

ACCOUNTABLE CARE ORGANIZATIONS: HOW ANTITRUST LAW IMPACTS THE EVOLVING LANDSCAPE OF HEALTH CARE

ELIZABETH L. ROWE*

Health-care costs are threatening to destroy the economy in the United States. More money is spent on health care in the United States than in any other country, yet several countries have a much higher quality of care. Accountable care organizations (ACOs), organizations that take responsibility for all health-care needs of patients and reap the benefits of keeping costs down if they provide a high enough standard of care at the same time, have been suggested as a way to both cut health-care spending and raise the quality of care. Because these organizations can have anticompetitive effects, however, they potentially run afoul of antitrust laws. To date, most doctors are afraid to join ACOs for fear of antitrust liability.

This Note argues that ACOs will indeed provide a higher quality of care at a lower cost. The efficiencies created by having several different physicians working together to care for a patient and sharing information in doing so cannot be matched by the system of fragmented care in place today. As a result of these positive benefits and the fact that health-care services markets do not operate in the same way as traditional markets, this Note asserts that room should be made in antitrust law for the establishment of ACOs. ACOs must be evaluated retrospectively to see if their anticompetitive effects outweigh the benefits they provide—and, accordingly, this Note argues ACOs should be presumptively legal at this point. Additionally, this Note argues a more general exception should be established in statute for ACOs because of the different ways in which health-care markets function. Finally, this Note asserts that ACOs that run afoul of antitrust laws should be fined rather than immediately dismantled to give doctors confidence that the organizations have staying power. These provisions are essential if ACOs are to form and achieve the considerable benefits they offer.

* J.D. 2012, University of Illinois College of Law; B.A. 2007, Political Science & Anthropology, Emory University. I would like to thank the *University of Illinois Law Review* members, editors, and staff for their hard work. I am particularly grateful to my husband and parents for their constant encouragement and confidence in me.

I. INTRODUCTION

Shortly after Wall Street collapsed in 2008, rapidly sending the United States into economic downturn, President Obama warned that “[b]y a wide margin, the biggest threat to our nation’s balance sheet is the skyrocketing cost of health care.”¹ The United States spends more on health care than any other country in the world, yet the higher spending is not associated with any increase in the quality of care.² Additionally, the regions within the United States with the highest health-care expenditures have, on average, lower quality of care and worse outcomes than regions with lower health-care costs.³ As a result of these and similar statistics, a number of health policy professionals suggest the idea of moving toward an accountable care organization (ACO) health-care model in which a group of health-care providers would assume responsibility for administering all of the necessary health care to a defined group of patients, as well as responsibility for keeping costs down and improving the quality of care in exchange for the providers splitting the shared savings with the third-party payer.⁴ Until either Congress or the Federal Trade Commission (FTC) and Department of Justice (DOJ) are clear on their antitrust policies regarding joint activities of health-care providers, however, hospitals and providers alike are unlikely to move into ACOs in adequate numbers out of fear of antitrust lawsuits.⁵ There should be greater exception for ACOs to set prices and clinically integrate than is currently allowed under federal regulations.

Part II of this Note discusses the concept of an alternative care organization, including the history and current state of antitrust law as it relates to health-care organizations. Part III analyzes the antitrust approach to ACOs that federal agencies are currently considering, as well as the opinions of health-care professionals and policy analysts as to how the government should approach antitrust protection and regulation of ACOs. Finally, Part IV proposes a solution to carve out enough antitrust protection for ACOs to encourage their development while still maintaining enough limits to continue protecting the market from traditional antitrust concerns. This Part further suggests ways in which antitrust law should adjust its approach to health-care professionals.

1. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER, June 1, 2009, at 36.

2. See Timothy Stoltzfus Jost et al., *The Role of Competition in Health Care: A Western European Perspective*, 31 J. HEALTH POL. POL’Y & L. 687, 689 (2006).

3. William B. Weeks et al., *Higher Health Care Quality and Bigger Savings Found at Large Multispecialty Medical Groups*, 29 HEALTH AFF. 991, 991 (2010).

4. Mark McClellan et al., *A National Strategy to Put Accountable Care into Practice*, 29 HEALTH AFF. 982–83 (2010).

5. See, e.g., Peyton M. Sturges, *Attorneys Say Clinical Integration Model Safest Way to Move Toward ACO Formation*, 19 HEALTH L. REP. (BNA) 825, at 2 (2010).

II. BACKGROUND

An ACO, at its most basic level, is a network or multiple networks of providers that work together to be held accountable for improving the quality of care for a defined group of individuals while controlling the rate of health-care spending at a sustainable level.⁶ ACOs are a proposed way to align the interests of third-party payers (usually insurance companies), providers, and patients to reduce inefficiencies present in current health-care systems that stem from “poor coordination and faulty transitions” between doctors in administering long-term care to patients.⁷ Currently, the majority of the health-care delivery system consists of physicians in small, single specialty practices that do not have the financial or organizational capacity to coordinate approaches for dealing with complex cases, share patient information through information technology systems, or generally provide care efficiently.⁸ As an administrator for the Center for Medicare and Medicaid Services noted, the current experience is one of “disorganized care. It is care in fragments. [Patients] have to tell [their] . . . story again over and over to everyone [they] meet. No one seems to talk to each other. Your record is forgotten or it’s unavailable.”⁹ A 2003 study found that the appropriate level of care was received by patients in the United States a mere fifty-five percent of the time.¹⁰ Most health policy experts attribute the poor quality of health care to the fragmentation resulting from the lack of coordination among providers.¹¹

6. McClellan et al., *supra* note 4, at 982–83; Robert Wood Johnson Foundation, *Health Policy Brief: Accountable Care Organizations*, HEALTH AFF., July 27, 2010, at 1 [hereinafter *Health Policy Brief*].

7. Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w45 (2007); see, e.g., AM. HOSP. ASS’N COMM. ON RESEARCH, ACCOUNTABLE CARE ORGANIZATIONS: AHA RESEARCH SYNTHESIS REPORT 5 (2010) [hereinafter AHA RESEARCH SYNTHESIS REPORT], <http://www.ftc.gov/os/comments/aco/100927aha.pdf> (discussing how payment approach “is closely related to the level of financial risk” assumed by providers, a key difference from the typical health maintenance organization (HMO) structure); AM. HOSP. ASS’N COMM., TRENDWATCH: CLINICAL INTEGRATION—THE KEY TO REAL REFORM 5 (Feb. 10, 2010), <http://www.aha.org/research/reports/tw/10feb-clinicinteg.pdf> (discussing how ACOs will align incentives).

8. Gail R. Wilensky et al., *Gain Sharing: A Good Concept Getting a Bad Name?*, 26 HEALTH AFF. w58, w59 (2007).

9. Workshop Regarding Accountable Care Organizations, and Implications Regarding Anti-trust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws, Morning Transcript 3 (Oct. 5, 2010) [hereinafter “Workshop Morning Transcript”], <http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopAMSessionTranscript.pdf>.

10. Lawrence P. Casalino, *The Federal Trade Commission, Clinical Integration, and the Organization of Physician Practice*, 31 J. HEALTH POL. POL’Y & L. 569, 580 (2006).

11. Taylor Burke & Sara Rosenbaum, *Accountable Care Organizations: Implications for Anti-trust Policy*, 19 HEALTH L. REP. (BNA) 358, at 1 (2010) (noting “that the fractured and fragmented state of American health care” stands in the way of improvement).

The concept of an ACO has been espoused by a number of health policy experts, but the name was coined by Dr. Elliott Fisher¹² and his colleagues in 2006 based on their research showing that “virtually all physicians are either directly or indirectly affiliated with a local acute care hospital, whether through their own inpatient work or through the care patterns of the patients they serve”—Fisher refers to these multi-specialty groups as “extended hospital medical staff.”¹³ Given the high degree of concentration of Medicare beneficiary care at certain hospitals and extended hospital medical staff that Fisher found throughout the country, Fisher proposed that those hospitals and medical staff be used as “loc[i] of accountability” for the Medicare population in particular regions.¹⁴ Hospitals are better suited than small, single-specialty groups to invest in the technology and health information systems necessary to coordinate the care of providers and measure the quality of care provided.¹⁵ ACOs would transform the health insurance landscape from that of simply paying health-care claims to that of providing integrated health care.¹⁶

For example, in a traditional fee-for-service model like the kind that dominated the market into the 1980s, health providers charged the patient or the insurance company for every itemized service that the patient received.¹⁷ The problem with traditional fee-for-service arrangements was that the incentive for the doctor was to provide as many procedures, tests, and other services as possible because the insurance company reimbursed the patient for every itemized transaction.¹⁸ The era of the managed care system was the proposed solution to cut the costs inherent in a traditional fee-for-service system.¹⁹ Under a managed care system, the health-care provider does not charge for every single service rendered to the patient, but instead a patient is entitled to receive certain services from the provider that are covered by a premium.²⁰ The problem with managed care is that the incentive is to provide as limited a number of services as possible to keep the costs under the capitated

12. Dr. Elliott Fisher is a Professor of Medicine and Community and Family Medicine at Dartmouth Medical School. See *Elliott S. Fisher, M.D., M.P.H.*, GEISEL SCH. OF MED. AT DARTMOUTH, <http://dms.dartmouth.edu/faculty/facultydb/view.php?uid=61> (last visited July 29, 2012). He also serves as co-chair of the National Quality Forum Committee which is developing national standards for measuring the efficiency of health care in the United States. *Elliott Fisher, MD, MPH*, DARTMOUTH COLL. INST. FOR SEC., TECH., & SOC’Y, <http://www.ists.dartmouth.edu/events/sith/bios/fisher.html> (last updated May 10, 2010).

13. Fisher et al., *supra* note 7, at w45; AHA RESEARCH SYNTHESIS REPORT, *supra* note 7, at 3.

14. Fisher et al., *supra* note 7, at w46.

15. *Id.* at w53.

16. See Burke & Rosenbaum, *supra* note 11, at 2.

17. See James E. Dalen, *Health Care in America: The Good, the Bad, and the Ugly*, 160 ARCHIVES INTERNAL MED. 2573, 2573 (2000).

18. See *id.*

19. See *id.*

20. See Jacob S. Hacker & Theodore R. Marmor, *How Not to Think About “Managed Care,”* 32 U. MICH. J.L. REFORM 661, 667–68 (1999).

amount paid to the provider.²¹ Furthermore, although managed care organizations were supposed to be the solution to control costs, and initially succeeded in doing so,²² the backlash over their methods for controlling costs led to a wave of state legislation that diminished their capacity to achieve such goals.²³ ACOs are similar to managed care organizations but place emphasis on the provider, rather than the insurer, as the locus of keeping costs down, emphasizing coordination of care between providers and holding the provider accountable for the quality of the care given.²⁴

The incentive to provide a high quality of care while controlling costs would be provided through some mechanism of financial rewards to providers (i.e., the locus of accountability).²⁵ There are three main projected advantages to using a hospital and its extended medical staff as a locus of accountability: (1) greater ability to measure provider performance; (2) greater ability to establish accountability for local decisions regarding capital investments, provider recruitment, and practice location; and (3) greater ability to improve the quality of care while simultaneously lowering the costs of administering health care.²⁶ ACOs would accomplish these goals partly through “legal agreements between hospitals, primary care providers, specialists, and other providers” to promote efficiency.²⁷ Hospitals and providers would need to facilitate coordination of care and share analysis of data on costs and outcomes and would be incentivized to do so.²⁸ The incentives would be through payment models that could take a variety of forms, all of which, in general, would link payments to quality improvements.²⁹ For example, “[s]pending for the population of patients in a particular ACO could be compared to targets based on past experience for the same patients, or to spending for similar patients in the community who were not assigned to the ACO,”

21. See Dalen, *supra* note 17, at 2573–74 (discussing the methods of keeping costs down by reducing services, reducing hospital stays, and reducing payments to physicians).

22. See *id.* at 2573 (“Managed care did, at least initially, dampen the escalating health care costs.”).

23. See BARRY R. FURROW ET AL., *HEALTH LAW: CASES MATERIALS AND PROBLEMS* 671–73 (6th ed. 2008); David A. Hyman, *Regulating Managed Care: What’s Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 222 (2000) (describing the patient’s bill of rights backlash to managed care organizations).

24. See Kelly Devers & Robert Berenson, Robert Wood Johnson Foundation, *Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality of Care?: Timely Analysis of Immediate Health Policy Issues*, Oct. 2009, at 3; McClellan et al., *supra* note 4, at 989–90 (discussing how ACOs are a critical step in the right direction).

25. Burke & Rosenbaum, *supra* note 11, at 4–5.

26. Fisher et al., *supra* note 7, at w52–53; see also Denis Cortese & Robert Smoldt, *Taking Steps Toward Integration*, 26 HEALTH AFF. w68, w69 (2007) (noting that multiphysician practice groups are more likely to adopt “evidence-based care processes” and to use “information technology (IT) to coordinate care effectively”).

27. AHA RESEARCH SYNTHESIS REPORT, *supra* note 7, at 3.

28. *Id.*

29. McClellan et al., *supra* note 4, at 983.

and if the ACO saved money, it would receive part of the savings.³⁰ Furthermore, providers within the ACO could be held to a minimum quality standard that they must meet to continue participating in the ACO.³¹

Another proposed incentivized approach is three-tiered; the ACO would achieve a higher level of risk and reward with each tier for which it becomes qualified.³² In the first tier, providers assume no financial risk and receive shared savings for managing costs and hitting quality benchmarks, while keeping costs under control.³³ In the second tier, providers receive shared savings for managing costs and achieving quality benchmarks but are liable for costs that exceed the target.³⁴ Finally, in the third tier, providers assume the greatest risk and are paid in full or partial capitation.³⁵ While there are a variety of methods health-care experts propose by which ACOs would achieve these goals, the focus of this Note is on antitrust challenges that ACOs may face rather than an analysis of the actual implementation or organization of ACOs. Thus, this Note will only discuss those aspects as they relate to antitrust law.³⁶

As health-care spending in the United States continues to increase, and the lack of improvement in the quality of health care to show for it remains,³⁷ the concept of ACOs, as an alternative to the managed care organizations and small physician practices that now dominate the health-care market, has increasingly caught the attention of health policy analysts.³⁸ In fact, as part of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act),³⁹ the Secretary of Health and Human Services has been granted authority to implement pilot ACO projects for

30. *Health Policy Brief*, *supra* note 6, at 3.

31. *Id.*

32. STEPHEN M. SHORTELL ET AL., BERKELEY CTR. ON HEALTH, ECON. & FAMILY SEC., IMPLEMENTING ACCOUNTABLE CARE ORGANIZATIONS 3 (2010), http://www.law.berkeley.edu/files/chefs/Implementing_ACOs_May_2010.pdf.

33. *Id.*

34. *Id.*

35. *Id.* at 3–4; *AHA Research Synthesis Report*, *supra* note 7, at 11. Capitation is a system of payment whereby the provider is paid a fixed fee to provide services to the health-care beneficiary for a fixed period of time. FURROW ET AL., *supra* note 23, at 676. “Capitation contracts reverse the typical incentive arrangements in provider arrangements. Rather than being paid for the number and type of services provided, the providers are paid based upon the number of members enrolled in their practice regardless of the nature or intensity of service utilization.” SHORTELL ET AL., *supra* note 32, at 15. Under a partial capitation system, “some services are prepaid through capitation but some remain fee-for-service,” which “can be a way of controlling risk while allowing for flexibility.” *Id.*

36. For a more in depth analysis of how ACOs plan to achieve the goals of improving quality of health care and reducing costs, see McClellan, *supra* note 4, at 987–90 (discussing barriers to the implementation of ACOs); *Health Policy Brief*, *supra* note 6, at 3 (discussing various payment models for ACOs); see generally Stephen M. Shortell et al., *How the Center for Medicare and Medicaid Innovation Should Test Accountable Care Organizations*, 29 HEALTH AFF. 1293 (2010); Devers & Berenson, *supra* note 24, at 1.

37. See Jost et al., *supra* note 2, at 689.

38. See Burke & Rosenbaum, *supra* note 11, at 2.

39. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119, 395 (2010) (to be codified as amended in scattered sections of 42 U.S.C.).

Medicare beneficiaries.⁴⁰ In the final reform bill of the Affordable Care Act, the Congressional Budget Office projected a \$5-billion savings in Medicare expenditures in the ten years after enactment of the bill.⁴¹ Another study indicates that ACOs could account for as much as \$15 billion a year in Medicare savings, bringing that ten-year estimate to \$150 billion.⁴² Even if these pilot programs prove to be successful, however, there is much speculation about the viability of ACOs outside of the Medicare market as a way to curb rising health-care costs in the private sector.⁴³

One of the main challenges to implementing ACOs is the barrier of antitrust law, as ACOs require a great deal of coordination between networks of providers and, often, between competitors, which can raise antitrust red flags.⁴⁴ ACOs could be particularly susceptible to allegations of horizontal price fixing (the setting of prices among competitors of the same level, “contrary to the workings of the free market” and “among competitors on the same level”),⁴⁵ improper exclusive dealing (“[a]n agreement requiring a buyer to purchase all needed goods or services from one seller”),⁴⁶ and improper collusive activity.⁴⁷ ACOs will likely have to exclude certain providers in the area from participation in the ACO, and the excluded providers could potentially bring antitrust challenges.⁴⁸ Additionally, ACOs will have to share its pricing information with competitors, which raises concerns about price fixing.⁴⁹ Finally, the probability of ACOs setting off antitrust red flags will likely increase as the market power of the particular ACO increases.⁵⁰ For this last reason, health policy analysts are generally more optimistic about the viability of ACOs in large cities where there is a bigger health-care market than the viability of ACOs in rural areas where successful ACOs are more likely to dominate the market.⁵¹ As antitrust law presently stands, there is some guidance from the DOJ and the FTC about how ACOs should be

40. *Id.*; McClellan et al., *supra* note 4, at 982.

41. CONGRESSIONAL BUDGET OFFICE, BUDGET OPINIONS: VOL. 1, HEALTH CARE 75 (2008), available at <http://www.cbo.gov/doc.cfm?index=9925>; McClellan et al., *supra* note 4, at 984–85.

42. Weeks et al., *supra* note 3, at 995.

43. See Sturges, *supra* note 5, at 1–2; Workshop Morning Transcript, *supra* note 9, at 56 (discussing how it is important to speak of antitrust regulation of ACOs in terms of Medicare and the private market, as most plan to operate in both markets).

44. See Sturges, *supra* note 5, at 1–2; C. Frederick Geilfuss & Renate M. Gray, *Accountable Care Organizations: Promise of Better Outcomes at Restrained Costs; Can They Meet Their Challenges*, 16 HEALTH INS. REP. (BNA) 23, at 23 (2010).

45. BLACK’S LAW DICTIONARY 1309 (9th ed. 2009).

46. *Id.* at 647.

47. Geilfuss & Gray, *supra* note 44.

48. *Id.*

49. *Id.*

50. *Id.* (“[Antitrust] issues are more acute to the extent that the ACO holds market power, as in smaller markets, or where the ACO ties up most of the providers of a particular type in a given market.”).

51. See *id.*

structured to avoid liability. This guidance largely comes from FTC decisions creating antitrust exceptions for “clinically integrated” multi-provider networks meeting certain criteria.⁵²

This Part of this Note provides an overview of antitrust law’s approach to health-care organizations and then goes on to discuss how the antitrust laws affect the organizational structure of provider practices and efforts to enter joint ventures.

A. *The Current Status of Antitrust Law As It Relates to Health Care*

When it comes to antitrust law, health-care providers are mostly concerned about running afoul of Section 1 of the Sherman Act, which states that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”⁵³ A few prohibited market transactions are considered to interfere with free competition to the extent that the actions are per se illegal.⁵⁴ Prohibited actions that are not deemed per se unlawful are analyzed instead under a rule of reason analysis, under which the conduct must have some broader good that outweighs the anticompetitive effect.⁵⁵ The Supreme Court has come down hard on efforts by physicians to integrate their services in ways similar to those in which ACOs would have to integrate, and while the agencies have tried to give back some of what the Court took away, their guidance has left much to be desired for providers wishing to integrate.⁵⁶

1. *Arizona v. Maricopa County Medical Society*

In 1982, the Supreme Court broadly held in *Arizona v. Maricopa County Medical Society* that efforts by nonintegrated medical care associations to set insurance fees were per se illegal as a violation of Section 1 of the Sherman Act.⁵⁷ The case involved an antitrust challenge by the State of Arizona to the Maricopa Foundation for Medical Care, of which about seventy percent of the doctors in Maricopa County were members. The foundation established a schedule of maximum fees that the participating doctors agreed to accept as payment in full for the services performed for patients in the plan.⁵⁸ The Court noted that the situation of

52. Robert Belfort, *Provider Participation in ACOs May Hinge on HHS Regulations*, 18 HEALTH CARE POL’Y REP. (BNA) 790, at 3 (2010).

53. 15 U.S.C. § 1 (2006).

54. Taylor Burke & Sara Rosenbaum, *Aligning Health Care Market Incentives in an Information Age: The Role of Antitrust Law*, 5 J. HEALTH & BIOMEDICAL L. 151, 165 (2009).

55. *Id.*

56. *See id.* at 161 (“[A] tremendous amount of uncertainty still exists regarding the antitrust assessment of clinically integrated physician joint ventures.”).

57. 457 U.S. 332, 335–36 (1982).

58. *Id.* at 339.

the medical associations was “not analogous to partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunities for profit.”⁵⁹ Rather, the fee arrangements between the associations were “among independent competing entrepreneurs” and, thus, “fit squarely into the horizontal price-fixing mold.”⁶⁰ The Court took a rather hard-line approach to the per se rule and left providers uneasy about entering joint ventures for fear that they would lack an acceptable amount of integration.⁶¹

2. Federal Agency Response to Maricopa

The *Maricopa* decision prompted the DOJ, together with the FTC (jointly, “the agencies”), to issue *Statements of Antitrust Enforcement Policy in Health Care* (“Agency Statements”)⁶² to expound upon what are permissible structures of health-care organizations in light of the Supreme Court’s ruling.⁶³ The Agency Statements carved out a “safety zone” for “joint activities by clinical provider entities that had achieved financial integration and that were *unlikely to have market power*,”⁶⁴ indicating that arrangements falling within a safety zone will not be challenged by the agencies absent “extraordinary circumstances.”⁶⁵ Furthermore, the agencies emphasized that falling outside of a safety zone would not automatically render the arrangement unlawful.⁶⁶

The Agency Statements distinguished between exclusive and non-exclusive joint ventures in terms of whether they fall into safety zones.⁶⁷ A joint venture in this context is a “physician-controlled venture in which the network’s physician participants collectively agree on prices or price-related terms and jointly market their services.”⁶⁸ An exclusive venture is one in which “the network’s physician participants are restricted in their ability to, or do not in practice, individually contract or affiliate with other network joint ventures or health plans.”⁶⁹ A nonexclusive venture is one in which “the physician participants in fact do, or are available to, affiliate with other networks or contract individually with health plans.”⁷⁰

59. *Id.* at 356.

60. *Id.* at 358.

61. FURROW ET AL., *supra* note 23, at 1133–34.

62. FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996) [hereinafter AGENCY STATEMENTS], <http://www.ftc.gov/bc/healthcare/industryguide/policy/hlth3s.pdf>.

63. Burke & Rosenbaum, *supra* note 11, at 5.

64. *Id.* (emphasis added).

65. AGENCY STATEMENTS, *supra* note 62, at 62–63.

66. *Id.* at 63.

67. *Id.* at 64.

68. *Id.* at 62.

69. *Id.* at 64.

70. *Id.*

The agencies will not defer to the terms of the contract or to the name of the joint venture to determine whether the joint venture is in fact nonexclusive but will instead look for “indicia of non-exclusivity,” such as (1) evidence that there are actually competing networks or managed care plans in the market; (2) evidence that participating physicians actually do or are willing to participate in or contract with other plans or networks; (3) evidence that participating physicians receive “substantial revenue” from other plans or networks; (4) the absence of evidence that participants are de-participating from other networks or plans; and (5) the absence of indication that physicians are coordinating on price or other competitive terms between networks.⁷¹

a. Agency Treatment for Joint Ventures, Exclusive or Nonexclusive

For exclusive joint ventures, the agencies will not bring an antitrust challenge (“absent extraordinary circumstances”) if the “participants share substantial financial risk” *and* if the participants “constitute 20 percent or less of the physicians” in the same specialty with hospital staff privileges in the relevant geographic market.⁷² Substantial financial risk is another criterion with no specific definition but examples include (1) agreement to provide services at a capitated rate;⁷³ (2) agreement to provide certain services to a health plan for a predetermined percentage of the plan premium; (3) use of “significant financial incentives” to get physician participants to achieve goals; and (4) agreement “to provide a complex or extended course of treatment that requires the substantial coordination of care among physicians in different specialties for a fixed, predetermined payment”⁷⁴ If the geographic market contains less than five physicians of a certain specialty, then the exclusive physician network may employ one physician of that specialty on a *nonexclusive* basis—meaning that the physician may affiliate with other networks or contract with other health plans—without causing the network to fall outside of the safety zone.⁷⁵

Similarly, for nonexclusive ventures the agencies will not challenge ventures (“absent extraordinary circumstances”) if the “physician participants share substantial financial risk and constitute 30 percent or less of the physicians” in the same specialty with hospital staff privileges in the relevant geographic market.⁷⁶ If the geographic market contains less

71. *Id.* at 66–67.

72. *Id.* at 64–65.

73. *See supra* note 35 (defining “capitation”).

74. AGENCY STATEMENTS, *supra* note 62, at 68–69.

75. *Id.* at 65.

76. *Id.*

than four physicians of a certain specialty, then the venture may include one physician of the specialty while still falling within the safety zone.⁷⁷

If a joint physician venture fails to meet either of the above exceptions, there are other criteria it can meet to prevent the agencies from filing an antitrust challenge. The agencies have focused on financial risk sharing “because it normally is a clear and reliable indicator that a physician network involves sufficient integration.”⁷⁸ If the joint network has the potential to create significant efficiencies and is not, on balance, anti-competitive, it will not necessarily raise substantial antitrust concerns.⁷⁹ Generally, in antitrust law price fixing and allocation of markets among competitors is per se illegal, which goes for agreements between health-care providers as well.⁸⁰ Agreements between physician network joint ventures can overcome the per se rule, however, and be analyzed under the rule of reason if the agreement “is likely to produce significant efficiencies that benefit consumers, and any price agreements (or other agreements that would otherwise be per se illegal) by the network physicians” will be legal if “reasonably necessary to realize those efficiencies.”⁸¹

b. Safety Zone for “Clinically Integrated” Joint Ventures

The agencies released revised Agency Statements in 1996 that provided further examples of financial integration and created a new safety zone for joint ventures that are sufficiently “clinically integrated.”⁸² The revised Agency Statements suggested that “[c]linical integration could be evidenced by the presence of organized processes to control costs and improve quality and by the significant investment of monetary and human capital in these processes.”⁸³ The FTC accepts requests for advisory opinions from physician groups seeking to establish joint ventures, and those that the FTC has issued up to this point have been a source of guidance for what criteria the FTC is focusing on when it looks for financial integration.⁸⁴ For example, the arrangements that have received approval from the FTC normally include indicia of clinical integration that justifies joint contracting in the absence of financial integration, which include an adequate number of diagnoses and diseases covered, agreement by physicians to refer within the network, both specialists and primary care physicians in the network, financial investment by the participating physicians, electronic technology to share patient information

77. *Id.* at 65–66.

78. *Id.* at 67–68.

79. *Id.* at 70.

80. *Id.* at 71.

81. *Id.* at 71–72.

82. Casalino, *supra* note 10, at 571–72.

83. *Id.* at 572.

84. Burke & Rosenbaum, *supra* note 11, at 10.

among multiple physicians, and a nonexclusive arrangement, to name a few.⁸⁵

Dr. Larry Casalino, an associate professor of public health and chief of the Division of Outcomes and Effectiveness Research in the Department of Public Health at Weill Cornell Medical College, has written extensively on the issue of physician integration and physician hospital relations.⁸⁶ He has concisely summarized the task of the FTC, DOJ, and the courts in analyzing whether the safety zone applies to physician joint ventures. For instance, Casalino claims the agencies and courts determine “whether the joint venture is really an attempt to create a better product or is simply a sham—a cover for price fixing.”⁸⁷ The more resources invested and financial risk shared by the participants, the greater the likelihood that the agencies or courts will not conclude that it is a sham cover for price fixing and they can move on to part two of the analysis.⁸⁸ If a requisite level of risk sharing is absent, the venture will be per se illegal (unless they demonstrate a degree of clinical integration).⁸⁹ If the joint venture is not per se illegal, the rule of reason is applied “to determine whether the benefits to consumers from the joint venture outweigh the costs due to the decrease in competition.”⁹⁰ If the benefits outweigh the costs, then the agencies or courts will determine if there are any restraints on competition.⁹¹ If there are restraints on competition, those restraints must be reasonably necessary to create the benefits.⁹²

If a joint venture does not meet the necessary degree of financial integration but demonstrates some degree of clinical integration, it will be subject to the rule of reason analysis instead of being deemed per se illegal.⁹³ What exactly constitutes clinical integration is, up to this point, unclear.⁹⁴ The FTC provides examples of joint ventures that would pass the threshold level of clinical integration but has not established any particular criteria that the joint venture must have, in part because it does not want to “channel market behavior, instead of encouraging market participants to develop structures responsive to their particular goals and the market conditions they face.”⁹⁵

85. *Id.* at 11–12 tbl.2.

86. *See, e.g.*, Casalino, *supra* note 10, at 582–83; Lawrence P. Casalino et al., *Benefits of and Barriers to Large Medical Group Practice in the United States*, 163 ARCHIVES INTERNAL MED. 1958 (2003); Stephen M. Shortell & Lawrence P. Casalino, *Health Care Reform Requires Accountable Care Systems*, 300 J. AM. MED. ASS'N 95, 95–96 (2008).

87. Casalino, *supra* note 10, at 582–83.

88. *Id.*

89. *Id.*

90. *Id.* at 576.

91. *Id.*

92. *Id.*

93. *Id.* at 577.

94. *See id.* at 578–79.

95. *Id.* at 579.

The example provided by the FTC was that of a hypothetical Independent Physician Association (IPA)⁹⁶ by the name of “Charlestown” that was established to “assume greater responsibility for managing the cost and quality of care rendered to Charlestown residents who are members of health plans.”⁹⁷ The IPA would, “prior to contracting [on a nonfinancial-risk basis] on behalf of competing doctors,” (1) “implement systems to establish goals relating to quality and appropriate utilization of services;” (2) “develop practice standards and protocols to govern treatment and utilization;” (3) “regularly evaluate both individual participants’ and the network’s aggregate performance;” (4) “modify individual participants’ actual practices, where necessary;” (5) “[subject participants who] fail to adhere to the network’s standards and protocols . . . to remedial action, including the possibility of expulsion;” (6) “engage in case management, pre-authorization . . . and concurrent and retrospective review of inpatient stays;” (7) “[invest] significant . . . capital to purchase the information systems necessary to gather aggregate and individual data . . . to measure performance . . . and to monitor patient satisfaction;” (8) “provide payers with detailed reports on the cost and quantity of services provided;” (9) “hire a medical director and support staff to perform the above functions and to coordinate patient care;” and (10) “involve network physicians in investing appreciable time in developing the practice standards and protocols.”⁹⁸

The Agency Statements provide some guidance for physician groups contemplating ACO participation but still leave a number of questions unanswered, such as what specifically constitutes clinical integration, what level of risk sharing creates sufficient financial integration to bring a joint venture into a financial integration safety zone, and what types of restraint on competition will pass the test of “reasonably necessary” to justify the increased quality and reduced costs that the ACO would produce.⁹⁹ Although the Agency Statements are not the law, courts afford them great deference when analyzing horizontal merger cases.¹⁰⁰

96. An IPA is “typically a physician-organized entity that contracts with payers on behalf of its member physicians” and typically “negotiates contracts with insurers and pays physicians on a fee-for-service basis with a withhold.” FURROW ET AL., *supra* note 23, at 955. “Physicians may maintain significant business outside the IPA, joint multiple IPAs, retain ownership of their own practices, and typically continue in their traditional style of practice.” *Id.*

97. AGENCY STATEMENTS, *supra* note 62, at 83.

98. *Id.* at 83–84.

99. See Casalino, *supra* note 10, at 577–78.

100. Jeff Miles, *Healthcare Antitrust Mergers and Merger Guidelines Revision: What Might It Mean for Healthcare Firms?*, HEALTH LAW., Dec. 2009, at 36.

3. *The Affordable Care Act*

The Affordable Care Act was signed into law by President Obama on March 23, 2010,¹⁰¹ and contains a provision allowing for the formation of ACOs to take part in a Medicare Shared Savings Program to be established on January 1, 2012.¹⁰² To qualify to participate in the Medicare Shared Savings Program, the ACO must (1) be willing to be held accountable for the “quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it;” (2) commit to participating for at least a three-year period; (3) have a “formal legal structure that would allow the organization to receive and distribute payments for shared savings;” (4) take on at least five thousand Medicare beneficiaries; (5) “have in place a leadership and management structure that includes clinical and administrative systems;” (6) define its “processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of . . . enabling technologies;” and (7) meet certain “patient-centeredness criteria specified by the Secretary.”¹⁰³

Section 3022 of the Affordable Care Act also provides the Secretary of Health and Human Services with authority to waive fraud and abuse laws “as necessary to carry out . . . statutory provisions” of the Act, and Center for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) have “authority to create additional exceptions or safe harbors as necessary.”¹⁰⁴ Thus, the Affordable Care Act provides considerable antitrust protections to ACO pilot programs that operate within the scope of Medicare. Whether such protections will be afforded to ACOs operating within the private sector of health care remains unclear.

B. *The Current State of Physician Joint Ventures*

Despite the agencies creating zones of safety and expanding antitrust protection for physician joint ventures, the number of physician joint ventures has declined.¹⁰⁵ Multispecialty practice groups tend to have much better infrastructure to bring about significant quality and cost improvements than do small physician groups, but physicians are

101. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119 (2010).

102. *Id.* § 3022, 124 Stat. at 395.

103. *Id.* § 3022, 124 Stat. at 395–96.

104. Workshop Regarding Accountable Care Organizations, and Implications Regarding Anti-trust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws, Afternoon Transcript 3 (Oct. 5, 2010) [hereinafter “Workshop Afternoon Transcript”], <http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopPMSessionTranscript.pdf> (statements of Troy Barsky, director of CMS’s Division of Technical Payment Policy).

105. Burke & Rosenbaum, *supra* note 11, at 6.

slow to seek bigger practices.¹⁰⁶ The reluctance of physicians to enter into joint ventures has been attributed to a number of factors, such as (1) their fear that even if they meet the criteria for the agencies' established safety zones, they still might be challenged; (2) their concern that the benefits of the joint venture will not justify the investment needed to achieve financial or clinical integration; (3) their uncertainty of what constitutes clinical integration; and (4) their concern that they will acquire market power and, thus, be condemned under the rule of reason.¹⁰⁷ As of 2006, a decade after the Agency Statements were issued, seventy-five percent of physicians were still practicing in groups of eight or fewer, with fifty-three percent of that figure practicing in a group of one to three.¹⁰⁸

In order for ACOs to make an effective impact on health-care reform, they will require increased movement from physicians from small or solo practice groups to large multispecialty groups.¹⁰⁹ Each ACO will likely need at least one hospital, fifty physicians, and at least five thousand patients.¹¹⁰ Increased guidance from federal regulatory agencies could serve as a catalyst for movement into ACOs.¹¹¹

III. ANALYSIS

Left to its own devices, the "health care industry has every financial incentive currently to be inefficient."¹¹² The current landscape of health care is one dominated by small, fragmented practices.¹¹³ Much research surrounding health-care reform points to that fragmentation as a main impediment to substantial reform¹¹⁴ and points to a need for health-care professionals to work collaboratively to bring about meaningful change.¹¹⁵ Lack of coordination between health-care providers is not only a hindrance to improving the quality of medical care but also contributes to skyrocketing costs of medical care in the United States. Atul

106. See Weeks et al., *supra* note 3, at 996.

107. Burke & Rosenbaum, *supra* note 11, at 5–6.

108. Casalino, *supra* note 10, at 570–71.

109. See, e.g., Burke & Rosenbaum, *supra* note 11, at 1–2 (noting that, despite the research surrounding clinical integration and its potential advantages, physicians, by and large, are still practicing in small groups); Devers & Berenson, *supra* note 24, at 1 (noting the need for health-care professionals "now usually working in separate institutional settings" to begin working together).

110. Maria T. Currier & Morris H. Miller, *Medicare Payment Reform: Accelerating the Transformation of the U.S. Healthcare Delivery System and Need for New Strategic Provider Alliances*, HEALTH LAWYER, Feb. 2010, at 1, 5.

111. See, e.g., Workshop Morning Transcript, *supra* note 9, at 95 (testimony of Dr. William Williams) (noting that the "main reason" he and his colleagues had trouble forming their organization "was getting physician buy-in. And the reason for that, number one, was the fear of an FTC investigation").

112. Burke & Rosenbaum, *supra* note 54, at 159.

113. Burke & Rosenbaum, *supra* note 11, at 1–2.

114. See *id.* at 1 ("Most observers agree that the fractured and fragmented state of American health care is both a cause of poor quality and inefficient care as well as a barrier to improvement.").

115. Devers & Berenson, *supra* note 24, at 1.

Gawande, reporting on the inefficiency of medical care for *The New Yorker*, provided the following apt analogy to demonstrate the way health care is administered in this country: instead of hiring a contractor to assemble and supervise a team to make all of the necessary home improvements, you hire each individual separately and, for example, pay the electrician for every single outlet he recommends and the plumber for every single faucet he installs, and so on.¹¹⁶ The incentive would be to recommend as many outlets and faucets as possible. The solution, Gawande says, is not to change who pays the electrician and plumber for the services, nor to hire more experienced professionals—rather, the solution is to change the payment incentives.¹¹⁷ Similarly, in the world of health care, whether the consumer, the insurance company, or even the government picks up the check makes little difference in improving the quality of health care or keeping it affordable.¹¹⁸ Rather, the focus of change should be on changing the incentives of the providers (or in Gawande’s hypothetical, the electricians and plumbers) who have the most control over the system; one does that by holding someone accountable for the totality of care given to patients.¹¹⁹

A number of studies suggest that larger multipractice specialty groups have more promise for delivering higher quality care and lower costs than small or solo physician practices.¹²⁰ On the other hand, the need to work “collaboratively” raises legitimate concerns about the legality of ACOs in the current framework of antitrust law.¹²¹ It is generally agreed that there are three essential features that ACOs must have to be effective: (1) the ability to provide a continuum of care to patients; (2) “the capability of prospectively planning budgets and resource needs;” and (3) “sufficient size to support comprehensive, valid, and reliable performance measurement.”¹²² The necessary organizational structure of ACOs is at odds with current antitrust law because the structure’s focus on physician collaboration is inherently antagonistic to traditional anti-

116. Gawande, *supra* note 1, at 43–44.

117. *Id.* at 44.

118. *Id.* Gawande responds to the argument that making consumers pay could help keep the prices down, but he argues that such arguments “miss the main issue” for they do not address the fact that the end goal is making doctors accountable for the totality of the care they give—not just making care cheaper. *Id.* at 43–44. Gawande also recounts a conversation he had with a cardiac surgeon where Gawande suggested, *arguendo*, the possibility of having consumer-driven health care in which people would have to pay with their own money (through medical savings accounts), which would drive consumers to bargain with doctors to reach a fair price; the surgeon jestingly suggested in response that an elderly woman needing bypass surgery would “haggle over the price as if he were selling a rug in a souk? . . . Any plan that relies on the sheep to negotiate with the wolves is doomed to failure.” *Id.* at 44 (internal quotations omitted).

119. *Id.*

120. See Fisher et al., *supra* note 7, at w54–w55; Jonathan D. Ketcham et al., *Physician Practice Size and Variations in Treatments and Outcomes: Evidence from Medicare Patients with AMI*, 26 HEALTH AFF. 195, 203 (2007); Weeks et al., *supra* note 3, at 996.

121. Geilfuss & Gray, *supra* note 44, at 26.

122. Devers & Berenson, *supra* note 24, at 2.

trust principles, but its potential benefits could help significantly to achieve a legitimate policy objective of reducing out-of-control health-care spending.¹²³

A recent statement by an FTC spokesman to an American Medical Association meeting, for example, demonstrates the legal uncertainty ACOs face. In response to requests for more guidance, the representative told them, “[w]hen a group of providers band together to eliminate competition, reduce choices, and increase prices to consumers, we try to stop them. . . . But, when we see a bonafide joint venture that is intended—and has the potential—to improve care and lower its cost, we won’t stand in the way.”¹²⁴ Although the statement, on one hand, contains words of encouragement for ACOs, it likely does little to diminish fears of would-be physician joint ventures because there is minimal guidance on what suffices as a “bonafide joint venture.”¹²⁵ The DOJ has also expressed a quasi-endorsement of ACOs, but rather than providing any further guidance, it merely reiterated the agencies’ policies promulgated in the 1993 and 1996 Agency Statements—that providers could avoid antitrust liability by financially integrating, clinically integrating, or both.¹²⁶

Section A of this Part provides a brief anecdotal comparison of a city with exorbitant health-care costs and a city with contained health-care costs as an example of the direction in which ACOs seek to take health care. Section B then provides an analysis of the various obstacles that health-care policy experts and health-care providers have identified in implementing ACOs and their proposed solutions to those problems.

A. McAllen, Texas and Grand Junction, Colorado: A Study of High-Cost, Poor-Quality Health Care and Low-Cost, High-Quality Health Care, Respectively

In 2009, Gawande reported on the health-care spending of the small town of McAllen, Texas, which has among the highest per capita spending on health care in the country.¹²⁷ In 2006, Medicare spent \$15,000 per enrollee in McAllen, which is twice as much as the average Medicare expenditure across the country and more than \$3000 more than the average annual income of a McAllen resident.¹²⁸ The greater expenditures could

123. See, e.g., Burke & Rosenbaum, *supra* note 54, at 153 (“[I]mproving the quality of health care and decreasing health care costs by integrating health services are foundational goals for the nation.”); Workshop Morning Transcript, *supra* note 9, at 11 (highlighting that Jon Leibowitz of the FTC recognizes that ACOs “offer[] a real opportunity for health care reform” by offering higher quality at lower costs).

124. Sturges, *supra* note 5, at 2 (stating that Leibowitz went on to say “[l]ooking to the future, though, there may be questions . . . [because] ACOs are in the very early stages of formation and evaluation, but there is already talk of their moving into the private sector”).

125. See, e.g., *id.*

126. *Id.*

127. Gawande, *supra* note 1, at 36.

128. *Id.*

not be attributed to either a general deteriorated health of the McAllen Medicare population as compared to the rest of the country or an increase in the quality of care administered to McAllen patients.¹²⁹ Rather, what was driving up costs was the amount of health-care services the patients received compared to the rest of country.¹³⁰

Gawande turned to Jonathan Skinner, an economist at Dartmouth's Institute for Health Policy and Clinical Practice, and to two independent firms to analyze the commercial insurance data for McAllen, who all confirmed that patients in McAllen "got more of pretty much everything—more diagnostic testing, more hospital treatment, more surgery, more home care."¹³¹ Yet, the abundance of tests performed and increased surgeries, among other services, did not improve the quality of care and was merely an "across-the-board overuse of medicine."¹³²

While the logical inference is that more expensive and more frequent health-care treatments lead to better quality and improved health, the four states with the highest level of Medicare spending actually rank near the bottom of the nation for the quality of patient care.¹³³ In fact, Dr. Elliott Fisher¹³⁴ and his colleagues discovered that patients in the highest spending regions across the country actually fare worse in terms of survival, ability to function, and patient satisfaction.¹³⁵ The reason is, in large part, the fact that "[c]omplications can arise from hospital stays, medications, procedures, and tests, and when these things are of marginal value the harm can be greater than the benefits."¹³⁶

An interesting aspect of Gawande's study is that hospital administrators in McAllen were unaware of the discrepancy between spending in their region as compared to the rest of the country.¹³⁷ The administrators could not come up with a reason why their costs would be higher but assumed that the costs were medically necessary because they deferred to hospital doctors' judgments to administer procedures and medications.¹³⁸

129. *Id.* at 37.

130. *Id.* at 38.

131. *Id.*

132. *Id.* at 39.

133. *Id.* The four states with the largest health-care expenditures are Louisiana, Texas, California, and Florida. *Id.*

134. See *supra* note 12 and accompanying text.

135. Gawande, *supra* note 1, at 39; Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care*, 138 ANNALS INTERNAL MED. 288, 293 (2003).

136. Gawande, *supra* note 1, at 39; see also *The Health of Nations: A Survey of Health-Care Finance*, ECONOMIST, July 17, 2004, at 4 (discussing how the rate of medical errors in hospitals resulting in deaths exceeds deaths caused by road accidents and that the "costs of waste, poor quality and inefficiency are enormous") (internal quotation marks omitted).

137. Gawande, *supra* note 1, at 39 (discussing how when confronted with the data, the chief operating officer of McAllen Heart Hospital, Gilda Romero, seemed genuinely surprised by the statistics and how the data was clearly new to the top administrators at Renaissance Hospital).

138. *Id.* ("[The CEO of the hospital] was certain that her doctors performed surgery only when it was necessary."); see also *id.* at 40 ("Health-care costs ultimately arise from the accumulation of indi-

Thus, it appears the problem stems directly from doctors who have individual financial incentives to increase the number of procedures for patients, which suggests that the key to controlling costs lies at the physician level rather than the administrative level.¹³⁹

At the opposite end of the spectrum is the community of Grand Junction, Colorado, which has among the least expensive health-care systems in the nation while enjoying some of the highest quality health care nationally.¹⁴⁰ The doctors in Grand Junction reached an agreement among themselves to be paid a similar fee whether they saw Medicare, Medicaid, or private-insurance patients to try to eliminate harmful financial incentives that lead to cherry-picking patients.¹⁴¹ The doctors also formed peer review committees that meet regularly to go over patient charts and identify weaknesses and inefficiencies in patient treatment.¹⁴² As a result of those regular meetings between physicians, complications decreased and quality increased.¹⁴³ Grand Junction is a leading example for ACOs of the potential benefits of increased physician coordination.¹⁴⁴

While McAllen and Grand Junction represent extreme opposites in terms of health-care costs and quality, the juxtaposition of the two examples demonstrates the direction health-care administration should move, and federal regulators should take note of the stark differences between the physician practices in these two cities. From an antitrust standpoint, the independent practices of physicians in McAllen led to excessive charges for the consumers, whereas in Grand Junction, the increased coordination of physicians worked to the benefit of consumers.¹⁴⁵ Thus, whatever harm there is to competition may very well be justified by the increased benefits to the consumers at large.

vidual decisions doctors make . . . [a]nd, as a rule, hospital executives don't own the pen caps. Doctors do.").

139. See, e.g., Devers & Berenson, *supra* note 24, at 4 ("Some believe that physician-centered organizations should lead ACOs because the resources that flow from the decisions physicians make with patients account for a major portion of overall health care costs, regardless of where the care actually takes place.").

140. Gawande, *supra* note 1, at 43.

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*; see also Workshop Morning Transcript, *supra* note 9, at 13–14.

145. See text accompanying notes 127–44.

B. The October 2010 Workshop Between Agencies and Physicians

The agencies have been acutely aware of the direction health care is moving and of the potential for ACOs to achieve health-care goals of improved quality and efficiency.¹⁴⁶ The agencies have been responsive to requests from the health-care industry to revise their antitrust policies concerning physician joint ventures, and on October 5, 2010, a public workshop was held between the FTC, the DOJ, the Department of Health and Human Services (HHS), the OIG, and the CMS to include “panel discussions and a listening session on certain legal issues related to [ACOs].”¹⁴⁷ At the meeting, the agencies stated that some of their objectives were to “[f]rom an antitrust perspective, . . . explore how to develop safe harbors so doctors, hospitals and other medical professionals know when they can collaborate and when they cannot” and “consider[] whether [the agencies] can put in place an expedited review process for those ACOs that fall outside of safe harbors as some may.”¹⁴⁸

One of the questions the agencies are grappling with is how to “design rules for ACOs that are flexible enough to allow the health-care community to collaborate to improve quality and decrease costs but obviously not to create undue market concentration and not to [effectively] end up fixing price.”¹⁴⁹ At the October 2010 workshop, the agencies sought the input of doctors who have their own experience to draw from in commenting on the tension between improving quality of patient care and abiding by the antitrust regulatory framework and hoped that physicians could be of assistance in outlining the regulatory solutions.¹⁵⁰

Overall, the tone of the agencies was one of encouragement for ACOs and of recognition that the antitrust regulations currently in place need adjustments to accommodate development of ACO trials.¹⁵¹ There was an acknowledgment that antitrust regulation is generally geared toward bad actors who try to abuse the system and that, in the context of ACOs, the agencies want to “use [their] enforcement and oversight authority judiciously to ensure that [the bad actors] cannot thwart the goals

146. See Burke & Rosenbaum, *supra* note 54, at 152; see also Thomas B. Leary, Guidance for Clinical Integration 2 (Apr. 2007, rev'd Sept. 2010) (working paper), <http://www.aha.org/content/00-10/070417clinicalintegration.pdf> (stating that efforts to improve quality and efficiency are of “critical importance”).

147. Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws, 75 Fed. Reg. 57,039, 57,039 (Sept. 17, 2010).

148. Workshop Morning Transcript, *supra* note 9, at 11.

149. *Id.* at 14.

150. *Id.* at 14–15.

151. *Id.* at 10–11 (Jon Leibowitz, chairman of the Federal Trade Commission, speaking of the promise of ACOs and how the workshop is an “unprecedented effort” by the federal agencies to coordinate antitrust laws and encourage the development of ACOs); *id.* at 15 (Dan Levinson, Inspector General of HHS stating that the “workshop is an opportunity for sharing views about what the government needs to do to ensure that bona fide ACOs striving to achieve the important goals of improving quality and achieving savings are not unduly inhibited by existing laws”).

of ACOs, compromise patient care or inappropriately increase costs to [their] programs.”¹⁵²

A panel consisting of a number of health-care specialists—many of whom have extensive experience with clinically integrated physician networks—responded to questions from representatives of the agencies who moderated the discussion.¹⁵³ The first question posed to the panel was whether they believed, based on their experiences with clinical integration, that the CMS should elaborate on its requirements so that physicians have some assurance of whether they are forming a legitimate joint venture.¹⁵⁴ A common response from the panel was that clinical integration does not take any specific form and cannot be specifically defined, but “when you see clinical integration, you know it.”¹⁵⁵ Dr. Sacks, Chief Executive Officer of Advocate Physician Partners in Chicago—an umbrella organization over eight physician-hospital organizations—noted what constitutes clinical integration ultimately has to do with “the outcome and the impact . . . on your patients [and] in the community that you serve, and you really know that in *retrospect*.”¹⁵⁶ Thus, it can be inferred that, from the physician standpoint, achieving clinical integration is best reviewed retrospectively rather than prospectively, as it can take many forms and is not easily defined.

Similarly, although physicians would appreciate guidance on how to avoid antitrust liability, they are not seeking specific requirements of what constitutes a clinically integrated network per se. One panelist emphasized a distinction between guidance and requirements, offering his opinion that guidance from the agencies is necessary for the development of ACOs but that prescribing certain requirements for ACOs could be problematic.¹⁵⁷ The panelist expressed concern that innovation would be stifled if the agencies set specific requirements for ACOs rather than allowing for different types of models to develop in the marketplace and emphasized that CMS should instead “focus[] much more on the outcome side and asking providers to be able to demonstrate outcomes.”¹⁵⁸ A similar concern was expressed by Dr. Larry Casalino,¹⁵⁹ who warned that the FTC should avoid “trying to make a cookbook” lest the FTC be

152. *Id.* at 17.

153. *Id.* at 17–21.

154. *Id.* at 22.

155. *Id.* A similar comment was made by Gloria Austin, Chief Executive Officer of Brown & Toland, a clinically integrated physician network of over 800 physicians who care for more than 300,000 patients in California. *Id.* at 18, 23 (“If you’re clinically integrated you will know it.”).

156. *Id.* at 23 (emphasis added).

157. *Id.* at 29 (comments of Harold Miller). Harold Miller is the executive director of the Center for Health Care Quality and Payment Reform and the President and CEO of the Network for Regional Healthcare Improvement, as well as an adjunct professor of public policy and management at Carnegie Mellon’s Heinz School of Public Policy and Management. *Id.* at 20.

158. *Id.* at 30.

159. *See supra* note 82 and accompanying text.

accused of “stifling innovation.”¹⁶⁰ Stifling innovation could be detrimental not only to encouraging competition in the market but also to responding to the regionally varying needs of patients, which differ from market to market.¹⁶¹ Dr. Casalino took the position that there actually is enough guidance from the FTC about what suffices as clinical integration and what constitutes an ACO.¹⁶² He similarly stated that the guidelines were clear enough and that providing more explicit guidelines would be a mistake, despite the fact that most provider groups feel guidance is lacking.¹⁶³ The discussion between the panelists and the agencies seemed to contain a common theme of striking balance between providing enough guidance to encourage physicians to form ACOs without the fear of anti-trust liability, but to be hesitant of providing so much guidance as to be overly prescriptive.¹⁶⁴

C. Public Comments Period

In addition to attending the agencies’ workshop, the agencies invited public comments on the issues to be addressed at the workshop.¹⁶⁵ The agencies received feedback about antitrust laws from a number of medical-, insurance-, and health-related organizations, such as the American Health Lawyers Association, the American Hospital Association, American Medical Association, Blue Shield of California, and the Journal of Health Politics, Policy and Law.¹⁶⁶ The comments tended to echo concerns at the workshop that ACOs be given a safe harbor but that the agencies should be cautious about being overly prescriptive.¹⁶⁷

A number of commenters voiced concerns that the market size thresholds in the Agency Statements¹⁶⁸ for falling under the rule of rea-

160. Workshop Morning Transcript, *supra* note 9, at 19, 28.

161. *Id.* at 88. (“[T]here shouldn’t be prescribed rules around what is required or not required. An ACO needs to respond to the patients that it’s serving, to the populations that it’s serving.”).

162. *Id.* at 28.

163. *Id.* at 92.

164. *See id.* at 2 (Don Berwick of the CMS stating that he thinks he speaks for everyone at the workshop when he says, “we want our cake and we want to eat it, too. We want cooperation without corruption. We want aggregation without hegemony, and we want synergy without collusion.”); *id.* at 27 (Dr. Casalino stating that the bar for clinical integration that passes antitrust muster should be somewhere between “a place where people who sincerely want to [clinically integrate] are encouraged to try . . . but that the rate of success will be reasonably high” but warning that it should not be set so that every single ACO succeeds).

165. Workshop Regarding Accountable Care Organizations, and Implications Regarding Anti-trust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws, 75 Fed. Reg. 57,039, 57,039 (Sept. 17, 2010).

166. *See Accountable Care Organizations and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback and Civil Monetary Penalty Laws*, FED. TRADE COMM’N (Nov. 17, 2010), <http://www.ftc.gov/os/comments/aco/index.shtm>.

167. *See, e.g.*, Statement of Fed’n of Am. Hosps. to the Fed. Trade Comm’n and Ctrs. for Medicare & Medicaid Servs. and Office of Inspector Gen. of Health & Human Servs. 2–3 (Oct. 27, 2010) [hereinafter Statement of Fed’n of Am. Hosps.], <http://www.ftc.gov/os/comments/aco/101027fah.pdf> (advising the importance of fostering innovation).

168. AGENCY STATEMENTS, *supra* note 62.

son analysis, rather than the per se rule, are currently set too low and that ACOs can be procompetitive even while assuming greater market size than the Agency Statements currently allow for.¹⁶⁹ Premier, Inc., a health-care alliance owned by nearly 200 hospitals, expressed concern that the providers outside of urban areas will be reluctant to join ACOs out of fear of antitrust liability arising from market share.¹⁷⁰

To be sure, not every health policy analyst is on board with the idea that ACOs deserve special antitrust treatment and caution that “[v]igilant scrutiny of conduct and market structure by antitrust enforcers is . . . critical.”¹⁷¹ But in general, the overall theme of the public comments very much resembled that of the workshop, which was general optimism about ACOs as an antidote to many of the problems contributing to inefficient health care in the country but with a desire for more guidance from the agencies about the best way to avoid antitrust challenges while simultaneously being given room to experiment with different organizational structures.

D. Proposed Ways to Change the Antitrust Laws to Further Development of Accountable Care Organizations

There is little doubt that the current state of antitrust law needs a facelift to provide the momentum needed to push providers into ACOs.¹⁷² The workshop and public comments period demonstrate a serious commitment on the agencies’ behalf to reconsider antitrust laws in light of the changing landscape of health care, and, in fact, the agencies have promised to come out with more guidance for the creation of ACOs in the near future.¹⁷³ At the time this Note was written, the agencies had not yet proposed an update to the 1996 Agency Statements, but the agencies released the *Statement of Antitrust Enforcement Policy Regard-*

169. See, e.g., Statement of Fed’n of Am. Hosps. to the Fed. Trade Comm’n, the Ctrs. for Medicare & Medicaid Services and the Office of Inspector Gen. of the Dep’t of Health and Human Servs. 6–7 (Sept. 27, 2010) [hereinafter Statement of AMA], <http://www.ftc.gov/os/comments/aco/100927ama.pdf> (stating that a “20 percent market share threshold is extremely low” and that a greater share will “often be procompetitive”).

170. Letter from Blair Childs, Senior Vice President of Public Affairs, Premier Inc., to Donald Berwick, Administrator, Centers for Medicare & Medicaid Services 35 (Oct. 19, 2010), <http://www.ftc.gov/os/comments/aco/101027premier.pdf>.

171. See Comments of Professor Thomas L. Greaney: Workshop Regarding Accountable Care Organizations 2 (Sept. 27, 2010) [hereinafter Greaney Comments], <http://www.ftc.gov/os/comments/aco/100927greaney.pdf>.

172. See, e.g., Belfort, *supra* note 52, at 1 (“[T]he content of forthcoming HHS regulations implementing the ACO legislation will have an enormous impact on whether the development of an ACO seems like a worthy experiment or a waste of scarce resources.”); Devers & Berenson, *supra* note 24, at 9 (discussing how the agencies must address certain regulatory issues before the ACO concept goes very far).

173. See, e.g., Jenny Gold, *Accountable Care Organizations, Explained*, NAT’L PUB. RADIO (Jan. 18, 2011), <http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained> (“[T]he U.S. Justice Department’s antitrust division promises to provide an expedited antitrust review process for [ACOs].”).

ing Accountable Care Organizations Participating in the Medicare Shared Savings Program in October 2011.¹⁷⁴

The question is really what type of guidance the regulations will provide and whether they will do enough to allay fears of antitrust liability. Whatever the agencies promulgate can have serious ramifications on the market for health care: “[A]ntitrust represents one of the great fields of law that determines the environment in which medical care is practiced and that all too often can be cited as the basis for the failure of collaboration within a market.”¹⁷⁵ Although increased collaboration is generally held to be the key to health-care reform,¹⁷⁶ it is too easy for providers to cite antitrust as the main reason for avoiding collaboration.¹⁷⁷ Just as the lack of guidance stifles movement toward change, however, there is an equally valid concern that overly prescriptive guidance will stifle innovation.¹⁷⁸ A third concern is that the agencies will be too lenient on ACOs, which could have legitimate anticompetitive effects that would not pass the rule of reason test, or that ACOs might become so comfortable in an antitrust safe harbor that they feel they can fall short of their promises to provide higher quality care without encountering any legal ramifications.¹⁷⁹ Thus, the solution must entail enough legal carrots and sticks to strike the balance between these competing concerns.

IV. SOLUTION

Considering the general lack of consensus about the best model by which to proceed as an ACO and the general belief among health-care professionals that ACOs will in fact need to function differently from market to market, the best approach to antitrust regulation of ACOs is one that is backward looking, rather than forward looking. The two main goals of ACOs are to improve quality of patient care and to reduce costs, and it will be hard to tell if ACOs can achieve those goals without

174. 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 2011 Agency Statement]. This Note proposes what the 2011 Agency Statement should have included—and many of my recommendations were in fact included in the 2011 Agency Statement in some form, but more guidance is needed for private-sector ACOs. I address how the actual 2011 Agency Statement compares to my recommendations at note 215, *infra*.

175. Burke & Rosenbaum, *supra* note 54, at 158.

176. *See id.* at 152.

177. *Id.* at 158 (“The problem today is that it is too easy for hospitals, insurers, and health care professionals (or more precisely, their lawyers) to point to antitrust law as a legal barrier to change. The specter of antitrust violations threatens to stifle systemic innovations among people and entities who otherwise are competitors but who join together for the common good.”).

178. *See supra* Part III.B–C.

179. *See, e.g.*, Greaney Comments, *supra* note 171, at 1–2 (“Proposals to water down these requirements would likely encourage providers to regard ACOs as ‘just another network’ and not devote the human and capital resources necessary to improve quality, change practice patterns and reduce costs.”).

giving them some room to experiment and then determining their success through outcome-based measurements.¹⁸⁰ Thus, rather than developing specific requirements for the legal structures of ACOs, the federal agencies should focus on developing quality-improvement measurements that would be strong indicators of whether the benefits of ACOs outweigh any harm on competition in the given area. After all, the agencies' approach to clinical integration is outcome driven; thus, their approach to regulation of ACOs—who have the same “basic purpose . . . for clinically integrated models of care delivery as articulated in the [Agency Statements]”¹⁸¹—should be outcome driven, as well. Furthermore, while the federal agencies typically view any harm to competition as posing the same threat across industries,¹⁸² perhaps health care should be the exception to the general rule. Although it is possible to make the argument for increased antitrust protection for ACOs that fit within the existing theory behind antitrust laws,¹⁸³ health care differs from other industries to a great enough extent that it warrants different antitrust considerations.

A. *Creating a Presumption of Legality and Reevaluating It Over Time*

The Agency Statements have had little effect on the proliferation of physician joint ventures in the past,¹⁸⁴ and, while there is a need for more guidance as to what falls within the agencies' safety zones, there is just as great of a need to leave room for experiment.¹⁸⁵ As a result, the best option is to allow for an outright presumption that ACOs fall within the safety zone carved out by the 1996 Agency Statements that allow for a rule of reason analysis.¹⁸⁶ By creating an outright presumption, the agencies will provide ACOs with the necessary amount of freedom to experiment with different legal structures and will foster innovation and competition among ACOs.

180. Workshop Afternoon Transcript, *supra* note 104, at 20 (statement of Marcie Zakheim) (discussing the importance of outcome-based measurements).

181. Burke & Rosenbaum, *supra* note 54, at 197.

182. See Workshop Morning Transcript, *supra* note 9, at 13 (statement of Jon Leibowitz) (stating that antitrust agencies enforce the laws “whether against doctors, hospitals, health care insurers, pharmaceutical companies . . . real estate agents or high tech companies”).

183. The general principle behind encouraging competition between businesses is that doing so maximizes consumer welfare. David A. Hyman & Peter Jacobson, *Is a Dose of Competition Just What the Doctor Ordered?*, 31 J. HEALTH POL. POL'Y & L. 423, 425 (2006). By allowing doctors to coordinate to deliver health care, the expected result is that consumer welfare will increase—both their physical welfare and financial welfare. See *id.*

184. See Casalino, *supra* note 10, at 573.

185. See, e.g., Statement of Fed'n of Am. Hosps., *supra* note 167, at 2–3 (advising the importance of fostering innovation).

186. Some health policy experts propose that the agencies go as far as providing an automatic exemption from the “*per se* price fixing charge” for certified ACOs, arguing that “the conditions that favor efficiency from an antitrust law perspective and those that favor efficiency from a health care delivery perspective would be able to reinforce one another.” Burke & Rosenbaum, *supra* note 54, at 199.

Over time, as it becomes more clear as to what, if any, specific behavior illegally constrains competition, the agencies might be prepared to come out with a revised version of the Agency Statements containing more specific criteria for ACOs. But at this stage in the game, the agencies risk backing themselves into a corner of unworkable rules. Additionally, the agencies should postpone application of the rule of reason analysis until an ACO has had a reasonable period of time to demonstrate efficiencies. Rather than investing time and effort into writing advisory opinions for each and every request to establish a joint venture, as has been the general practice of the agencies under the Agency Statements,¹⁸⁷ the agencies should simply require that joint ventures wishing to become ACOs file a notice with the agencies stating the specifics of their organizational structure so that the ACO is on the agencies' radar. Upon registration, the agencies could provide some kind of default certification to the ACO that would allow the ACO to begin its operation but would permit agency review in some predetermined number of years.

This system should give providers enough assurance to enter ACOs without fear of antitrust liability. Similarly, this system of retrospective review should allay fears of cynics who believe that loosened antitrust rules will encourage anticompetitive behavior among ACOs; while the rules will be temporarily loosened—at the beginning—the ACOs will still have to answer to the agencies for their behavior further down the road and will still have to demonstrate procompetitive effects to pass the rule of reason analysis.

Furthermore, ACOs, as part of their definition,¹⁸⁸ will have mechanisms in place to measure and report the quality and cost of care, and such data could be of great use to the agencies in assessing whether consumers are really receiving improved care at lower costs in a given area, which could be useful to the agencies in assessing whether ACOs are having an overall net benefit to the consumers and thereby satisfying the rule of reason analysis.¹⁸⁹

What is clear is that there is the potential for policy synergy between emerging federal ACO policy on the one hand and antitrust policy on the other. How the federal government coordinates these

187. See Casalino, *supra* note 10, at 573.

188. See McClellan et al., *supra* note 4, at 985–86 (“A core principle and design feature for all ACOs is the implementation of a robust quality measurement strategy.”); SHORTELL ET AL., *supra* note 32, at 14 (noting that the success of ACOs is contingent upon “determining qualification standards,” among other requirements).

189. See AGENCY STATEMENTS, *supra* note 62, at 76–82 (describing how the rule of reason is applied); see also McClellan et al., *supra* note 4, at 989 (“[B]ecause the purpose of regulatory monitoring of provider (and other) integration and consolidation is to protect consumers, the transparent cost and quality measurement activities available through ACOs should help clarify whether consumers are receiving better care at a lower overall cost.”).

policy levers . . . should be counted as one of the most closely watched follow-on activities of national health reform.¹⁹⁰

One example of this policy synergy lies in the collection of data concerning quality of medical care in this country. Currently, if you try to look up statistics on medical costs and utilization in this country, the data will be at least three years old.¹⁹¹ The United States keeps better statistics about “crops and cows than [it does] about patients.”¹⁹² In the Medicare Modernization Act of 2003, Congress expressed concern about the speed of improvement in the quality of care in medicine and mandated that the Institute of Medicine (IOM) investigate improvement in the quality of infrastructure.¹⁹³ The IOM recommended, in its report to Congress, that the federal government implement national reporting standards for quality and cost measurements and warned that merely specifying a universal system of measurements would not be enough; rather, the IOM suggested that an independent board be established within HHS to set standards, collect data, and issue reports.¹⁹⁴ The organizational structure of ACOs will make the adoption of national measurement standards much more feasible than they are under the current fragmented health-care system.¹⁹⁵ “The administrative complexity of data collection methods and auditing procedures for 5,000 hospitals would be much less daunting than those required to collect and audit data on the 500,000 physicians practicing in the United States.”¹⁹⁶ In exchange for greater leniency on the front-end of ACO establishment, the agencies should require that ACOs annually report their quality and cost measurement data to the agencies, which would serve the dual purposes of helping the agencies assess any anticompetitive effects of ACOs and helping to create a national system of health-care data that can be used to create uniform quality measurement standards.

If, upon review, a previously certified ACO is unable to pass the rule of reason test, it will be necessary to impose some sort of penalty without rendering the entire joint venture unlawful. The system of retroactive antitrust review will not encourage physicians into ACOs if they can be dismantled just as quickly as they were created. Instead, a system

190. Burke & Rosenbaum, *supra* note 11, at 14.

191. Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, at 34, 41.

192. *Id.*

193. COMMITTEE ON REDESIGNING HEALTH INS. PERFORMANCE MEASURES, PAYMENT, AND PERFORMANCE IMPROVEMENT PROGRAMS, INST. OF MED., PERFORMANCE MEASUREMENT: ACCELERATING IMPROVEMENT 2 (2005) [hereinafter PERFORMANCE MEASUREMENT REPORT], available at <http://www.iom.edu/Reports/2005/Performance-Measurement-Accelerating-Improvement.aspx>; see Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173 § 109, 117 Stat. 2173 (2003).

194. PERFORMANCE MEASUREMENT REPORT, *supra* note 193, at 5, 6.

195. Fisher et al., *supra* note 7, at w52 (“Aggregating performance measurement to the level of large physician groups is the only approach . . . to achieving [the dual objective of the IOM of measuring total costs and health outcomes].”).

196. *Id.*

of monetary penalties is the most suitable method for dealing with any anticompetitive effects of ACOs, and only in the event of repeated failure to produce procompetitive efficiencies would it be appropriate to respond with decertification of the ACOs.

B. Creating a More General Exception in Antitrust Law for Health Care

While creating a general presumption that ACOs fall within the rule of reason analysis will help spur increased coordination between physicians, that is just a temporary solution. It is also time that the agencies and the courts reconsider their overall attitude about competition in the health-care industry. It has been a long-held belief among health policy experts that “health care is not like other goods and services that are appropriately allocated by the market.”¹⁹⁷

For example, a free-market economy is based on a number of assumptions that are not true for health care.¹⁹⁸ A free-market economy consists of rational actors with symmetrical access to information who make free choices and voluntary transactions and where supply is regulated by demand.¹⁹⁹ In the world of health care, consumers rarely have adequate information regarding the choices they make,²⁰⁰ and very often they have little control, or free choice, over their decision to obtain health care or what type of care to receive; much of their decision-making authority is actually delegated to providers who can essentially “create a demand for their own services.”²⁰¹ Furthermore, the demand for health care is universal, as everyone needs it, but the supply is limited. In sum, “[p]roducing health care is not like producing widgets: the evidence suggests that improving health care takes extensive and ongoing collaboration among key players in a joint, information-driven, approach that causes those who otherwise might be competitors to come together to confront problems and devise solutions.”²⁰² Thus, to treat the health-care market under antitrust laws the same as any other market is to ignore glaring differences.

Moreover, antitrust case law on health care developed in an era of health care that did not at all resemble modern-day health care.²⁰³ For

197. Hyman & Jacobson, *supra* note 183, at 424.

198. FURROW ET AL., *supra* note 23, at 565–66.

199. *See id.*

200. Burke & Rosenbaum, *supra* note 54, at 163–64 (noting the “special relationship” that exists between patients and providers due to an asymmetry of information); *see also* Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 818 (2011) (discussing the “variety of circumstances [that] undermine the neoclassical assumption that buyers and sellers possess adequate information to assess the quality and costs of the services provided”); Jost et al., *supra* note 2, at 691 (“Often neither patients nor doctors have the information needed to discriminate between new [pharmaceutical] products.”).

201. FURROW ET AL., *supra* note 23, at 566.

202. Burke & Rosenbaum, *supra* note 54, at 155.

203. *See, e.g.*, FURROW ET AL., *supra* note 23, at 953.

example, consistent with its 1975 ruling in *Goldfarb v. Virginia State Bar*,²⁰⁴ the Supreme Court continues to reject the notion that health care should be entitled to antitrust exemptions on the grounds that the market operates differently.²⁰⁵ Moreover, the agencies are more stringent with their antitrust analysis when scrutinizing competition in the health-care context than when not.²⁰⁶ As costs continue to spiral out of control in the United States and effectively exclude people from the health-care market,²⁰⁷ the proposed solution from the agencies is to increase competition.²⁰⁸ The FTC and DOJ adamantly believe that competition is the answer to lowering the cost of health care and increasing efficiency;²⁰⁹ however, the agencies simultaneously recognize that competition does little to increase access to health care.²¹⁰ From the perspective of antitrust enforcers, unequal access to health care is just part of the market working properly.²¹¹

The approach taken by the agencies in promoting competition as the panacea to health-care problems is grounded in the belief that increasing access to health care is not a governmental role;²¹² however, while the United States has not embraced universal health care as a fundamental right as other nations have,²¹³ the passage of the Patient Protection and Affordable Care Act (PPACA) represents a shift in this policy attitude. Although the United States has still not adopted a universal health-care program like that of Canada or Europe, the PPACA now mandates health insurance coverage for all individuals and imposes tax penalties on those who fail to obtain coverage.²¹⁴ The agencies' approach to antitrust enforcement in the health-care industry should be revised to conform with the overall objective of universal coverage adopted by the government.

204. 421 U.S. 773 (1975).

205. Burke & Rosenbaum, *supra* note 54, at 163–64.

206. Statement of AMA, *supra* note 169, at 3.

207. See, e.g., FURROW ET AL., *supra* note 23, at 564 (discussing how increased insurance premiums are causing employers to drop coverage, which results in a higher number of uninsured persons).

208. DEPT OF JUSTICE & FED. TRADE COMM'N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION 41 (2004), <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

209. Jost et al., *supra* note 2, at 687.

210. Hyman & Jacobson, *supra* note 183, at 425 (noting that the agencies emphasized the “limitations of competition in addressing the problem of access and the uninsured”).

211. *Id.* at 424.

212. See *id.*

213. See Jost et al., *supra* note 2, at 688.

214. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 5000A, 124 Stat. 119, 244 (2010).

V. CONCLUSION

Although the FTC and DOJ are making substantial efforts to accommodate the development of ACOs, more than just a revision of the Agency Statements is needed both to ensure participation in ACOs and to ensure that ACOs will not, in practice, produce net anticompetitive effects or fail to live up to their expectations of producing higher quality health care and maintainable costs. The best way to hold ACOs accountable to antitrust law is to implement a retrospective system of review that creates an initial presumption that a proposed ACO is lawful within the framework of antitrust law and then to periodically review the ACO to confirm that the ACO is producing efficiencies that pass the rule of reason analysis. ACOs should do their part to report their quality and cost measurement data to the agencies to assist them with the review process and to work towards the eventual establishment of national quality and cost standards that would benefit the health-care system in the United States overall.²¹⁵

Even if the proliferation of ACOs produces anticompetitive effects, it is time for antitrust enforcers, both the agencies and courts, to revise their general approach to competition in the health-care industry. Health-care transactions do not work like the average marketplace transaction, and applying a strict procompetition approach that ignores problems of access to health care is no longer consistent with the general approach of the federal government to encourage universal health-care coverage. Antitrust law is a major impediment to increased coordination of care between providers, and changes in antitrust law have big implications for health-care reform in general. As the consensus changes about the direction in which health care should move, it is important that antitrust law remain flexible to allow for such movement.

Moreover, the current approach to antitrust in the health-care industry is rooted in a bygone era of health care and should come up to speed with the current realities of the state of health care in America—a reality in which an estimated 47 million Americans are uninsured,²¹⁶ and

215. In this Note, I suggest that the agencies should release revised and updated policies for ACOs. I recommend that the updated policies presume that ACOs that register with the agencies are legal and that the antitrust agencies evaluate the ACOs retrospectively using data that the ACOs should be required to report. The 2011 Agency Statement, *supra* note 174, was released in October 2011 after this Note was originally written and includes those recommendations to some extent. The 2011 Agency Statement says that the FTC and DOJ will not require mandatory antitrust review as a condition of entry into the Shared Savings Program and will apply rule of reason analysis to ACOs that meet certain eligibility criteria. *Id.* The agencies will monitor the progress and effects of ACOs through data collected by the Centers for Medicare and Medicaid Services. *Id.* The updated Agency Statements do provide significantly more guidance for ACOs without being overly prescriptive, but the Agency Statements only apply to ACOs that plan on participating in the Medicare Shared Savings Program. *Id.* Thus, it remains unclear whether such guidelines would apply to private-sector ACOs, as well, which is the main focus of this Note.

216. FURROW ET AL., *supra* note 23, at 561.

another estimated 25 million Americans between the ages of 19 and 64 are underinsured.²¹⁷ ACOs have the potential to raise the quality of health care in the United States while lowering costs, albeit possibly through some anticompetitive means, so that premiums can decrease, thereby increasing the number of Americans that can afford coverage.

It has been stated that the goal of antitrust law is to “change the incentives of business firms to ensure that the pursuit of private profit more fully promotes social welfare.”²¹⁸ If that is indeed the end goal, then it is hard to see how ACOs, in theory, based on their stated objectives, would be antagonistic to this goal. In fact, the concept of an ACO seems to parallel this goal by striving to make health care more affordable. If, in practice, ACOs fail to live up to the hype of providing better, more affordable care, then there is a legitimate reason for antitrust regulators to step in. From the outset, however, it is impossible to tell whether that will be the case. There is a reason why the PPACA calls for a *pilot* ACO program rather than something more permanent—there is no way to know whether the program will work because when it comes to reforming health care, it is impossible to come up with a master plan.²¹⁹ But “[t]he history of American agriculture suggests that you can have transformation without a master plan, without knowing all the answers up front,” and “[g]overnment has a crucial role to play [in health-care reform]—not running the system but guiding it, by looking for the best strategies and practices and finding ways to get them adopted, county by county.”²²⁰ Thus, the best thing from a regulatory standpoint is to step to the side, give ACOs a reasonable amount of time to experiment, and wait and see. The health-care system stands to gain much more than it does to lose by carving out a temporary zone of antitrust protection for ACOs.

217. Cathy Schoen et al., *How Many Are Underinsured? Trends Among U.S. Adults, 2003 and 2007*, 27 HEALTH AFF. w298, w300 (2008) (web exclusive).

218. Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, 62 N.Y.U. L. REV. 1020, 1024 (1987).

219. Cf. Gawande, *supra* note 191, at 38.

220. *Id.* Gawande compares the current health-care crisis to the American agricultural crisis of the early 1900s, which also had fragmentation as a cause. *Id.* at 35. The United States Department of Agriculture stepped in and invested heavily in data collection so that farmers had the necessary information to forecast properly. *Id.* at 36. Eventually, through a “feedback loop of experiment and learning and encouragement,” the productivity of American farmers spiked, surpassing that of other Western countries. *Id.*

