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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***Bob Leibenluft** is a partner in Hogan Lovells LLP. He headed the FTC's Health Care Division during the drafting of the DOJ/FTC 1996 Statements of Antitrust Policy in Health Care. The author wishes to thank Caitlin Russo, an associate at Hogan Lovells, for her assistance on this article.*

[1] Patient Protection and Affordable Care Act, Pub. L 111-48 124 Stat. 119 (2010) (Affordable Care Act).

[2] Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011) [hereinafter Final ACO Antitrust Policy Statement], *available at* http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf. The antitrust agencies initially issued a Proposed Statement, which is also discussed in this article. Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21,894 (Apr. 19, 2011) [hereinafter Proposed ACO Antitrust Statement], *available at* http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf.

[3] *See* Fed. Trade Comm'n, Competition in the Healthcare Marketplace (Nov. 7, 2011), *available at* http://www.ftc.gov/bc/healthcare/index.htm (compiling all FTC antitrust health care actions and industry guidance since 1982); *see also* Dep't of Justice, Antitrust Div., Antitrust Division: Summary of Health Care Cases (Nov. 7, 2011), *available at* http://www.justice.gov/atr/public/health_care/0000.htm (providing summaries of all DOJ health care cases since 1983).

antitrust laws apply in the health care setting, the antitrust enforcement agencies in 1993[4] 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 withholds 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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[4] U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Policy in Health Care (1993).

[5] U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Policy in Health Care (1996) [hereinafter Health Care Statements], *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/hlth3s.pdf.

[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 *1*996 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* 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).

[11] *See* Am. Hospital Ass'n, *Getting More Reform from Health Reform: Five Barriers to Clinical Integration in Hospitals (and What to Do About Them)*, *available at* http://www.mha.org/mha/public_site/advocacy/Federal/hcr/fivebarriers.PDF; *see also* Am. Med. Ass'n, *Statement of the A.M.A. to the FTC, CMS, and Officer of Inspector General of HHS Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws* 6–9 (Sept. 27, 2010), *available at* http://www.ama-assn.org/resources/doc/washington/aco-comments-27sept2010.pdf.

skepticism that clinical integration alone, without substantial financial risk, can bring about significant efficiencies, a view also articulated by FTC Commissioner J. Thomas Rosch.[12] 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.[13]

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.[14] This concept found its way into the Affordable Care Act[15] 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.[16]

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.[17] 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-

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[12] J. Thomas Rosch, Commissioner, Fed. Trade Comm'n, *Accountable Care Organizations: What Exactly Are We Getting?* 6–8 (Nov. 17, 2011), *available at* http://www.ftc.gov/speeches/rosch/111117fallforumspeech.pdf.

[13] *See, e.g.*, Re: Follow-Up to 2002 MedSouth Inc., FTC Staff Advisory Opinion 7 n.9 (June 18, 2007), *available at* http://www.ftc.gov/bc/adops/070618medsouth.pdf; *see also* Eric T. Nielsen, M.D., Chief Medical Officer, *Greater Rochester Independent Practice Association, Making Clinical Integration a Reality—the GRIPA Story* 18 (May 29, 2008), *available at* http://www.ftc.gov/bc/healthcare/checkup/pdf/Nielsen%20Presentation%20-%20Clinical%20Integration%20Workshop.pdf.

[14] *See* Elliott S. Fisher, Mark B. McClellan, John Bertko, Steven M. Lieberman, Julie J. Lee, Julie L. Lewis & Jonathan S. Skinner, *Fostering Accountable Health Care: Moving Forward In Medicare*, 28 HEALTH AFF., Jan. 27, 2009, at w219–31, *available at* http://content.healthaffairs.org/content/28/2/w219.full.pdf+html; *see also* David Newman, *Accountable Care Organizations and the Medicare Shared Savings Program* (May 4, 2011), *available at* http://healthlegislation.blogspot.com/2011/05/accountable-care-organizations-and.html.

[15] Affordable Care Act, *supra* note 1.

[16] *See* Donald M. Berwick, *Launching Accountable Care Organizations—The Proposed Rule for Medicare Shared Savings Programs*, NEW ENG. J. MED., Mar. 31, 2011, at 1, *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1103602; John K. Iglehart, *The ACO Regulations—Some Answers, More Questions*, 364 NEW ENG. J. MED., Apr. 28, 2011, at E35, *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1103603.

[17] John K. Iglehart, *Assessing an ACO Prototype-Medicare's Physician Group Practice Demonstration*, 364 NEW ENG. J. MED., Jan. 20, 2011, at 198–200, *available at* http://www.nejm.org/doi/full/10.1056/NEJMP1013896.

pitals 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 anti-competitive 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 gov-

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[18] *See, e.g.*, Paul B. Ginsburg, *Wide Variation in Hospital and Physician Payment Rates Evidence of Provider Market Power*, Center for Studying Health System Change, Research Brief no. 16 (Nov. 2010), *available at* http://hschange.org/CONTENT/1162/1162.pdf; Robert A. Berenson, Paul B. Ginsburg & Nicole Kemper, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*, 29 Health Aff., Feb. 25, 2010, at 699–700, *available at* http://content.healthaffairs.org/content/29/4/699.html.

[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.[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.[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.[22]

CMS estimates that the average ACO will spend $589,000 in start-up investment costs, and $1.27 million annually in operating costs.[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.[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."[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.[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.

The ACO Antitrust Policy Statement's position recognizing rule of reason treatment and ancillarity for ACOs that participate in the MSSP should not be a surprise to experienced antitrust counselors. Nevertheless, by explicitly confirming these positions, the Statement will give important assurances and encouragement not only to ACOs participating in the MSSP, but to other provider initiatives that can now look to the CMS MSSP requirements for insights into what the antitrust agencies view as having the potential to create significant efficiencies.

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

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[20] ACO Antitrust Policy Statement, *supra* note 2, at 67,027.

[21] *See* Dep't of Health and Human Servs., Centers for Medicare & Medicaid Servs., Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,976 (Nov. 2, 2011) [hereinafter CMS Final Rule].

[22] *Id.* at 67,910.

[23] *Id.* at 67,969.

[24] Final ACO Antitrust Policy Statement, *supra* note 2, at 67,028.

[25] *Id.*

[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.[27] To determine whether the safety zone is available, the ACO first must 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.[28]

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."[29] 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."[30] 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."[31] The approach to geographic market is even more prescriptive—based on PSAs that have their origin in the Stark II regulations[32]—and are built around patient flow

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[27] Final ACO Antitrust Policy Statement, *supra* note 2, at 67,028–29.

[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.[33] 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.

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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

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[33] *See* Fed. Trade Comm'n & Dep't of Justice, Improving Health Care: A Dose of Competition ch. 4: Competition Law: Hospitals (2004), *available at* http://www.justice.gov/atr/public/health_care/204694/chapter4.htm (stating that the Elzinga-Hogarty Test was not designed to analyze hospital mergers and should not be used as the sole basis for defining geographic market); *see also* Kenneth G. Elzinga & Anthony W. Swisher, *Limits of the Elzinga-Hogarty Test in Hospital Mergers: The* Evanston *Case*, 18 Int'l J. Econ. Bus. 133, 144 (2011).

[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.

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.

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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[39] Proposed ACO Antitrust Statement, *supra* note 2, at 21,897–98; Dep't of Health and Human Servs., Centers for Medicare & Medicaid Servs., Proposed Rule, 76 Fed. Reg. 19,528, 19,629–30 (Apr. 7, 2011) [hereinafter CMS Proposed Rule].

[40] *See Comments on the Proposed DOJ/FTC Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations in the Medicare Shared Savings Program/CMS Proposed Rule on Medicare Shared Savings Program: Accountable Care Organizations*, Am. Bar Ass'n Sections of Antitrust Law and Health Law 2–4 (May 31, 2011), *available at* http://www.ftc.gov/os/comments/aco-comments/00045-60109.pdf; *see also* Letter from Rick Pollock, Executive V.P., Am. Hospital Ass'n, to Christine Varney, Ass't Att'y Gen., Antitrust Div., Dep't of Justice, Jon Leibowitz, Chairman, Fed. Trade Comm'n, and Donald Berwick, Administrator, CMS 13–16 (May 31, 2011), *available at* http://www.aha.org/advocacy-issues/letter/2011/113105-let-pollack-doj-ftc-hhs.pdf; Letter from Dr. Michael Maves, Executive V.P., CEO, Am. Medical Ass'n, to Donald Clark, Secretary, FTC 7–8 (May 26, 2011), *available at* http://www.ama-assn.org/resources/doc/washington/aco-antitrust-reform-proposal-comment-letter.pdf.

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

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41 CMS Proposed Rule, *supra* note 39, at 19,630.

42 *See, e.g.*, Richard D. Raskin, Ben J. Keith & Brenda E. Jenny, *Delegation Dilemma: Can HHS Require Medicare ACOs to Undergo Pre-Clearance by the Antitrust Agencies?*, 20 Health L. Rep. (BNA) 961 (June 23, 2011).

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]

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.

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

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[45] *Id.* at 67,030.

[46] *Id.* at 67,030–31.

[47] *See* Paul B. Ginsburg, *Reforming Provider Payment—The Price Side of the Equation*, 365 New Eng. J. Med. 1268–70 (Oct. 6, 2011), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1107019.

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 to150 ACOs would participate in the MSSP.[48] 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.[49] 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

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[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.

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.

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[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. ●