on where patients receive the most Medicare services, the CMS acknowledges that ACOs may have an incentive to avoid patients from “at-risk” populations, who are less likely to be healthy and compliant. CMS will monitor ACOs for such avoidance behavior and those caught may be penalized. How successful CMS will be at detecting avoidance behavior remains to be seen because it may be quite subtle. Likewise, depending on the exact contract language, an ACO contracting with a private payer may also have an incentive to improve the health of its patient population by attracting healthier patients. Two examples of possible ACO avoidance behavior are the use of selective marketing targeted at desirable patients (such as at health clubs) and the closing of clinics with a disproportionate number of unhealthy or noncompliant patients. ACOs could also manipulate their quality scores by preventing providers who disproportionately serve undesirable patients from joining.

Not only may ACO incentives be misaligned to accomplish the aim of better care for individuals, the physicians employed by ACO participants also may have misaligned incentives. Health care providers may monitor the contributions of their physicians to achieving savings and high quality scores, and high performers may receive higher compensation and low performers may be threatened with termination unless their performance improves. As a result, the best performing physicians, from the perspective of the ACO participant, are more likely not to be those who care for the chronically ill or disadvantaged patient populations, but rather the physicians whose patients have few health problems to begin with (or at least the patients who follow the physician’s instructions).

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20 A Medicare beneficiary may not even know if he or she is assigned to a particular ACO and may not care because services can be obtained from any provider, not just from the assigned ACO. In the case of an ACO contracting with a private payer, it remains to be seen how the assignment of patients will occur.


22 In the case of a physician provider network, one factor in determining whether it is “clinically integrated” (and therefore the network participants are able to jointly negotiate with private payers) is whether the network has a mechanism in place to ensure adherence to protocols, which would entail monitoring physician performance and disciplining poor performers. *See Fed. Trade Comm’n & U.S. Dep’t of Justice, Improving Health Care: A Dose of Competition 37* (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.
Thus, ACOs will not necessarily improve the care of individual patients. ACOs may point to their improved quality scores, but such evidence is at best imperfect and can be subject to gaming. Therefore, improvements in quality scores should not be accepted at face value as evidence of the ACO’s procompetitive benefits. Rather, the antitrust agencies should investigate how the ACO achieved the quality score improvements.

**ACOs May Not Result in Better Health for Populations.** A second motivation for the ACO experiment is to achieve better health for populations. Some patient populations may achieve better health when care is provided through ACOs. For example, younger, employed patients who take an active role in maintaining their health may achieve better results, as may patients with chronic health problems but without risk factors for treatment noncompliance. These patients might benefit from enhanced communication among their various specialist providers. Both of these patient populations could generate shared savings and contribute to higher quality scores for ACOs, which in turn may compete vigorously for these patients.

On the other hand, subsets of the general population are likely to be less desirable to ACOs. Two examples are patients with health conditions whose incidence or severity would be largely unaffected by improvements in coordination of care and patients who ACOs perceive as having a higher risk of noncompliance with treatment plans.

Better coordination of care within an ACO’s physician practices could conceivably eliminate some of the language, cultural, and socioeconomic barriers that lead to noncompliance. However, real “coordination of care” for these at-risk patients may require a significant investment in practice resources, such as office staff responsible for calling patients to remind them of appointments or checking that they are taking their medications as prescribed. Whether the expected shared savings are sufficient to give ACOs the incentive to undertake such investments remains to be seen. As for patients who continue their noncompliance despite their ACO’s sincere attempts to improve their health, they may be made to feel unwelcome (e.g., have difficulty getting an appointment) and, in extreme cases, may be discharged by their providers.23

For the antitrust authorities, once again, the implication is that evidence of better performance scores for an ACO’s patient population is not conclusive that they now enjoy better health. This does not mean that such evidence is irrelevant but rather that the antitrust agencies should investigate whether the improvements in reported results could have occurred without a general improvement in the health of the ACO’s patient population.

**ACOs May Not Lower Health Care Costs.** The third aim of the ACO experiment—lower growth in health care expenditures—is unlikely to be realized solely through improved coordination of care. The Physician Group Practice (PGP) Demonstration Project, on which the CMS Shared Savings Program was modeled, did not produce particularly impressive results.24 At the conclusion of the five-year project, only seven of the ten PGP participants had received any shared savings. Moreover, there is some doubt as to how many, if any, of the PGP participants fully recovered their cost of participating. One study concludes that by the end of the third year, most PGP par-

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23 Even outside the ACO context, patients are sometimes discharged by their providers if, for example, they treat their physician abusively or repeatedly schedule appointments for which they fail to show up.

Participants had not broken even on their initial investment. At a minimum, the results of the PGP Demonstration Project do not provide much of a basis for believing that savings from the CMS Shared Savings Program will be significant.

Nor is the evidence from the private payer market particularly impressive. A “modest slowing of spending growth and improved quality of care” was reportedly obtained in the first year of the global payment system called the Alternative Quality Contract (AQC) implemented by Blue Cross Blue Shield of Massachusetts (BCBS). Under the AQC system, providers assumed accountability for spending and were eligible to receive bonuses for quality. All of the AQC groups earned quality bonuses, and total BCBS payments to the AQC groups are believed to have exceeded the estimated first year savings.

While the realization of substantial shared savings could be strong evidence of procompetitive benefits, the antitrust agencies will have to rule out other explanations. It is possible, even likely, that realized shared savings will reflect a combination of better coordination of care, restricting or delaying care, and strategic changes to an ACO’s patient population. It will be important for the antitrust agencies to isolate the percentage of realized shared savings attributable to better coordination of care. Failure to do so may lead the antitrust agencies’ efficiencies estimates to be biased upwards.

**Hazards of Relying on Quality Metrics to Ensure Care Quality**

Payment systems such as capitation, bundled payments, and shared savings create provider incentives for the underprovision of care. One mechanism to control these incentives is to monitor performance on certain quality metrics. For example, CMS’s Final Rule includes a requirement that an ACO perform satisfactorily on certain quality measures before it can receive any shared savings. The BCBS AQC awards bonuses based on provider performance on quality measures.

While well intentioned, quality metrics may not reliably measure the quality of care provided. Therefore, the antitrust agencies should be wary of concluding that quality of care has improved based on evidence of an improvement in scores on reported quality measures. Likewise, the antitrust agencies should be wary of concluding that evidence that an ACO has performed satisfactorily on the set of reported quality measures means that it has not engaged in such socially undesirable behavior as restricting or delaying care in ways not reflected in CMS’s metrics.

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25 See Trent T. Haywood & Keith C. Kosel, *The ACO Model—A Three-Year Financial Loss?*, 364 N. Eng. J. Med. e27 (2011). In the Final Rule, the CMS notes a commenter’s assertion that none of the PGP participants had received enough shared savings to fully recover their investment, but the CMS does not comment on the accuracy of this assertion. Medicare Shared Savings Program: Accountable Care Organizations, *supra* note 1, at 67,804.

26 Average spending increased for both the AQC enrollee sample and a control group, but the increase was 1.9 percent less per quarter for the former. Savings were “derived largely from shifts in outpatient care toward facilities with lower fees; from lower expenditures for procedures, imaging, and testing; and from a reduction in spending for enrollees with the highest expected spending.” Zirui Song et al., *Health Care Spending and Quality in Year 1 of the Alternative Quality Contract*, 365 N. Engs. J. Med. 909, 909 (2011).

27 The Final Rule employs thirty-three quality measures. Seven of those measures are based on patients’ responses to survey questions intended to assess their satisfaction with various issues, including access to timely care, access to specialists, and the patient’s rating of his or her physician. Another subset of these quality measures are “process measures,” which assess whether specific recommended health screenings or interventions were completed by the ACO providers and staff. A third subset of measures—“outcomes measures”—track the end result of care and include clinical data, such as blood pressure and laboratory test results for patients with certain clinical conditions. CMS Final Rule, *supra* note 1, at 67,889–90.

**Intrinsic Limitations of Quality Metrics.** Each type of proposed quality measure has some intrinsic limitations. For example, survey measures are subjective and potentially can be influenced by patient attitudes toward their provider. Process measures may underestimate the level of quality provided if the process being measured could be influenced by patient refusal or other patient-specific issues. Outcomes measures may not reflect actual quality of care delivered because they are influenced by many external variables, including patient socioeconomic background, individual patient compliance, and individual patient health factors.

In fact, many process and outcomes measures are largely outside the ACO's (or the individual physician's) control. An ACO's performance on these quality measures depends not only on whether its physicians took the steps within their control to improve their patients' health but also on whether the ACO's patients complied with the physicians' instructions. Another “lack of control” problem is that the outcomes measures reflect the care provided by both the ACO and non-ACO providers.

The use of outcomes measures assumes that actions taken by the ACO physicians will lead to better patient outcomes. When this is not the case, unintended consequences could result. For example, scores on some outcomes measures may be significantly lower within certain patient demographic groups, even with high quality provider care, and this in turn could potentially discourage ACOs from recruiting patients who are members of these groups or from providing accessible services in certain communities.

The reliability of metrics for measuring the quality of care is also limited by the available data, which are likely to come from medical documentation or claims data. The latter have well-known limitations, including that they only reflect services paid by the insurer and frequently are inaccurate. The data also reflect only the services the patient received, not the services the physician recommended.

**Problems with Clinical Practice Guidelines.** At first glance, it may appear that quality measures that implement clinical practice guidelines (CPGs) would be fairly noncontroversial and could only lead to better quality of care. After all, CPGs are evidence-based and established by various public and private industry groups with the goal of increasing overall quality of care by standardizing how physicians manage certain common medical problems. Nevertheless, there are potential problems with respect to CPGs because some “standard” guidelines may not be universally accepted within a specialty and in some cases may be controversial. Therefore, an ACO may receive a relatively low score on a quality metric simply because its physicians adhere to a different (but no less scientifically sound) CPG than the one on which the performance measure is based.

**Teaching to the Test.** Another problem with using quality metrics to counter ACOs’ adverse incentives is that, regardless of the measures selected, they may be subject to “teaching to the test.” ACOs may develop strategies aimed at improving quality metric scores without regard to the best interests of individual patients. Moreover, in an ideal practice environment, good performance on one required quality measure would be strongly positively correlated with good performance on other related but non-reported quality measures. But the existence of a positive spillover effect from required quality measures to non-reported quality measures should be empirically verified,

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29 For example, the physician may recommend that a patient receive an influenza or pneumococcal vaccination, or have a mammogram or colonoscopy, but the patient may refuse.

not assumed. ACOs (and individual physicians) have an incentive to make a special effort to score high on whatever quality measures are reported and pay less attention to those that are not reported.

The antitrust agencies should pay close attention to the limitations of quality metrics and the circumstances under which their scores can be misleading indicators of quality of care. The antitrust agencies should not take realized improvements on quality metrics as evidence of an ACO’s procompetitive benefits unless they determine that the improvements are due to better coordination of care and not to some socially undesirable reason.

Conclusion
The Policy Statement may achieve its purpose in screening for the ACOs posing the greatest anticompetitive risks and thereby requiring further analysis of their competitive effects. But the devil will be in the details. Higher prices may be due to an increase in market power or simply reflect a large improvement in the quality of care provided. Large shared savings may be due to improved patient health from better coordination of care or from restricting types of care not tracked by reported quality metrics. Improvements on quality metrics may reflect a general increase in the quality of care provided or simply reflect “teaching to the test.”

If ACOs are to fulfill CMS’s aims, as well as the hopes of health care reform advocates more generally, the antitrust agencies must not accept ACOs’ efficiency claims at face value, but instead must investigate the extent to which the claimed efficiencies are illusory. That does not mean that the agencies should pay no attention to the magnitude of realized shared savings or an ACO’s improved scores on quality metrics, but rather that the agencies must dig deeper and learn how the ACO obtained those results. ●