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Antitrust Review of Accountable Care Organizations: An Assessment of FTC and DOJ's Relaxed Approach to regulating Physician-Hospital Networks

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ANTITRUST REVIEW OF ACCOUNTABLE CARE ORGANIZATIONS:
AN ASSESSMENT OF FTC AND DOJ’S RELAXED APPROACH TO
REGULATING PHYSICIAN-HOSPITAL NETWORKS*

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INTRODUCTION

Commentators have long identified poor coordination between health care providers, particularly physicians and hospitals, as a key contributor to the continuing cost and quality problems plaguing the United States health care delivery system.¹ This lack of coordination

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1. See, e.g., Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. WEB EXCLUSIVE, w44, w55–w56 (2007).

undermines continuity of care, leading to medical error² and unnecessary or duplicative services.³ There are a number of factors that contribute to this coordination failure—the fragmentation of providers; diverging economic incentives facing different provider groups; and the technological, structural, and legal barriers to sharing patient information between providers, to name only a few.⁴

Providers, insurers, regulators, and policymakers have made a number of attempts to increase coordination between physicians and hospitals with only limited success.⁵ Most notably, the increase in insurer bargaining power accompanying the rise of managed care⁶

2. A highly debated report by the Institute of Medicine (“IOM”) estimated that between 44,000 and 98,000 patients die each year in hospitals due to medical error. COMM. ON QUALITY HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1* (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 2000). IOM identified the “decentralized and fragmented nature of the health care delivery system” and “patients see[ing] multiple providers in different settings, none of whom has access to complete information” as key causes of medical errors. *Id.* at 3. For a discussion of the strengths and weaknesses of the IOM analysis, compare Clement J. McDonald, Michael Weiner & Siu L. Hui, *Deaths Due to Medical Error Are Exaggerated in Institute of Medicine Report*, 284 JAMA 93, 93–94 (2000) (arguing that the IOM Report exaggerates the number of deaths attributable to medical error because it fails to consider limitations of the studies that form the basis of the IOM’s estimates), with Lucian L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, 284 JAMA 95 *passim* (2000) (arguing that limitations in the studies underlying the IOM Report had the effect of both understating and overstating the number of deaths attributable to medical error, suggesting that IOM’s estimates were likely reasonable).

3. Commentators have cited imaging as one area where unnecessary or duplicative services are commonly provided. *See, e.g.*, John K. Iglehart, *Health Insurers and Medical Imaging Policy—A Work in Progress*, 360 NEW ENG. J. MED. 1030, 1030 (2009). Studies have estimated that more than twenty billion dollars is wasted each year on unnecessary or duplicative imaging. AM. HEALTH INS. PLANS, ENSURING QUALITY THROUGH APPROPRIATE USE OF DIAGNOSTIC IMAGING 2 (2008), available at <http://www.ahip.org/content/default.aspx?docid=24057>.

4. *See* Thomas (Tim) Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, 71 U. PITT. L. REV. 217, 225–30 (2009).

5. *See* Jeff Goldsmith, *Accountable Care Organizations: The Case for Flexible Partnerships Between Health Plans and Providers*, 30 HEALTH AFF., 32, 34–35 (2011).

6. While managed care entities can take on a variety of forms, the two most common structures are health maintenance organizations (“HMOs”) and preferred provider organizations (“PPOs”). Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse*, 31 GA. L. REV. 373, 379 (1997). “HMOs both bear the risk of financing health care and provide care themselves,” either through employed providers or independent providers contracting with the HMOs. *Id.* In a PPO, a physician agrees to accept discounted fee-for-service payments and other cost and utilization control measures from an insurer in return for being included in the insurer’s limited provider network. *Id.* In 2010, approximately sixty-six million individuals were enrolled in HMO plans and fifty-three million individuals were enrolled in PPO plans in the United States. *Managed Care Fact Sheets*, MCOL, <http://www.mcareol.com/factshts/factnati.htm> (last visited Nov. 16, 2011).

prompted physicians and hospitals to ally in order to ward off steep payment cuts.⁷ However, as managed care plans became unpopular with consumers and lost their clout in the marketplace, these alliances began to break down.⁸ Some physician groups exacerbated this move away from coordination by developing ambulatory surgical centers and other outpatient treatment centers that directly compete with inpatient services offered by hospitals.⁹ Regulations limiting the ways in which hospitals can collaborate with physicians also weakened alliances.¹⁰

The Patient Protection and Affordable Care Act of 2010 (“PPACA”)¹¹ includes a number of initiatives intended to reverse this trend and improve coordination between provider groups, including physicians and hospitals. These initiatives include pilot testing of bundled payments to physicians and hospitals¹² as well as payments to providers to reduce unnecessary hospital readmissions.¹³ Perhaps the most promising vehicle for improving coordination of care between physicians and hospitals is the Medicare Shared Savings Program,¹⁴ which provides for the establishment of accountable care organizations (“ACOs”). ACOs are networks of primary care physicians, specialists, hospitals, and other providers that contract with the Centers for Medicare & Medicaid Services (“CMS”) to supply medical services for a defined population of Medicare Part A and Part B¹⁵ beneficiaries.¹⁶ ACOs must develop and implement

7. Lawrence P. Casalino, *The Federal Trade Commission, Clinical Integration, and the Organization of Physician Practice*, 31 J. HEALTH POL. POL'Y & L. 569, 570–71 (2006).

8. See Fisher et al., *supra* note 1, at w54 (summarizing the trend away from physician-hospital collaboration).

9. See *id.*; Goldsmith, *supra* note 5, at 34.

10. See Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 150–53 (2003) (discussing the legal barriers to development of gainsharing contracts between hospitals and physicians); V. Michel Magloire Marcoux, Comment, *Why Healthcare Fraud and Abuse Laws Should Allow Appropriate Hospital Gainsharing*, 59 ALA. L. REV. 539, 539–40 (2008) (same).

11. Pub. L. No. 111-148, 124 Stat. 119 (codified in scattered sections of 42 U.S.C.).

12. 42 U.S.C.A. § 1395cc-4 (West Supp. 2011). Under the payment bundling pilot program, CMS will make a single payment to groups of hospitals, physicians, and other providers for “an episode of care provided to an applicable beneficiary around a hospitalization in order to improve . . . coordination, quality, and efficiency.” See § 1395cc-4(a)(1).

13. Mark McClellan et al., *A National Strategy to Put Accountable Care into Practice*, 29 HEALTH AFF. 982, 987 (2010).

14. § 1395jjj.

15. The Medicare program provides medical coverage for seniors and the disabled and has four components: an inpatient hospital benefit (Part A); an outpatient benefit that covers both items and services (Part B); a private plan benefit (Medicare Advantage); and

processes and technologies to coordinate patient care and improve quality and efficiency and will share in any resulting cost savings to Medicare for the patient population.¹⁷ Hospitals have been particularly bullish about ACOs, with over seventy percent of hospital managers believing their institution will participate in an ACO in the next five years.¹⁸

However, the promise offered by the Shared Savings Program does not come without substantial risks, both to patients and payers. These risks include the potential for excess utilization and, conversely, for rationing care.¹⁹ Arguably, the most significant concern is that the joint negotiation of payment rates by providers will allow dominant market players to extract substantial price concessions from insurers, further increasing the already skyrocketing growth of health care costs in the United States. Recent reports of a wave of consolidation among health care providers following passage of the PPACA²⁰ and rapidly increasing provider payment rates as a result of increased bargaining leverage²¹ have only fueled these concerns. While price fixing does not pose a substantial concern with Medicare ACOs since CMS sets Part A and Part B payment rates,²²

a prescription drug benefit (Part D). The Shared Savings Program is limited to items and services covered by Part A and Part B. See § 1395jjj(a)(1). As of September 2011, forty-nine million beneficiaries were enrolled in the Medicare program. KAISER FAMILY FOUND., FACT SHEET: MEDICARE SPENDING AND FINANCING (2011), available at <http://www.kff.org/medicare/upload/7305-06.pdf>. Medicare spending is expected to reach five hundred fifty-five dollars in 2011. *Id.*

16. See, e.g., McClellan et al., *supra* note 13, at 982–83.

17. See *id.*

18. Stephen M. Shortell, Lawrence P. Casalino & Elliott S. Fisher, *How the Center for Medicare and Medicaid Innovation Should Test Accountable Care Organizations*, 29 HEALTH AFF. 1293, 1294 (2010).

19. See Elliott S. Fisher & Stephen M. Shortell, *Accountable Care Organizations: Accountable for What, to Whom, and How*, 304 JAMA 1715, 1715 (2010).

20. Robert Pear, *As Health Law Spurs Mergers, Risks Are Seen*, N.Y. TIMES, Nov. 21, 2010, at A1.

21. Robert A. Berenson, Paul B. Ginsburg & Nicole Kemper, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*, 29 HEALTH AFF. 699, 699 (2010).

22. Medicare reimburses Part A providers, which are typically hospitals, through a prospective payment system—a form of bundled payment. See Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 YALE J. ON REG. 499, 500–07 (1990). Medicare's prospective payment system gives hospitals a single payment for all of the services furnished to a beneficiary with a particular diagnosis during a single episode of care. See *id.* at 505–06. Medicare Part B providers are reimbursed on a fee-for-service basis, receiving a payment for each service provided to a beneficiary. Alice G. Gosfield, *Value Purchasing in Medicare Law: Precursor to Health Reform*, 20 AM. J.L. & MED. 169, 173–77 (1994). The payment rates are set out by CMS in

potential ACO participants have expressed interest in marketing their ACOs to private payers as well,²³ where joint price negotiation is a significant concern.

To provide guidance to ACOs operating in the private market, the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”), in consultation with CMS, recently released their final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*²⁴ (“ACO Statement”). The ACO Statement was the product of a contentious rulemaking process, during which release of the draft version of the document was repeatedly delayed, reportedly as a result of disagreements between FTC and DOJ about how rigorous antitrust review should be for ACOs that include both physicians and hospitals.²⁵ Following release of the draft version of the ACO Statement and CMS’ proposed rule implementing the Shared Savings Program, prospective ACO participants widely criticized both documents as overly burdensome and insufficiently flexible to allow for robust participation in the program.²⁶ The final ACO Statement and CMS implementing regulations for the Shared Savings Program (the “Rule”) were released together in October 2011.

Prospective participants requested that ACOs satisfying the Shared Savings Program requirements be immune from antitrust enforcement for their private sector activities, stating that without such protection from antitrust liability risk, they would be deterred from participating.²⁷ The final ACO Statement stops short of

an annual fee schedule and are designed to reflect the relative value of different services, inflation, and changes in technology. *Id.*

23. See Michael Wroblewski, Deputy Dir., FTC Office of Policy Planning, Remarks at the Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physicians Self-Referral, Anti-Kickback and Civil Monetary Penalty Laws 18 (Oct. 5, 2010) [hereinafter ACO Workshop], available at <http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopAMSessionTranscript.pdf> (“ACOs that participate in the Medicare Shared Savings Program are likely to use the same organizational and operational structure for private payers.”).

24. 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 ACO Statement].

25. See Robert Pear, *Antitrust Concerns Are Raised on New Law’s Doctor-Hospital Collaborations*, N.Y. TIMES, Feb. 9, 2011, at A19.

26. See, e.g., *infra* note 83 (outlining Cleveland Clinic’s criticism of the proposed rule).

27. Letter from Charles N. Kahn, President, Fed’n of Am. Hosps., to Donald Berwick, Adm’r, CMS (Oct. 27, 2010), available at <http://www.ftc.gov/os/comments/aco/101027fah.pdf> (“[T]here [should] be a ‘statutory requirements’ safe-harbor, such that when an ACO meets the integration requirements established by CMS for the Medicare program, and is

immunizing all private sector ACOs from antitrust enforcement, but it does establish an antitrust safety zone for certain ACOs that satisfy CMS' final Rule and meet market share and exclusivity requirements.²⁸ With one notable exception,²⁹ FTC and DOJ's antitrust enforcement policy treats ACOs that include nonphysician entities, particularly hospitals ("hospital ACOs"), the same as ACOs that include only physicians. This enforcement regime represents a stark change from FTC and DOJ's *Statements of Antitrust Enforcement Policy in Health Care*³⁰ ("Guidelines")—the primary document governing health care antitrust enforcement policy over the last fifteen years—under which provider networks, including hospitals, are subject to more rigorous antitrust scrutiny. In particular, under the Guidelines, an antitrust safety zone does not exist for provider networks that include hospitals, while a safety zone does exist for physician-only networks.³¹ Under the final ACO Statement, both types of networks are eligible for the antitrust safety zone provided they satisfy all requirements.

This Comment argues that FTC and DOJ went too far in relaxing the antitrust review regime for hospital networks for purposes of the ACO program. The agencies correctly recognized that the unique benefits of hospital participation warrant creation of a safety zone for hospital ACOs. However, in electing to implement a safety zone for hospital ACOs that largely mirrors that of physician ACOs, the agencies failed to adequately account for the singular competitive risks posed by hospital participation. Hospital ACOs should be subject to more searching antitrust review than physician-only ACOs because of high concentration in the hospital sector—particularly notable when compared to substantial fragmentation in the physician marketplace; unique vertical and horizontal integration risks posed by hospital ACOs; and concerns about making hospitals the dominant entity in medical care provision. This Comment recommends that the

approved by CMS, the antitrust agencies should refrain from an enforcement action for price-fixing if the ACO uses the same organizational structure in dealings with private payers.”).

28. ACO Statement, *supra* note 24, at 67,028–29. For an extended discussion of the market share and exclusivity requirements, see *infra* Part II.C.

29. For purposes of the ACO antitrust safety zone, hospitals and ambulatory surgical centers must be nonexclusive to a particular ACO, a requirement that does not exist for all other potential ACO participants. ACO Statement, *supra* note 24, at 67,028–29.

30. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care*, 4 Trade Reg. Rep. (CCH) ¶ 13,153, at 20,799 (1996) [hereinafter *Guidelines*].

31. See *infra* Part II.B.

agencies revise the ACO Statement to require hospital ACOs to engage in two-sided financial risk sharing in order to qualify for the safety zone. This addition is necessary because financial integration clearly evidences participants' intent to create efficiencies and has a demonstrable record of driving efficiencies through decreased utilization and less hospital intensive care. This examination of the antitrust enforcement issues with hospital ACOs also illustrates the close interrelationship between CMS' Rule and FTC and DOJ's ACO Statement, demonstrating that changes to one of the documents will in many cases require a simultaneous change to the other.

Part I of this Comment outlines the statutory and regulatory Medicare ACO requirements, as well as some existing entities that will likely serve as models for ACOs, paying particular attention to the potential role of hospitals in ACOs. Part II presents the competitive framework for health care providers, discussing how antitrust statutes have historically been applied in the health care sector and FTC and DOJ's antitrust enforcement regime for Medicare ACOs. Part III considers arguments for and against heightened antitrust barriers for hospital ACOs and assesses the agencies' decision not to subject hospital ACOs to heightened antitrust scrutiny. Part III also evaluates how CMS' Shared Savings Program Rule impacts antitrust review of ACOs offered in the private market, concluding that loosening ACO program participation regulations will often require a tightening of antitrust enforcement regulations.

I. ACCOUNTABLE CARE ORGANIZATIONS

ACOs are intended to be networks of providers that are accountable for the cost and quality of care of a defined population of patients, with ACO participants jointly sharing in any cost savings resulting from the increased care coordination and efficiency offered by the network. Before outlining the statutory and regulatory requirements for participation in the Medicare Shared Savings Program and introducing some existing health care delivery entities that may serve as models for ACOs, it is useful to provide some background on the conceptual development of ACOs, the policy goals they were designed to achieve, and the legislative history of the Shared Savings Program.

A. *Conceptual Background*

ACOs, which were first introduced by Professor Elliott Fisher and his colleagues at the Dartmouth University Center for Health

Policy and Clinical Practice, were originally designed to reduce Medicare spending growth in certain hospital services areas by leveraging the fact that Medicare beneficiaries tend to receive “most of their care from relatively coherent local delivery systems comprising physicians and the hospitals where they work or admit their patients.”³² Professor Fisher realized that this group of providers, or “extended hospital medical staff,” which the authors identified empirically through beneficiary claims data, could be used as a “locus of accountability” for quality and cost performance.³³ His team envisioned savings accruing through more coordinated care and more efficient capacity decisions by local providers, which would then slow the growth in use of expensive discretionary “supply-sensitive” services such as imaging and testing, frequently offered by hospitals.³⁴ Thus, from the outset, hospitals were viewed as a critical component of the ACO model.

Over time, the ACO concept evolved to also incorporate physician payment reform, most notably through the use of population-based shared savings payments.³⁵ Shared savings is a form of one-sided risk sharing, under which a provider benefits from any decreases in expenditure relative to a preestablished baseline, but is not liable for any increase in expenditure.³⁶ Under the original ACO shared savings model, a variety of providers would band together and agree to be jointly accountable for the cost and quality of care for an empirically defined population of patients.³⁷ If the expenditures for the population were less than a preestablished benchmark, with no associated decline in the quality, ACO members would be entitled to a bonus payment covering a portion of the savings to Medicare.³⁸ The key insight underpinning a population-based shared savings system is that patients already receive the vast majority of their care through the extended hospital staff defined above.³⁹ These organic provider referral networks allow for meaningful provider performance

32. Fisher et al., *supra* note 1, at w44. The authors found that on average 72.7% of beneficiaries’ physician visits and 63.5% of beneficiaries’ hospital admissions fell within these limited networks of physicians and hospitals. *Id.* at w48.

33. *Id.* at w45–w51.

34. *Id.* at w53.

35. See Elliott S. Fisher et al., *Fostering Accountable Health Care: Moving Forward in Medicare*, 28 HEALTH AFF. WEB EXCLUSIVE w219, w222–23 (2009).

36. McClellan et al., *supra* note 13, at 984.

37. Fisher et al., *supra* note 35, at w222–23.

38. *Id.* at w222.

39. *Id.* at w227.

assessment without having to resort to closed provider networks, which are unattractive to many patients.⁴⁰

From these conceptual bases—the establishment of a multiprovider locus of accountability and physician payment reform through shared savings—four policy rationales for ACOs become apparent. First, ACOs are intended to decrease provider fragmentation and foster improved coordination of care among providers.⁴¹ Second, this improved coordination is expected to create more robust mechanisms for provider performance measurement.⁴² Third, the ACO shared savings payment method is designed to align the utilization incentives facing different groups of providers, particularly physicians and hospitals.⁴³ Typically physician and hospital utilization incentives diverge since physicians are paid on a fee-for-service basis and thus have an incentive to increase utilization,⁴⁴ whereas hospitals are reimbursed prospectively and thus have an incentive to only provide the minimum treatment necessary once a patient has been admitted.⁴⁵ However, under a shared savings system both physicians and hospitals arguably have an incentive to control costs in order to maximize their bonus payment.⁴⁶ Moreover, proponents of ACOs also see shared savings payments as a first step toward bundled payments for hospitals and physicians. Under a bundled payment model, providers jointly receive a single payment

40. In health plans with closed provider networks, patients only have access to providers that are under contract with the plan. Closed provider networks are frequently used by HMOs and other managed care plans, but are unpopular with patients because they restrict patients' abilities to choose their own health care providers. Berenson et al., *supra* note 21, at 701. Consumer displeasure with restraints on provider choice has been identified as one cause of the backlash against managed care in the late 1990s. *Id.*

41. See Shortell et al., *supra* note 18, at 1294.

42. See McClellan et al., *supra* note 13, at 985–87.

43. See Shortell et al., *supra* note 18, at 1294.

44. See James C. Robinson, *Theory and Practice in the Design of Physician Payment Incentives*, 79 MILBANK Q. 149, 151–52 (2001).

45. Under a prospective payment system, a provider is reimbursed at a predetermined rate for treating a particular patient with a particular illness. See Mark A. Hall, *Rate Appeals Under Medicare's New Payment System: Reflections on the Meaning of "Prospectivity"*, 38 U. FLA. L. REV. 407, 408 (1986). Prospective payment systems create two incentives for hospitals: (1) an incentive to increase the number of patients admitted to hospitals (the "extensive margin"), see *infra* note 263 and accompanying text, and (2) an incentive to provide the minimum care necessary once a patient has been admitted (the "intensive margin"), see James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 210 (1996).

46. McClellan et al., *supra* note 13, at 984–85 ("Participating providers are also held accountable for a portion of any excessive spending through reductions in future bonus payments.").

covering the entire continuum of care for a patient with a single condition or procedure.⁴⁷ Bundled-payment programs are desirable because they have been shown to both increase quality and lower costs.⁴⁸

Finally, ACOs are constructed to shift patient care away from hospitals to the primary care setting. Commentators have long advocated delivery models that drive such a shift, citing studies of integrated care systems finding substantial aggregate cost savings due solely to less hospital intensive care.⁴⁹ Moreover, a move toward primary care is attractive to CMS because reducing avoidable hospital services represents the largest opportunity to control Medicare costs.⁵⁰ While hospitals have traditionally pushed back against efforts to control inpatient volume,⁵¹ allowing hospitals to capture some of the cost savings associated with less hospital intensive care may make them more amenable to such efforts.

These policy rationales also appear to have motivated Congress to include ACOs in the PPACA. Early versions of the health reform legislation in the House of Representatives⁵² and the Senate⁵³ included ACO programs.⁵⁴ While the legislative record on ACOs is relatively thin,⁵⁵ Congress appears to have viewed ACOs as providing

47. Shortell et al., *supra* note 18, at 1294.

48. Martin Gaynor, Carnegie Mellon Univ., Presentation to MedPAC, Provider Integration and Impacts on Competition (Oct. 2, 2009), available at <http://www.medpac.gov/transcripts/Gaynor%20presentation.pdf> (accessed by scrolling to page twenty of the presentation slides).

49. See, e.g., Willard G. Manning et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment*, 77 AM. ECON. REV. 251, 265–67 (1987).

50. Goldsmith, *supra* note 5, at 33.

51. For example, in the 1990s, numerous hospitals acquired physician practices in an effort to stave off potential cuts resulting from the Clinton administration's health reform efforts. *See id.*

52. Health Care for America Act, H.R. 3962, 111th Cong. § 1301 (as introduced in the House, Oct. 29, 2009).

53. America's Health Future Act of 2009, S. 1796, 111th Cong. § 3022 (2009).

54. While the House bill language regarding ACOs largely tracked that of the Senate, there were two key differences. First, the House bill only called for pilot testing of Medicare ACOs, rather than full implementation of an ACO program as is provided in the Senate bill. Taylor Burke & Sara Rosenbaum, *Accountable Care Organizations: Implications for Antitrust Policy*, 19 HEALTH L. REP. (BNA) 358, 359–61 (2010), available at <http://www.rwjf.org/files/research/57509.pdf>. Second, the House bill provided for the testing of a variety of payment methods including performance target and partial capitation models, whereas the Senate bill only included a shared savings payment model. *Id.* at 360.

55. This thin legislative record likely reflects both that the Shared Savings Program is a small part of a large, complex bill and that there was no conference to integrate the House and Senate bills.

a legal mechanism for a variety of providers to integrate and become jointly responsible for the quality and cost of care of defined populations of patients.⁵⁶ Congress intended for the ACO program to expand upon CMS' Medicare Physician Group Practice demonstration project, established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,⁵⁷ by allowing for participation of nonphysician providers.⁵⁸ In addition, Congress appears to have viewed the ACO program and hospital-physician bundled payment programs as intimately related, placing the payment-bundling pilot program immediately after the Shared Savings Program in the bill.⁵⁹ As Senator Maria Cantwell explained during the Finance Committee's markup of its draft of the bill, "accountable care organizations and global budgeting . . . will definitely move [the health care system] towards this goal of really driving down costs."⁶⁰ In the context of hospital participation in ACOs, this connection is notable since payment bundling pilot programs are required to include at least one hospital.⁶¹

Congress's decision to include ACOs in the PPACA appears to stem from a recommendation by the congressionally established Medicare Payment Advisory Committee ("MedPAC").⁶² In its June

56. See S. REP. NO. 111-89, at 168 (2009) ("There are no existing laws that directly address the ability of organizations or systems of integrated providers to share in the efficiency gains resulting from the joint responsibility for and care of Medicare beneficiaries. However, while some providers who deliver care in a vertically integrated managed care environment under Medicare are able to achieve these efficiency gains (e.g., a staff-model managed care organization), other providers face obstacles to this type of practice and related potential sharing (e.g., fee-for-service providers who practice across a range of separate legal entities).").

57. Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

58. See S. REP. NO. 111-89, at 169 ("Accountable care organizations would go beyond the [Physician Group Practice demonstration project] model, which is based on physician groups, to include additional providers.").

59. See The Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. §§ 3022-3023 (2010) (enacted as Pub. L. No. 111-148, 124 Stat. 119).

60. *Executive Committee Meeting to Consider Health Care Reform: Hearing Before the S. Comm. on Fin.*, 111th Cong. 278 (2009) (statement of Sen. Maria Cantwell, Member, Comm. on Fin.), available at <http://finance.senate.gov/library/transcripts/download/?id=8d183331-c6bc-43e5-bb3a-66d230e7e209>.

61. 42 U.S.C.A. § 1395cc-4(c)(2)(A) (West Supp. 2011).

62. See S. REP. NO. 111-89, at 168 ("MedPAC has been among the proponents that have encouraged this type of gain sharing through accountable care organizations."); see also *Executive Business Meeting to Consider an Original Bill Providing for Health Care Reform: Meeting of the S. Comm. on Fin.*, 111th Cong. 195 (2009) (statement of Mark Miller, Dir., MedPAC), available at <http://finance.senate.gov/library/transcripts/download>

2009 report to Congress, MedPAC recommended that Congress consider introducing ACOs to the Medicare program, explaining that “[t]he goal is to create an incentive for providers in the ACO to constrain volume growth while improving the quality of care.”⁶³ MedPAC suggested two ACO models: a voluntary, bonus-only model and a mandatory, bonus-and-withhold model.⁶⁴ Under either MedPAC model, ACOs would include physicians, specialists, and, at a minimum, one hospital.⁶⁵ However, unlike the MedPAC recommendation, neither the Senate nor House bills mandated hospital participation in ACOs. The legislative record does not provide any guidance on why Congress altered the original MedPAC model in this fashion.

There are at least two ways to interpret Congress’s decision not to mandate hospital participation in ACOs. ACOs were primarily expected to drive savings through reducing spending growth for hospital services, and thus Congress may have been concerned that requiring hospital participation in ACOs would undermine the effectiveness of the program since hospital members would have an incentive to minimize their own revenue losses and not maximize savings. Physician-only ACOs would not face the same incentive problem because they could drive savings for their patient population through decreasing hospital services expenditures without an attendant decrease in the volume of services rendered by their physician members. This interpretation is supported by the results of the Physician Group Practice demonstration project, where participating entities closely affiliated with hospitals failed to achieve significant cost savings, while group practices unaffiliated with hospitals did.⁶⁶ Alternatively, Congress may have viewed hospitals as an important component of ACOs but also wanted the ACO

[/?id=2eff87ab-56d7-47b7-a46e-4b4f5c0f2c2b](#) (“[T]here are a number of things in the bill that MedPAC has recommended There are many things in the bill where we are testing ideas—bundling, accountable care organizations, that type of thing.”).

63. MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO CONGRESS: IMPROVING INCENTIVES IN THE MEDICARE PROGRAM 39 (2009), available at http://www.medpac.gov/documents/jun09_entirereport.pdf.

64. *Id.* at 43. Under the bonus-only model, the provider would receive a bonus payment if the spending growth for its assigned patient population was less than a pre-established baseline. *See id.* at 43–44. Under the bonus-and-withhold model, providers would receive bonus payments if expenditures for their patient population were less than a preestablished baseline, but would have a portion of their prospective payment withheld if expenditures substantially exceeded expectations. *See id.* at 46.

65. *Id.* at 39.

66. John K. Iglehart, *Assessing an ACO Prototype—Medicare’s Physician Group Practice Demonstration*, 364 NEW ENG. J. MED. 198, 200 (2011).

structure to be extremely flexible in order to maximize provider participation in the program. The latter interpretation is supported by Congress's desire for the ACO program to expand upon the Physician Group Practice demonstration project by including new provider groups and its belief that the Shared Savings Program is intimately related to the payment bundling pilot.

B. Statutory Requirements

The PPACA participation requirements for the Shared Savings Program, which must be in place by January 1, 2012,⁶⁷ flow from the policy goals underlying the development of ACOs. Reflecting concerns over lack of coordination among providers, the PPACA allows for the formation of ACOs by a broad variety of providers and suppliers, ranging from independent physician practices to hospitals. Entities eligible to participate in the program are

- (A) ACO professionals in group practice arrangements.
- (B) Networks of individual practices of ACO professionals.
- (C) Partnerships or joint venture arrangements between hospitals and ACO professionals.
- (D) Hospitals employing ACO professionals.
- (E) Such other groups of providers of services and suppliers as the Secretary determines appropriate.⁶⁸

Despite the fact that hospitals were initially viewed as a critical component of ACOs, primary care physicians, who are "central" to ACO quality and cost saving goals,⁶⁹ are the only type of provider that must be included in a Medicare ACO.⁷⁰

In order to participate in the Shared Savings Program, prospective ACOs must satisfy governance, quality, and accountability requirements set forth in the statute.⁷¹ In particular, ACOs must establish a formal legal structure that allows for the

67. 42 U.S.C.A. § 1395jjj(a)(1) (West Supp. 2011).

68. § 1395jjj(b)(1).

69. See McClellan et al., *supra* note 13, at 985 ("Although the [ACO] itself is ultimately held accountable for all costs related to this defined patient population—including costs for providers not participating in the ACO—the model itself is rooted in existing relationships between primary care physicians and their patients.").

70. See § 1395jjj(b)(2)(D) ("The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO.").

71. § 1395jjj(b)(2).

receipt and distribution of shared savings payments and a “leadership and management structure that includes clinical and administrative systems.”⁷² The ACO must also agree to participate in the program for at least three years and have sufficient primary care capacity to care for the minimum five thousand Medicare beneficiaries that will be assigned to it.⁷³ With regard to quality, ACOs must adopt “processes to promote evidence-based medicine,” to use new technologies to coordinate care and monitor patients, and to satisfy “patient-centeredness criteria.”⁷⁴ Finally, “[t]he ACO shall be willing to become accountable for the quality, cost, and overall care” of the beneficiaries assigned to it.⁷⁵ To that end, the ACO must develop and implement quality and cost reporting processes and must provide feedback on the implementation of those processes to CMS.⁷⁶

The statutory payment structure largely follows the original payment reform recommendations for ACOs. Under the statute, ACOs are eligible to receive two payments from Medicare. First, “payments shall continue to be made to providers of services and suppliers participating in an ACO . . . under Parts A and B . . . in the same manner as they would otherwise be made.”⁷⁷ Therefore, hospital ACO participants will be reimbursed under the Medicare Part A prospective payment system, while other ACO providers will be reimbursed under the Part B fee-for-service payment system. Second, ACO participants will receive an annual shared savings payment if two criteria are satisfied: (1) “the ACO meets quality performance standards established by [CMS]” and (2) the risk-adjusted per capita expenditures for the ACO’s assigned beneficiaries are a certain percentage below a benchmark determined by CMS.⁷⁸ The benchmark will be specific to each ACO and will be adjusted for the characteristics of the beneficiaries assigned to it.⁷⁹ The shared savings payment will be a percentage, determined by CMS, of the total savings generated by the ACO relative to the preestablished benchmark.⁸⁰ Thus, regardless of whether participants qualify for the shared savings payment, they will still be no worse off than they

72. § 1395jjj(b)(2)(C), (F).

73. § 1395jjj(b)(2)(B), (D).

74. § 1395jjj(b)(2)(G)–(H).

75. § 1395jjj(b)(2)(A).

76. § 1395jjj(b)(2)(G).

77. § 1395jjj(d)(1)(A).

78. § 1395jjj(d)(1)(A)–(B).

79. § 1395jjj(d)(1)(B)(ii).

80. § 1395jjj(d)(2).

would have been if they had not participated in the program, since they will still receive their fee-for-service or prospective payment.

C. Regulatory Framework

CMS' Rule⁸¹ implementing the Shared Savings Program provides clarity on a number of key aspects of the program. The Rule departs in a number of important ways from the agency's proposed rule,⁸² which had been subject to substantial criticism from prospective ACO participants and other industry stakeholders as being overly proscriptive and unduly burdensome.⁸³ While the Rule fills in numerous statutory gaps by addressing a wide variety of issues such as quality measures, beneficiary assignment, marketing, and use of health information technology, four policies set forth in the document are particularly relevant to antitrust review of ACOs.

First, the Rule requires that ACOs adopt a leadership and management structure that facilitates clinical integration and ensures ACOs lead to quality and efficiency improvements.⁸⁴ In particular, ACO participants must demonstrate a "meaningful commitment" to clinical integration by, for example, making substantial financial investments in the ACO or expending substantial time and effort in overseeing the ongoing operations of the ACO.⁸⁵ ACOs must also develop evidence-based clinical guidelines and processes for evaluating participants' adherence to those guidelines.⁸⁶ Furthermore, ACOs must implement remedial measures, including the potential for expulsion, to deal with participants who fail to adhere to guidelines.⁸⁷ CMS emphasizes that these requirements are intended to harmonize Shared Savings Program participation requirements with antitrust

81. Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425) [hereinafter Rule].

82. Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19,527 (proposed Apr. 7, 2011) (to be codified at 42 C.F.R. pt. 425) [hereinafter Proposed Rule]. CMS drafted the proposed and final rules in conjunction with FTC and DOJ. *See id.* at 19,534.

83. *See, e.g.*, Letter from Delos M. Cosgrove, CEO, Cleveland Clinic, to Donald M. Berwick, Adm'r, CMS 1 (May 26, 2011), available at <http://www.medcitynews.com/wordpress/wp-content/uploads/Cleveland-Clinic-ACO-letter.pdf> ("[A]fter reviewing [the Proposed Rule], we are disappointed generally with its content."). In particular, Cosgrove, CEO of the Cleveland Clinic, said "the Proposed Rule is replete with (1) prescriptive requirements that have little to do with outcomes, and (2) many detailed governance and reporting requirements that create significant administrative burdens." *Id.* at 1.

84. Rule, *supra* note 81, at 67,976.

85. *Id.* at 67,824–25, 67,976.

86. *Id.* at 67,976.

87. *Id.*

enforcement policies by incorporating many of the criteria FTC and DOJ focus on in antitrust review of health care provider networks.⁸⁸

Second, during the first three years of the program, prospective ACOs must agree to contract with CMS under one of two payment tracks. In order to understand the difference between the two tracks, it is first necessary to distinguish between one-sided and two-sided risk-sharing payment structures. In a one-sided financial risk-sharing system, the provider benefits from any decreases in expenditure for a covered patient population, but is not liable for any increases in expenditures.⁸⁹ As noted above, the original ACO concept relied on a shared savings system, which is a form of one-sided risk sharing.⁹⁰ However, under a two-sided, or “symmetric,” risk-sharing system, the provider benefits from any cost savings, but is also at least somewhat at risk for any excess expenditures.⁹¹ ACOs that opt for payment Track 1 would engage only in one-sided risk sharing during the three-year contract, sharing in any savings if realized expenditures were less than a predetermined target, but not being held liable for losses if realized expenditures were to exceed the target.⁹² This is a significant change from the proposed rule, under which entities choosing Track 1 were required to switch to a two-sided risk-sharing payment model for the third year of the contract.⁹³ ACOs that select payment Track 2 would agree to engage in two-sided risk sharing during all three years of the contract.⁹⁴ In return for bearing greater risk, ACOs that choose Track 2 are also eligible to share in a higher proportion of any savings accruing to Medicare.⁹⁵ ACOs contracting under Track 1 during the first three years of the program must shift to the two-sided model in future contract periods.⁹⁶

88. See *id.* at 67,824 (“[T]he purposes of the Shared Savings Program and the Antitrust Agencies’ clinical integration requirements are complementary and, indeed, mutually reinforcing.”); see also Proposed Rule, *supra* note 82, at 19,542 (“It is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration.”).

89. See McClellan et al., *supra* note 13, at 984.

90. See *supra* note 36 and accompanying text.

91. See McClellan et al., *supra* note 13, at 984.

92. Rule, *supra* note 81, at 67,985–86.

93. Proposed Rule, *supra* note 82, at 19,603.

94. Rule, *supra* note 81, at 67,985.

95. *Id.* at 67,986–87 (providing that ACOs participating in the one-sided model may “receive shared savings payments of up to 50 percent of all savings” relative to the benchmark, while ACOs participating in the two-sided model may receive payment may “receive shared savings payments of up to 60 percent of all savings” relative to the benchmark).

96. *Id.* at 67,985.

Third, primary care physicians who wish to participate in the Shared Savings Program may only be a member of one ACO.⁹⁷ For purposes of this requirement, the term “primary care physicians” includes “physicians with a designation of internal medicine, geriatric medicine, family practice and general practice.”⁹⁸ The main reason for this primary care exclusivity requirement is that CMS will assign beneficiaries to the ACO from which they receive the plurality of their primary care services.⁹⁹

Finally, the Rule recommends that ACOs that “may present competitive issues” voluntarily request antitrust review by FTC or DOJ before participating in the program.¹⁰⁰ This also represents a significant change from the proposed rule, which would have required that prospective ACOs holding a market share exceeding fifty percent submit, as a condition for participating in the Shared Savings Program, a letter from FTC or DOJ stating that neither agency intends to challenge the proposed ACO.¹⁰¹ In the final Rule, CMS does not provide guidance on what particular market share level would present sufficient competitive concerns to warrant preliminary antitrust review. However, in the proposed rule, CMS suggested that ACOs with market shares exceeding thirty percent for any service provided by two or more participants in the ACO consider seeking antitrust clearance by FTC and DOJ or implement conduct restrictions to minimize competitive concerns.¹⁰² CMS elected to drop the antitrust preclearance requirement in the final rule in part due to concerns expressed by stakeholders¹⁰³ that the agency’s authority under the Social Security Act and PPACA is insufficiently broad to allow the agency to participate in antitrust enforcement.¹⁰⁴

97. *Id.* at 67,811. Because CMS will identify ACO physician participants using tax identification numbers, it is possible that the limited group of primary care physician who bill under two tax identification numbers will be able to participate in more than one ACO. *Id.* at 67,810–11.

98. *Id.* at 67,975.

99. *Id.* at 67,810–11.

100. *Id.* at 67,842.

101. Proposed Rule, *supra* note 82, at 19,629.

102. *Id.* For purposes of this recommendation, market share is calculated using ACO participants’ primary service areas (“PSA”). For a more extensive discussion of the use of PSAs in calculating market share, see *infra* Part II.C.

103. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass’n, to Donald M. Berwick, Adm’r, CMS, Christine Varney, Assistant Att’y Gen., DOJ, & Jon Leibowitz, Chairman, FTC 7 (May 31, 2011), available at <http://www.aha.org/aha/letter/2011/113105-let-pollack-doj-ftc-hhs.pdf>.

104. Rule, *supra* note 81, at 67,841.

D. Existing Models

Commentators have identified five existing types of practice arrangements—ranging from highly vertically and horizontally integrated delivery entities to coalitions of geographically dispersed independent physicians—that could serve as models for Medicare ACOs.¹⁰⁵ Many of these models were also tested as part of the Physician Group Practice demonstration project.¹⁰⁶ On one end of the spectrum are integrated delivery systems, in which hospitals, physician practices, and even insurance plans are owned by a single entity.¹⁰⁷ These organizations are generally highly financially and clinically integrated, using electronic health records, practice guidelines, and other tools to supply cost-effective, coordinated care.¹⁰⁸

A second ACO model, multispecialty physician group practices, are highly clinically integrated organizations with member providers often using common electronic health record technology and adhering to jointly established treatment guidelines.¹⁰⁹ These entities typically employ a variety of mechanisms to provide coordinated, efficient care and include physicians, physician groups, and hospitals.¹¹⁰ Multispecialty physician group practices differ from integrated delivery systems in that they generally do not own or have a close affiliation with an insurance plan, but instead contract with multiple local insurance carriers.¹¹¹

Physician-hospital organizations (“PHOs”), which are partnerships between independent physicians or physician groups and at least one hospital, are a third potential model for ACOs.¹¹² PHOs

105. Shortell et al., *supra* note 18, at 1294–95; *see infra* Table 1.

106. The demonstration project included ten participants with a variety of types of organizational structures including “free-standing physician groups, academic faculty practices, integrated delivery systems, and a network of small physician practices.” Iglehart, *supra* note 66, at 198. The program had mixed success, with half of the participants receiving a bonus payment during at least one of the project’s four years. *Id.* at 199.

107. Shortell et al., *supra* note 18, at 1294. Staff model HMOs such as Kaiser Permanente and Group Health Cooperative are examples of integrated delivery systems. *Id.*

108. *Id.*

109. See Stephen M. Shortell & Lawrence P. Casalino, *Health Care Reform Requires Accountable Care Systems*, 300 JAMA 95, 95–96 (2008).

110. Shortell et al., *supra* note 18, at 1294–95. Examples of multispecialty physician group practices include Mayo Clinic and The Cleveland Clinic. *Id.* at 1294.

111. *Id.*

112. *Id.* at 1295. Advocate Health Care is one example of a PHO. *Id.* For a discussion of Advocate Health Care as a model for ACOs, see Mark C. Shields et al., *A Model for*

were first widely established in the 1990s in order to give providers more leverage in negotiating payment rates with managed care plans, allow providers to directly negotiate with self-insured employers, and better coordinate care.¹¹³ However, PHOs waned in popularity as patient demand for broad provider networks limited insurers' negotiating leverage.¹¹⁴ Generally, PHO is a separate legal entity, managed by a board of directors composed of physician and hospital representatives of member organizations and empowered to enter into contracts on behalf of its members.¹¹⁵ Because the members remain independent, PHOs generally "entail[] relatively little clinical integration among participants,"¹¹⁶ although some PHOs involve significantly greater clinical integration.¹¹⁷

Independent practice associations ("IPAs"), which also became popular in the 1990s during the rise of managed care, act as intermediaries between independent physicians and health insurers.¹¹⁸ While IPAs can take on a broad variety of structures, most IPAs fall into one of two primary models. In the first model the IPA acts as a payment negotiating organization, communicating offers between insurers and individual physicians and, in some cases, entering into contracts on the physicians' behalf.¹¹⁹ In the second model the IPA continues to serve as a negotiating and contracting agent, but also facilitates administrative and clinical integration of member practices.¹²⁰ Regardless of which model is used, IPAs are often, but

Integrating Independent Physicians into Accountable Care Organizations, 30 HEALTH AFF. 161 *passim* (2011).

113. See Tricia A. Shackelford, *Physician-Hospital Organizations: A U.S. Trend and Overview*, 12 HEALTH L. 24, 24 (2000).

114. See Fisher et al., *supra* note 1, at w54.

115. Thomas L. Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust*, 79 CORNELL L. REV. 1507, 1519 (1994); Julie Y. Park, Comment, *PHOs and the 1996 Federal Antitrust Enforcement Guidelines: Ensuring the Formation of Procompetitive Multiprovider Networks*, 91 NW. U. L. REV. 1684, 1692-94 (1997).

116. Greaney, *supra* note 115, at 1519.

117. See Shortell et al., *supra* note 18, at 1295.

118. Gregory D. Adams & Fred S. McChesney, *Not Good Enough for Government Work: Geographic Market Definition and the FTC's Case Against Chicagoland Physician Associations*, 6 J. COMPETITION L. & ECON. 771, 775 (2010). One example of an IPA with a high level of clinical integration is Hill Physicians Group in Northern California. Shortell et al., *supra* note 18, at 1295.

119. See PETER R. KONGSTVEDT, *ESSENTIALS OF MANAGED HEALTH CARE* 31-33, 73-74 (5th ed. 2007).

120. *Id.* at 74.

not always, affiliated with a particular hospital or hospital network¹²¹ and can involve varying degrees of clinical integration.¹²²

On the least integrated end of the spectrum are virtual physician organizations. These networks of independent practices, often located in rural areas, invest in infrastructure that thereby facilitates the provision of coordinated and cost-effective care.¹²³ One widely cited example of a virtual physician organization is Community Care of North Carolina,¹²⁴ which provides care primarily for Medicaid patients through a group of local networks of independent physicians.¹²⁵ Virtual physician organizations are viewed as a promising avenue for bringing more coordinated care to areas where the provider market is currently highly fragmented.¹²⁶

121. Adams & McChesney, *supra* note 118, at 775.

122. Cf. Shortell et al., *supra* note 18, at 1295 (“[IPAs] consist of individual physician practices that came together largely for purposes of contracting with health plans. Over time, however, many of these have evolved into more-organized networks of practices that are actively engaged in practice redesign, quality improvement initiatives, and implementation of electronic health records.”).

123. *See id.*

124. *See, e.g., id.*

125. *See* L. Allen Dobson, Jr., *Community Care of North Carolina: An Enhanced Medical Home Model*, 70 N.C. MED. J. 219, 220 (2009).

126. *See* AM. MED. ASS'N HOUSE OF DELEGATES, ACCOUNTABLE CARE ORGANIZATION (ACO) PRINCIPLES (2010), available at <http://www.ama-assn.org/ama1/pub/upload/mm/399/aco-principles.pdf>.

Table 1: Existing Practice Arrangements that are Models for ACOs

Practice Type	Members	Level of Integration	Example(s)
Integrated delivery system	Hospitals, physician practices, and, in some cases, insurance plans	Highly financially and clinically integrated	Kaiser Permanente, Group Health Cooperative
Multispecialty group practice	Physician group practices and hospitals	Highly clinically integrated, but not necessarily financially integrated	Mayo Clinic, Cleveland Clinic
Physician-Hospital Organization (PHO)	Independent physicians, physician groups, and at least one hospital	Relatively little clinical integration, some financial integration through joint contracting with payers	Advocate Health Care
Independent Practice Association (IPA)	Independent practices, generally affiliated with hospital or hospital group	Varying levels of clinical and financial integration, typically less than multispecialty group practices	Hill Physicians Group
Virtual physician organization	Independent physician practices	Varying levels of clinical integration, little or no financial integration	Community Care of North Carolina

II. THE COMPETITIVE FRAMEWORK FOR HEALTH CARE PROVIDERS

The preceding section demonstrates that ACOs are intended to be networks of providers designed to improve quality and efficiency by strengthening coordination between their members, particularly physicians and hospitals. While the statute and Rule place some constraints on how ACOs must be organized, there is still a broad variety of practice arrangements that have been identified as possible

models for ACOs. This large number of potential structures also makes it difficult for antitrust regulators to establish a single enforcement policy for ACOs since different types of ACOs may raise different antitrust concerns.

Three documents are particularly relevant to antitrust review of ACOs: (1) Section 1 of the Sherman Act; (2) FTC and DOJ's *Statements of Antitrust Enforcement Policy in Health Care* ("Guidelines"); and (3) FTC and DOJ's *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* ("ACO Statement"). Section 1 of the Sherman Act, which outlaws concerted acts by competitors to restrain competition, is the primary antitrust statute relevant to health care provider joint ventures.¹²⁷ The Sherman Act is criminally enforced by DOJ and civilly enforced by DOJ, FTC, and private litigants. As noted above, DOJ and FTC jointly issued the Guidelines, which outline the agencies' enforcement policies for provider joint ventures. FTC has further clarified the Guidelines through a number of advisory opinions regarding proposed health care provider joint ventures.¹²⁸

A. *The Sherman Act*

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce."¹²⁹ As the statutory language suggests, a party seeking to establish a claim under Section 1 must first prove the existence of a concerted action to restrain trade by distinct economic entities.¹³⁰ With joint ventures, a key question is whether the venture should be treated as a single economic entity, and thus not subject to Sherman Act liability, or a concerted act by competitors.¹³¹ The Supreme Court recently held in *American Needle, Inc. v. National Football League*¹³² that in making such a

127. Taylor Burke & Sara Rosenbaum, *Aligning Health Care Market Incentives in an Information Age: The Role of Antitrust Law*, 5 J. HEALTH & BIOMEDICAL L. 151, 166 (2009).

128. For a topical list of FTC's health care sector advisory opinions, see generally HEALTH CARE DIV., FED. TRADE COMM'N, TOPIC AND YEARLY INDICES OF HEALTH CARE ANTITRUST ADVISORY OPINIONS BY COMMISSION AND STAFF (2010), available at <http://www.ftc.gov/bc/adops/indexfin062010.pdf>.

129. 15 U.S.C. § 1 (2006).

130. *Am. Needle, Inc. v. Nat'l Football League*, 130 S. Ct. 2201, 2208 (2010).

131. *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 356–57 (1982).

132. 130 S. Ct. 2201 (2010).

determination, “[t]he relevant inquiry...is whether there is a ‘contract, combination . . . or conspiracy’ amongst ‘separate economic actors pursuing separate economic interests’...such that the agreement ‘deprives the marketplace of independent centers of decisionmaking.’”¹³³ In *Arizona v. Maricopa County Medical Society*,¹³⁴ which dealt with a joint venture among physicians, the Court said “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” should be treated as single entities and not subject to the Sherman Act,¹³⁵ demonstrating that financial risk sharing is a critical component in determining whether a joint venture should be immune from Sherman liability.

If Section 1 is found to be applicable, a court must then determine whether the arrangement is either per se illegal or should be analyzed under the so-called “rule of reason.” While the plain language of Section 1 would seem to outlaw all agreements that restrain trade, beginning with *Standard Oil Co. of New Jersey v. United States*,¹³⁶ the Court has consistently held that only “unreasonable” restraints on trade violate the Sherman Act.¹³⁷ In applying this rule of reason, the factfinder must “decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.”¹³⁸ This analysis requires a balancing of the anticompetitive effects of an agreement against any procompetitive justifications.¹³⁹ Under the rule of reason, the plaintiff first bears the burden of demonstrating anticompetitive effects resulting from the concerted activity, which the defendant can then rebut by showing superseding procompetitive benefits.¹⁴⁰ The initial showing of anticompetitive effects can be an expensive, time-consuming process, requiring a court to weigh voluminous

133. *Id.* at 2212 (internal citations omitted).

134. 457 U.S. 332 (1982).

135. *Id.* at 356.

136. 221 U.S. 1 (1911).

137. *Maricopa*, 457 U.S. at 343; *Standard Oil*, 221 U.S. at 59–60. Prior to the *Standard Oil* decision, the Court interpreted Section 1 according to its plain meaning. See Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?*, 42 U.C. DAVIS L. REV. 1375, 1389–92 (2009).

138. *Maricopa*, 457 U.S. at 343.

139. One of the earliest formulations of this test was put forth by Justice Brandeis in *Chicago Board of Trade v. United States*, stating that the “test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” 246 U.S. 231, 238 (1918).

140. Stucke, *supra* note 137, at 1385.

information regarding the relevant product and geographic markets as well as complex economic analyses from both parties' experts.¹⁴¹ For these reasons, scholars often criticize the rule of reason.¹⁴² Plaintiffs' attorneys and some scholars have also decried the rule of reason review as a de facto rubber stamp for defendants.¹⁴³

In an effort to deal with these concerns as well as skepticism over courts' competency to deal with complex economic issues,¹⁴⁴ the Court has identified certain practices for which there is an irrebuttable presumption of anticompetitiveness.¹⁴⁵ These "per se" illegal activities include market allocation agreements,¹⁴⁶ bid rigging,¹⁴⁷ group boycotts,¹⁴⁸ and, of particular relevance to ACOs, horizontal price-fixing.¹⁴⁹ Unlike rule of reason analysis, if an activity is deemed per se illegal, it is irrelevant whether the defendants can put forth a procompetitive justification for the activity.¹⁵⁰ In *Maricopa*, the Supreme Court held that a horizontal agreement between nonintegrated physicians to set maximum prices constituted a per se violation of the Sherman Act.¹⁵¹ Since the late 1970s, however, the Court has narrowed the applicability of the per se rules in favor of expanded use of the rule of reason,¹⁵² suggesting that the *Maricopa* facts might receive different treatment by the current Court.

In addition to the two traditional standards of review, FTC, with at least some encouragement by the courts, has sought to develop a third standard of review—the "quick-look"—that lies somewhere between rule of reason and per se analysis.¹⁵³ Under this approach, certain concerted activities are deemed to be "inherently suspect"

141. *Maricopa*, 457 U.S. at 343; see Stucke, *supra* note 137, at 1384–86.

142. See, e.g., John J. Flynn, *The Role of Rules in Antitrust Analysis*, 2006 UTAH L. REV. 605, 634 (2006); Stucke, *supra* note 137, at 1387.

143. See, e.g., Stucke, *supra* note 137, at 1384 n.33.

144. *Id.* at 1399–1407.

145. *Burke & Rosenbaum*, *supra* note 127, at 168.

146. *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972).

147. *Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211, 236–38 (1899).

148. *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207, 211–12 (1959).

149. *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 212–13 (1940).

150. See *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 351 (1982) ("The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some.").

151. *Id.* at 332.

152. See Stucke, *supra* note 137, at 1407–10. For example, in *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, the Supreme Court held that all vertical restraints should be reviewed under the rule of reason, reversing prior case law treating certain vertical restraints such as resale price maintenance as per se unlawful. 551 U.S. 877, 907 (2007).

153. See Stucke, *supra* note 137, at 1410–15.

and thus presumptively anticompetitive, shifting the initial burden of proof to defendants to show an arrangement's procompetitive benefits.¹⁵⁴ However, due to lack of clarity on what activities warrant quick-look analysis, courts have been hesitant to widely apply the new test.¹⁵⁵

B. *The Guidelines*

In the face of substantial restructuring in the health care sector as a result of the rise of managed care, FTC and DOJ jointly issued the Guidelines in an effort to give market participants greater clarity about the agencies' opinion of the applicability of antitrust laws to a number of provider arrangements.¹⁵⁶ The agencies updated and expanded the Guidelines in 1994 and 1996,¹⁵⁷ but they have not revisited them since. While the Guidelines lack binding legal authority, some courts have viewed them as persuasive.¹⁵⁸ The Guidelines are also important because the vast majority of antitrust actions against provider networks over the last decade have been dealt with administratively by FTC, rather than in the courts.¹⁵⁹ The Guidelines are broken up into nine "Statements." The first seven statements deal with mergers and joint ventures involving hospitals; provider provision of fee- and non-fee-related information to health care services purchasers; provider exchanges of price and cost information; and joint purchasing arrangements among health care providers.¹⁶⁰ The final two statements, dealing with physician network joint ventures and multiprovider networks, are particularly relevant to ACOs.

154. *Id.* at 1410.

155. *Id.* at 1413–15. It is important to note, however, that the Fifth Circuit accepted FTC's use of the quick-look framework in *North Texas Specialty Physicians v. FTC*, which involved an FTC challenge to a collective bargaining agreement among physicians. 528 F.3d 346, 359–63 (5th Cir. 2008).

156. *Guidelines*, *supra* note 30, at 20,799.

157. *Id.*

158. See *Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1548–49 (11th Cir. 1996); *United States v. Health Choice of Nw. Mo., Inc.*, No. 95-6171-CVSJ6, 1996 WL 773322, at *10–11 nn.4–5 (W.D. Mo. Oct. 22, 1996); *United States v. HealthCare Partners, Inc.*, No. 395-CV-01946RNC, 1996 WL 193753, at *4 (D. Conn. Feb. 15, 1996).

159. Following a series of unsuccessful attempts by DOJ to challenge mergers in the health care sector, in recent years DOJ has been "reluctant" to bring health care antitrust cases to court. See Greaney, *supra* note 4, at 231. However, over the same time period, FTC has not been similarly reticent about bringing administrative antitrust actions against health care providers. For a list of such actions, see generally HEALTH CARE DIV., FED. TRADE COMM'N, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2010), available at <http://www.ftc.gov/bc/110120hcupdate.pdf>.

160. *Guidelines*, *supra* note 30, at 20,799.

Statement 8 deals with physician network joint ventures, defined as “physician-controlled venture[s] in which the network’s physician participants collectively agree on prices or price-related terms and jointly market their services.”¹⁶¹ Examples of physician network joint ventures include IPAs and PPOs.¹⁶² Absent the separate regulations set out in the ACO Statement, physician-only ACOs would be analyzed under Statement 8.

Statement 8 sets out a three-part process for assessing whether an arrangement will be subject to enforcement action by FTC or DOJ. First, the agencies will determine if the arrangement falls within one of two “antitrust safety zones.”¹⁶³ The first safety zone covers “exclusive” networks in which individual physician participants have little opportunity to affiliate or contract with other physician networks or health plans. The second safety zone covers non-exclusive networks where participants are able to affiliate or contract with other networks or health plans.¹⁶⁴ Statement 8 provides a number of “indicia of non-exclusivity,” such as physician member participation in other networks or managed care plans and the presence of other “viable competing networks or managed care plans” in the market.¹⁶⁵ An exclusive network falls into a safety zone if all of its physician participants “constitute 20 percent or less of the physicians in each physician specialty with active hospital staff privileges in the relevant geographic market.”¹⁶⁶ The agencies set a lower bar for nonexclusive networks, requiring physician participants constitute no more than thirty percent of the relevant market, as defined in the particular case.¹⁶⁷

In addition, to qualify for either safety zone, physician participants in the joint venture must bear “substantial financial risk” with regard to the services provided by the network.¹⁶⁸ Examples include capitated payment, as well as bonus-and-withholding programs tied to quality and cost-containment goals,¹⁶⁹ suggesting

161. *Id.* at 20,814.

162. *Id.* For a description of PPOs and IPAs, see *supra* notes 6, 118–22 and accompanying text.

163. *Guidelines*, *supra* note 30, at 20,815.

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.* at 20,815–16.

168. *Id.*

169. *Id.* at 20,816. Under capitation, which is the primary mechanism managed care uses to counteract the incentive for overutilization under fee-for-service, providers are paid a fixed amount to furnish a defined set of services to a patient or population of

that some form of two-sided risk sharing is necessary to satisfy the substantial financial risk requirement. The two-sided risk-sharing requirement mirrors the standard for treating a joint venture as a single economic entity for antitrust purposes set out in *Maricopa*.¹⁷⁰

Second, if the arrangement does not fall within a safety zone, the agencies will determine whether the arrangement is per se illegal or should be analyzed under the rule of reason. In order to avoid per se treatment, two criteria must be satisfied: (1) the network must involve “substantial” integration likely to produce procompetitive efficiencies and (2) joint contracting must be “subordinate and reasonably related to” achievement of these efficiencies.¹⁷¹ Integration can be demonstrated through (a) substantial financial risk sharing or (b) clinical integration.¹⁷² Substantial financial risk sharing, which the agencies say is a “reliable” indicator of an arrangement’s potential to achieve efficiencies, is defined the same way as it is for the purposes of the safety zones, requiring two-sided risk sharing.¹⁷³ The clinical integration prong, which was added as part of the 1996 revision to the Guidelines¹⁷⁴ and has been the subject of substantial scholarly debate,¹⁷⁵ also deals with the likelihood of the joint venture to produce significant procompetitive efficiencies.¹⁷⁶ Clinical integration can be evidenced by a program that demonstrates

a high degree of interdependence and cooperation among the [participating] physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to

patients. Robinson, *supra* note 44, at 149. Since capitated payments do not vary with services actually provided, providers have an incentive to ration care in order to maximize the difference between the payment they receive and the costs they incur in providing care. *Id.* For a discussion of bonus-and-withhold models, see *supra* note 64.

170. See *supra* note 135 and accompanying text.

171. See Letter from Markus H. Meier, Assistant Dir., FTC Bureau of Competition Health Care Div., to Christi J. Braun & John J. Miles, Ober, Kaler, Grimes, & Shriver 1 (Sept. 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf>.

172. *Guidelines*, *supra* note 30, at 20,817.

173. *Id.* at 20,816.

174. Scott D. Danzis, Note, *Revising the Revised Guidelines: Incentives, Clinically Integrated Physician Networks, and the Antitrust Laws*, 87 VA. L. REV. 531, 533–34 (2001).

175. Compare Burke & Rosenbaum, *supra* note 127, at 159, 163 (arguing that FTC and DOJ should offer broader antitrust protection for clinically integrated provider joint ventures), with Danzis, *supra* note 174, at 536–37 (recommending that the agencies’ favorable treatment of clinical integration under the revised guidelines be revisited).

176. *Guidelines*, *supra* note 30, at 20,817.

further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.¹⁷⁷

The agencies emphasize that other arrangements may also evidence clinical integration.¹⁷⁸

Finally, the agencies lay out a four-part test for applying the rule of reason in the context of physician network joint ventures. First, the agencies define the relevant product and geographic markets.¹⁷⁹ The second step involves an analysis of “the competitive effects of the physician [network] joint venture.”¹⁸⁰ Third, the agencies balance potential anticompetitive effects against any procompetitive efficiencies likely attributable to the joint venture.¹⁸¹ In the fourth and final step, the agencies consider the impact of the arrangement on collateral agreements by physicians within the network.¹⁸²

Physician network joint ventures are a subset of the arrangements covered by Statement 9, which deals with multiprovider networks.¹⁸³ As their name suggests, multiprovider networks differ from physician network joint ventures in that they can include non-physician providers such as hospitals and dentists.¹⁸⁴ Therefore, in the absence of the ACO Statement, ACOs that include hospitals would be reviewed under Statement 9.

Unlike with physician network joint ventures, Statement 9 does not establish antitrust safety zones for multiprovider networks. The agencies explain that “[b]ecause multiprovider networks involve a large variety of structures and relationships among many different types of health care providers, and new arrangements are continually developing, the Agencies are unable to establish a meaningful safety zone for these entities.”¹⁸⁵

Given this lack of a safety zone, the key antitrust determination for multiprovider networks is whether the entity is per se illegal or should be analyzed under the rule of reason. Multiprovider networks that exhibit (1) substantial integration—clinical or financial—and (2)

177. *Id.*

178. *Id.* at 20,817, 20,819.

179. *Id.* at 20,818.

180. *Id.* at 20,818–19.

181. *Id.* at 20,819.

182. *Id.*

183. *Id.* at 20,826 n.44.

184. *Id.*

185. *Id.* at 20,826.

demonstrate that joint negotiation is reasonably necessary to achieve this integration warrant rule of reason analysis.¹⁸⁶ As was the case for physician network joint ventures, substantial financial risk sharing exists if participants bear two-sided financial risk.¹⁸⁷ Statement 9 uses more general language than Statement 8 regarding what constitutes clinical integration, stating that as a result of the wide variety of multiprovider networks no specific guidance on clinical integration is possible.¹⁸⁸ Furthermore, “[t]he Agencies will consider the particular nature of the services provided by the network in assessing whether the network has the potential for producing efficiencies that warrant rule of reason treatment.”¹⁸⁹

The three-step rule of reason analysis for multiprovider organizations differs from the rule of reason analysis for physician network joint ventures in that it considers the competitive impact of both horizontal and vertical restraints. First, the agencies define the relevant product and geographic markets.¹⁹⁰ This process is substantially more complex for multiprovider networks than physician-only networks, requiring analysis of the individual services provided by the network, such as particular physician-member specialties and hospital services, as well as the market for the network itself.¹⁹¹ The second step, competitive analysis, is broken up into three prongs: (a) horizontal analysis, (b) vertical analysis, and (c) analysis of the potential impact of exclusion of particular providers or classes of providers.¹⁹² The horizontal analysis prong is similar to the competitive effects analysis for physician network joint ventures, examining the network’s market share in each area serviced by the network (which may include, among others, hospital services, individual physician specialties, primary care).¹⁹³ The vertical analysis

186. See Letter from David R. Pender, Acting Assistant Dir., FTC Bureau of Competition Health Care Servs. & Prods. Div., to Clifton E. Johnson & William H. Thompson, Hall, Render, Killian, Heath & Lyman 3 (Mar. 28, 2006), available at <http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf> (explaining per se treatment of joint price negotiation by members of PHO would only be avoided “if the competitive restraints were determined to be ‘ancillary’ to—i.e., related and subordinate to, and reasonably necessary to achieve the efficiencies of—some primary, potentially efficiency-enhancing economic integration among the joint venture’s participants”).

187. *Guidelines*, *supra* note 30, at 20,827.

188. *Id.*

189. *Id.*

190. *Id.* at 20,828.

191. *Id.*

192. *Id.* at 20,828–30.

193. *Id.* at 20,828–29.

prong is designed to assess whether one network participant's market power will have anticompetitive effects in the relevant markets for other network participants.¹⁹⁴ The final step involves a balancing of anticompetitive effects against any procompetitive efficiencies.¹⁹⁵

C. *The Statement of Antitrust Enforcement Policy for ACOs*

The ACO Statement, which outlines antitrust enforcement policy for commercial ACOs that also participate in the Shared Savings Program, incorporates many of the concepts outlined in the Guidelines, but it also differs in certain key ways. As many observers expected,¹⁹⁶ an ACO that “meets CMS’s eligibility requirements for, and participates in, the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in commercial markets” will be subject to rule of reason treatment.¹⁹⁷ The ACO Statement says that the rule of reason is appropriate because CMS’ proposed eligibility criteria for Medicare ACOs are “broadly consistent with the indicia of clinical integration . . . set forth in the [Guidelines].”¹⁹⁸ Moreover, the clinical integration required to participate in the Medicare ACO program is sufficiently robust that the agencies “will treat joint negotiations with private payers as reasonably necessary to an ACO’s primary purpose of improving health care delivery.”¹⁹⁹

The level of scrutiny that a commercial ACO satisfying the Shared Savings Program participation criteria will receive depends on the ACO’s share of its participant’s primary service areas (“PSA”).²⁰⁰

194. *Id.* at 20,829–30.

195. *Id.* at 20,830.

196. *See, e.g.*, Thomas L. Greaney, Chester A. Myers Professor & Co-Dir. of the Ctr. for Health Care Studies at Saint Louis Univ. Sch. of Law, Comments to the Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physicians Self-Referral, Anti-Kickback and Civil Monetary Penalty Laws 1 (Sept. 27, 2010), available at <http://www.ftc.gov/os/comments/aco/100927greaney.pdf> (“[T]he requirements of the Shared Savings Program closely parallel the standard for meaningful clinical integration under antitrust law.”).

197. ACO Statement, *supra* note 24, at 67,028.

198. *Id.* at 67,027.

199. *Id.* at 67,028.

200. PSAs are not a new concept; CMS first introduced PSAs in the second phase of its regulations implementing the physician self-referral, or “Stark” law, which prohibits physicians from making referrals to entities with which they have a financial relationship. *See Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, 76 Fed. Reg. 21,894, 21,899 n.42 (Apr. 19, 2011) [hereinafter Proposed Statement].

The ACO Statement defines a PSA “as the lowest number of postal zip codes from which [an ACO] participant draws at least 75 percent of its patients.”²⁰¹ While noting that PSAs do not constitute a formal geographic market, the agencies state that PSAs are a useful tool to gauge the competitive risk posed by an ACO.²⁰²

PSAs are calculated in a three-step process. First, the agencies will identify each service offered by a least two independent participants in the ACO.²⁰³ For physicians, a service is defined as the physician participant’s primary specialty.²⁰⁴ For inpatient and outpatient treatment facilities, service lines are defined using preexisting CMS billing categories such as cardiac care or musculoskeletal procedures.²⁰⁵ Second, the agencies will determine the PSA for each service offered by two or more participants in the ACO.²⁰⁶ Third, the agencies will calculate the ACO’s share in each PSA for each service offered by more than two participants in the ACO.²⁰⁷ PSA shares for physician services are calculated by looking at the total Medicare fee-for-service allowed charges.²⁰⁸ Outpatient service shares are calculated using Medicare fee-for-service payments during the most recent calendar year, and inpatient service shares are calculated using state-level all-payer hospital discharge data.²⁰⁹

Depending on its PSA shares, an ACO will fall into one of two antitrust review categories. ACOs that have PSA shares thirty percent or less for each service provided by two or more ACO participants will fall into a safety zone and will not be scrutinized by FTC or DOJ.²¹⁰ Importantly, in order for an ACO to qualify for the safety zone, hospitals and ambulatory surgery centers must be nonexclusive to the ACO, regardless of PSA share.²¹¹ The

201. ACO Statement, *supra* note 24, at 67,031.

202. *Id.* at 67,028.

203. *Id.* at 67,031.

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.* One potential drawback to using Medicare claims information to calculate PSA shares for physician and outpatient services is that there are likely geographic consumption differences between the Medicare and non-Medicare populations. For example, Medicare patients, who are older, may be less willing to travel long distances to access health care services than non-Medicare patients. Moreover, share information may also be skewed by the fact that Medicare patients use a different mix of services than non-Medicare patients. See Judith R. Lave et al., *Costing Medical Care: Using Medicare Administrative Data*, 32 MED. CARE (Supp.) JS77, JS80 (1994).

210. ACO Statement, *supra* note 24, at 67,028.

211. *Id.* at 67,028–29.

nonexclusivity requirement means that hospital and ambulatory surgical center ACO participants must retain the right to contract with payers independently or through another provider group or ACO.²¹² The ACO Statement notes that “the indicia of non-exclusivity” set out in the Guidelines will be used to determine whether an ACO participant is in fact nonexclusive.²¹³ By comparison, the Shared Savings Program Rule requires primary care ACO participants to be exclusive to one ACO.²¹⁴

ACOs with PSA shares exceeding thirty percent in some service areas will be subject to standard rule of reason review, with the agencies bringing an antitrust enforcement action if the ACO’s anticompetitive effects exceed its potential to generate efficiencies.²¹⁵ The ACO Statement identifies four particular types of conduct that will warrant scrutiny for ACOs in this category: (1) preventing payers from incentivizing enrollees to choose certain providers; (2) tying sales of ACO services to purchase of services of affiliated providers outside the ACO; (3) exclusive contracting among ACO participants, with the exception of primary care physicians; and (4) restricting a payer’s ability to make cost, quality, and efficiency data available to its enrollees.²¹⁶ The agencies also note that regardless of PSA share, ACOs should not share competitively sensitive information such as pricing data among their members.²¹⁷

212. *Id.* at 67,028.

213. *Id.* at 67,028 n.30.

214. *See supra* notes 97–99 and accompanying text.

215. ACO Statement, *supra* note 24, at 67,027, 67,029.

216. *Id.* at 67,029–30.

217. *Id.* at 67,029.

Table 2: Antitrust Review Standards for Provider Networks under the Guidelines and for Accountable Care Organizations under the ACO Statement

	Guidelines	ACO Statement
Requirements for receiving rule of reason review	Clinical integration or financial integration	Satisfaction of Medicare Shared Savings Program participation requirements
Safety zone for physician-only networks	Yes, with clinical integration, financial integration, and market share limitations	Yes, with satisfaction of Shared Savings Program participation requirements and market share limitations (no financial integration requirement)
Safety zone for physician-hospital networks	No	Yes, in addition to satisfying physician ACO safety zone requirements, hospital members must be non-exclusive to the ACO
Market share caps to fall under safety zone	Twenty percent market share limit for networks with exclusive members, thirty percent market share limit for non-exclusive networks	Thirty percent PSA share limit, regardless of whether members are exclusive or non-exclusive

III. ASSESSING WHETHER HOSPITAL ACOS SHOULD FACE HEIGHTENED ANTITRUST REVIEW

As the analysis in Part II demonstrates, the antitrust enforcement environment for provider networks participating in the Shared Savings Program is significantly less burdensome under the ACO Statement than the Guidelines.²¹⁸ For example, in order to qualify for the physician-network joint venture safety zone under the Guidelines, physician networks must engage in two-sided financial risk sharing—a requirement not present under the ACO Statement. Similarly,

218. See *supra* Table 2 (comparing key provisions of the *Guidelines*, *supra* note 30, and the ACO Statement, *supra* note 24).

exclusive physician-only ACOs are subject to a more relaxed enforcement environment under the ACO Statement, facing a thirty percent market share cap to qualify for the safety zone, rather than the twenty percent share cap under the Guidelines.

FTC and DOJ's less rigorous approach to antitrust enforcement is particularly apparent in the context of hospital ACOs—the focus of this Comment. Whereas the Guidelines do not include an antitrust safety zone for provider networks that include hospitals, the ACO Statement does provide one. With the exception of the nonexclusivity requirement for hospitals and ambulatory surgical centers, the conditions for qualifying for the safety zone are equivalent for physician-only ACOs and hospital ACOs. While this Comment applauds FTC and DOJ's decision to extend the safety zone to ACOs that include hospitals, it also argues that the conditions for qualifying for the safety zone are insufficiently robust to address the unique competitive risks posed by hospital ACOs relative to physician ACOs. In particular, hospital ACOs should be required to engage in two-sided financial risk sharing in order to qualify for the safety zone. This added requirement is necessary to ensure that hospital ACOs consistently drive sufficient efficiencies to outweigh potential competitive harms associated with joint price negotiation.

Before arguing that FTC and DOJ have gone too far in relaxing their antitrust review standards for hospital ACOs, it is useful to consider some arguments for and against heightened antitrust review standards for ACOs that include hospitals.

A. Reasons for Establishing Higher Antitrust Barriers for Hospital ACOs

One reason ACOs that include hospitals pose greater competitive risk and thus warrant differential treatment is that the hospital market is generally far more concentrated than other provider markets.²¹⁹ In response to reimbursement pressures accompanying the rise of managed care, more than 900 hospitals merged between 1994 and 2000.²²⁰ This consolidation was only exacerbated by FTC and DOJ's reluctance to challenge hospital mergers following a series of failed enforcement efforts.²²¹ As a result of this wave of consolidation, over ninety percent of the nation's

219. See Greaney, *supra* note 4, at 231–35.

220. Gaynor, *supra* note 48.

221. See Greaney, *supra* note 4, at 231.

population lived in concentrated hospital markets by 2003.²²² Moreover, there are already anecdotal reports that new market pressures created by PPACA are driving a second wave of consolidation in the hospital sector.²²³ This consolidation has been shown to have significant anticompetitive effects, with hospitals in concentrated markets able to negotiate substantial price increases.²²⁴ These adverse price consequences are only exacerbated when the formation of hospital systems allows the systems to leverage a “flagship” or “must-have” hospital “to obtain higher payment rates for all hospitals in the system, including those that would not have such status as independent hospitals.”²²⁵ These price increases have occurred in the absence of evidence of any significant scale economies or other efficiencies.²²⁶ Evidence also suggests that hospital consolidation has, at best, a neutral impact on quality, and, at worst, a negative impact on quality.²²⁷

While the hospital market has become highly concentrated, the physician market has remained largely fragmented. There was a trend toward consolidation among physicians into large multispecialty groups and IPAs during the rise of managed care, but the number of such organizations has been in decline since managed care plans lost popularity,²²⁸ with physicians shifting into “mid-size, single-specialty groups.”²²⁹ As of 2008, “[t]wo thirds of all physicians . . . practice in

222. *Id.*

223. See Pear, *supra* note 20; see also Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 844 (2011) (“[T]he path of ACO development could prove profoundly anticompetitive. One concern flows from what might come to be called the ‘2010 Health Reform Merger Wave’—a rush to consolidation induced in part by hospitals and physicians wanting to be assured they will be in a strong bargaining position.”).

224. See Berenson et al., *supra* note 21, at 699, 702; Gaynor, *supra* note 48 (noting that price increases due to hospital consolidation range from five percent to fifty percent depending on the level of concentration in the market). See generally Martin Gaynor & Deborah Haas-Wilson, *Change, Consolidation, and Competition in Health Care Markets*, 13 J. ECON. PERSP. 141, 152 (1999) (reviewing the economic literature on the price and quality consequences of hospital consolidation); William B. Vogt & Robert Town, *How Has Hospital Consolidation Affected the Price and Quality of Hospital Care?*, *Research Synthesis Report No. 9*, ROBERT WOOD JOHNSON FOUND. (Feb. 2006), http://www.rwjf.org/pr/synthesis/reports_and_briefs/pdf/no9_researchreport.pdf (assessing the likely effects of hospital consolidation on prices, costs, and quality of healthcare).

225. Berenson et al., *supra* note 21, at 702.

226. Greaney, *supra* note 4, at 231.

227. Gaynor, *supra* note 48 (stating that evidence regarding the impact of consolidation on quality is “less firm than for price,” but “[o]n balance, evidence suggests consolidation lowers quality”).

228. Casalino, *supra* note 7, at 573.

229. Greaney, *supra* note 4, at 234.

groups of fifty or fewer, and one-third work either solo or in a practice of two.”²³⁰ Commentators attribute this continuing fragmentation to uncertainty over the legal viability of nonrisk-bearing clinically integrated networks, lack of financial incentives to spur integration, the desire of physicians to maintain their independence,²³¹ and market failures in the health care delivery system.²³²

A second reason hospital ACOs raise more competitive concerns than physician ACOs is that there would be less horizontal competition in the provider market if hospitals and physicians jointly form ACOs. Historically, there was little direct competition between hospitals and physicians, with hospitals acting as the “workshop” where physicians practiced.²³³ However, in recent years, direct competition between hospitals and physicians has become far more prevalent.²³⁴ Hospitals have entered into the physician services market through the purchase of physician practices.²³⁵ Similarly, physicians have entered into product areas traditionally controlled by hospitals through the development of physician-owned diagnostic and ambulatory surgical centers.²³⁶ This trend toward increased competition between physicians and hospitals, which could be reversed if physicians and hospitals jointly form ACOs, positively affects cost and quality.²³⁷ FTC’s recent challenge of the hospital system Carilion Clinic’s acquisition of physician-owned outpatient imaging and surgical centers indicates that the agency is concerned by

230. Burke & Rosenbaum, *supra* note 127, at 153–54.

231. Casalino, *supra* note 7, at 573–75.

232. See Greaney, *supra* note 223, at 817–20. For example, information asymmetries between providers and patients make it difficult for patients to factor quality into their health care consumption decisions, limiting quality competition between providers. Were providers to compete on quality, there would be a market incentive to collaborate to improve care.

233. See James F. Blumstein, *Of Doctors and Hospitals: Setting the Analytical Framework for Managing and Regulating the Relationship*, 4 IND. HEALTH L. REV. 211, 213 (2007).

234. See *supra* note 9 and accompanying text.

235. Goldsmith, *supra* note 5, at 33.

236. See *id.* at 34.

237. See, e.g., Complaint at 6, Carilion Clinic, F.T.C. File No. 081-0259 (July 23, 2009), 2009 WL 2251279 at *5, available at <http://www.ftc.gov/os/adjpro/d9338/090724carilioncmpt.pdf> (“[C]ompetition from [physician-owned imaging and surgical centers] spurred [hospital system] Carilion to improve the quality, services, and amenities at its own outpatient facilities, to the benefit of consumers . . .”).

agreements that curtail this trend toward increased direct competition between hospitals and physicians.²³⁸

Third, hospital ACOs deserve heightened antitrust scrutiny due to the unique concerns posed by vertical integration. Vertical analysis is necessary when hospital-physician ventures cover services in practice areas in which hospitals and physicians generally do not directly compete, particularly hospital-based services such as anesthesiology, radiology, and pathology.²³⁹ While antitrust regulators have traditionally focused more on concerns posed by horizontal integration,²⁴⁰ vertical integration among providers also raises substantial competitive issues.²⁴¹ There is substantial risk that since the hospital market is more concentrated, and thus less competitive than the physician market, “doctors may acquire market power by integrating with a hospital.”²⁴² As one payer explains:

[W]e have to be particularly attentive to the circumstances of markets in which there are dominant hospitals, which are likely to be the primary sources of aggregation into ACO kinds of structures. . . . [T]he potential to have the market forces create a kind of centrifugal force around hospitals that already have dominant market positions, where the impact of further aggregation and the aggregation of physicians and other kinds of entities, into a single entity around those hospitals . . . in the commercial market, that is a terrible threat.²⁴³

In fact, there is already anecdotal evidence from California of physicians leveraging hospitals’ market power to negotiate higher reimbursement rates.²⁴⁴ A second competitive concern with vertical integration among physicians and hospitals is that more hospitals will deny privileges to physicians with whom they are not aligned.²⁴⁵ This denial of privileges could deter entry of competitor ACOs,

238. *See id.* at *7. Carilion’s acquisition of the physician-owned facilities would have reduced the number of competitors in the market from three to two. *Id.* at *5.

239. *See Park, supra* note 115, at 1702.

240. *See id.*

241. *See Gaynor, supra* note 48.

242. *Id.*

243. Elizabeth Gilbertson, Chief of Strategy, Hotel Emp. & Rest. Emp. Int’l Union, Remarks at ACO Workshop, *supra* note 23, at 38.

244. Berenson et al., *supra* note 21, at 703 (quoting a benefit consultant as stating that “Sutter [hospital system] has figured out a way to lock physicians into their hospitals to allow physicians to piggyback on Sutter’s negotiating leverage”).

245. *See* Mark L. Mattioli, *Can Preventing Diversion of Profitable Patients Justify Hospitals’ Economic Credentialing Under the Antitrust Laws*, J. HEALTH & LIFE SCI. L., Apr. 2008, at 39, 42–43.

particularly physician-only ACOs. There are a number of theoretical efficiencies with vertical integration between physicians and hospitals, including cost and quality improvements through more coordinated care and reduced transaction costs. However, empirical efforts have failed to reveal cost savings or quality improvements resulting from these potential efficiencies in practice.²⁴⁶

A final argument in favor of creating heightened regulatory barriers for hospital ACOs is that, absent such restrictions, hospitals will become the dominant players in the provider marketplace.²⁴⁷ The primary reason for this concern is that hospitals' incentives to maintain inpatient volume may be at odds with the efficiency goals of ACOs.²⁴⁸ This concern was borne out in the results of CMS' Physician Group Practice demonstration project, where participating entities closely affiliated with hospitals, though not academic medical centers, failed to earn performance payments for decreasing expenditures.²⁴⁹ In fact, for the project as a whole, most savings accrued in the outpatient rather than inpatient settings.²⁵⁰ This may reflect that "the presence of a hospital was a potential deterrent to achieving savings . . . since these systems may be unable to reduce avoidable admissions or use lower cost care substitutes without affecting their inpatient revenue."²⁵¹ A second, related concern is that past hospital efforts to merge with physicians have "incurred catastrophic economic losses" due to "inadequate resources and weak governance."²⁵² If similar losses occur as a result of the move toward formation of hospital ACOs, a hospital may look to offset these losses "through horizontal mergers with other hospitals, to become sufficiently dominant in its market to force private insurers to pay higher rates not only for the hospital's services but also for those of its physician employees."²⁵³

246. See Gaynor, *supra* note 48 (stating that empirical work shows that hospital-physician integration has "no impact" on costs and "mixed results" on quality).

247. See Goldsmith, *supra* note 5, at 33-34; see also Lawrence P. Casalino, Livingston Farrund Professor of Pub. Health & Chief, Div. of Outcomes and Effectiveness Research, Dep't of Pub. Health, Weill Cornell Med. Coll., Remarks at ACO Workshop, *supra* note 23, at 74 ("[T]here's a lot of reasons to be concerned about a system that would be basically dominated by hospitals with their physicians employed.").

248. See Shortell et al., *supra* note 18, at 1294 ("The typical hospital business model today is based on generating net income from the inpatient margin—in other words, total payments for inpatient care minus the costs of inpatient treatment.").

249. Iglehart, *supra* note 66, at 200.

250. *Id.*

251. *Id.* (internal quotation marks omitted).

252. See Goldsmith, *supra* note 5, at 33-34.

253. *Id.* at 34.

B. Reasons for Not Establishing Higher Antitrust Barriers for Hospital ACOs

There are also at least three reasons for not subjecting hospital ACOs to more stringent antitrust review. Most significantly, hospitals have access to financial resources and administrative expertise critical to formation of ACOs. Establishing an ACO will require participants “to make sizable investments . . . in consulting services, new information technology, utilization management tools, and management support.”²⁵⁴ Given the substantial fragmentation in the physician marketplace, with most physicians continuing to practice independently or in small groups,²⁵⁵ physicians are unlikely to raise enough capital to cover the up-front costs required to form an ACO.²⁵⁶ In addition, establishing and running an ACO will likely require significant expertise in managing and operating a large provider system, a skill set that a hospital system is more likely to have than independent physicians or small physician groups.²⁵⁷ Consequently, as one observer has noted, “in many communities, the hospital is the only organized care delivery entity capable of executing the [ACO] model.”²⁵⁸

A second argument against creating a heightened regulatory standard for hospital ACOs is that hospitals are arguably the most promising vehicle for generating savings in the health care system.²⁵⁹ There are two primary ways to drive savings in hospital services expenditures: decreasing the number of hospital admissions (the extensive margin) and decreasing the costs of care while patients are in hospitals (the intensive margin). Research suggests that limiting unnecessary hospital readmissions—when a patient is rehospitalized soon after being discharged—could save the Medicare program seventeen billion dollars per year alone.²⁶⁰ While most care that

254. *Id.* at 33–34.

255. *See supra* notes 228–32 and accompanying text.

256. The need for substantial up-front investment has been identified as a primary cause of the slow uptake of health information technology by physicians. Cecil B. Wilson, President, Am. Med. Ass’n, Remarks at ACO Workshop, *supra* note 23, at 62.

257. *Cf.* Robert Kocher & Nikhil R. Sahni, *Physicians Versus Hospitals as Leaders of Accountable Care Organizations*, 363 NEW ENG. J. MED. 2579, 2580 (2010) (“[P]hysicians have seldom demonstrated the ability to effectively organize themselves into groups, agree on clinical guidelines, and devise ways to equitably distribute money.”).

258. Goldsmith, *supra* note 5, at 33.

259. *See supra* note 50 and accompanying text.

260. Stephen F. Jencks, Mark V. Williams & Eric A. Coleman, *Rehospitalizations Among Patients in the Medicare Fee-for-Service Program*, 360 NEW ENG. J. MED. 1418, 1426 (2009).

prevents readmissions occurs outside of the hospital, hospitals can still play an important role in preventing readmissions²⁶¹ by providing better education to discharged patients and facilitating the smooth transition of discharged patients to outpatient physicians.²⁶² However, under the current payment framework, hospitals have little incentive to take additional steps to prevent readmissions because their revenue increases with the number of episodes of care.²⁶³ In-hospital care costs can be reduced by eliminating provision of duplicative services, such as imaging, and by preventing costly medical errors.²⁶⁴ Shifting to a shared savings payment model will allow hospitals to capture some of their lost revenue due to less hospital intensive care, potentially making them more amenable to actively participating in—or at least not undermining—cost-saving efforts. While physician-only ACOs may be able to reduce hospital expenditures by limiting unnecessary admissions, if antitrust barriers for hospital ACOs are set too high, hospitals may try to recoup revenue losses attributable to physician ACOs by purchasing physician practices, further enhancing hospitals' market power.²⁶⁵

A final reason that hospitals may not warrant differential treatment is that in certain areas, the market power of hospitals is not materially different than that of highly sought-after physician groups.²⁶⁶ While cases where physician groups have equivalent market

261. *Id.* at 1427.

262. *Cf.* Eric A. Coleman et al., *The Care Transitions Intervention: Results of a Randomized Controlled Trial*, 166 ARCHIVES INTERNAL MED. 1822, 1826 (2006) (finding that improved patient discharge instructions and facilitation of patient transition to outpatient treatment reduces rehospitalizations).

263. Reed Abelson, *Hospitals Pay for Cutting Costly Readmissions*, N.Y. TIMES, May 9, 2009, at B1.

264. *See supra* notes 2–3 and accompanying text.

265. This risk speaks to the difficult balancing act facing antitrust regulators. If hospitals are given relatively wide latitude to participate in ACOs, there is an incentive for additional consolidation among and between hospitals and physicians in order to increase bargaining leverage. On the other hand, if hospitals are excluded from participation and face revenue losses due to decreased patient volume, they are likely to merge with other hospitals or acquire physician groups to make up for these losses through new revenue streams and higher prices generated through greater bargaining power. For this reason, one commentator has suggested that further provider consolidation as a result of PPACA is unavoidable. *See* Lawrence Casalino, Livingston Farrund Professor of Pub. Health & Chief, Div. of Outcomes and Effectiveness Research, Dep't of Pub. Health, Weill Cornell Med. Coll., Remarks at ACO Workshop, *supra* note 23, at 74 (noting that the move of physicians into larger provider organizations is “happening very, very quickly and there's no question that the ACO phenomenon will accelerate that”).

266. *See* Berenson et al., *supra* note 21, at 703 (citing Brown & Toland and Hill Physicians as two San Francisco Bay Area IPAs that have substantial market power).

power to hospitals are in the minority,²⁶⁷ it may not make sense to subject hospitals to more stringent review when their market power is not materially different than that of certain groups of physicians. A corollary to this argument is that even if hospitals are unable to participate in ACOs due to high entry barriers, physician ACOs that include the vast majority of physicians that practice at a “must-have” hospital can still leverage the market power of the hospital without being formally aligned with the hospital.²⁶⁸

C. *Safety Zone Requirements Insufficiently Robust for Hospital ACOs*

The above discussion demonstrates that there are both benefits and risks to encouraging hospital participation in ACOs. An ideal antitrust safety zone would mitigate the unique risks with hospital participation in ACOs without materially undermining any associated benefits. This Comment argues that while their unique benefits warrant extension of the antitrust safety zone to hospital ACOs, the requirements for the safety zone set out in the ACO Statement are insufficiently robust to address their unique risks.

Before discussing the weaknesses of the safety zone, it is first worth noting that the current safety zone goes a long way toward minimizing competitive risks of hospital participation in ACOs. The market share component, which requires that ACOs have less than a thirty percent share in each PSA, addresses the hospital market concentration, horizontal integration, and vertical integration concerns. Including a market share limitation is necessary to ensure that ACO participants are unable to exercise substantial market power. Any ACO market share limitation must balance two competing interests: ensuring the ACO is large enough to allow for robust performance measurement while still being small enough to prevent the ACO from exercising too much market power. ACOs are statutorily required to have sufficient primary care physicians to support five thousand beneficiaries.²⁶⁹ However, depending on what type of performance measures are used, even larger beneficiary

267. See Robert Galvin, CEO, Equity Healthcare, Remarks at ACO Workshop, *supra* note 23, at 66 (stating hospitals are usually the primary cause of price increases, but in some markets dominant groups of specialists or primary care doctors also have substantial market power).

268. Cf. Berenson et al., *supra* note 21, at 703 (noting insurers have found that even in the absence of a formal negotiating structure, “certain physician groups ‘look like they are owned’ by hospitals”).

269. See 42 U.S.C.A. § 1395jjj(b)(2)(D) (West Supp. 2011).

populations may be necessary.²⁷⁰ On the other hand, it is important for the safety zone market share cap to be set sufficiently low so that ACOs are unable to negotiate substantial price increases or deter entry of competitors. While setting an exact threshold is difficult in the absence of market experience with ACOs, the thirty percent threshold used in the ACO Statement, which is in line with the threshold for nonexclusive physician networks under the Guidelines, is a reasonable starting point.

Determination of a relevant market requires characterizing both geographic and product markets. The Supreme Court has defined a geographic market as the “area of effective competition . . . in which the seller operates, and to which the purchaser can practicably turn for supplies.”²⁷¹ As is the case with many industries, regulators and courts have historically had difficulty defining geographic markets for health care services, particularly physician and hospital services.²⁷² The primary advantage of using PSAs, as required by the ACO Statement, is that PSAs inherently include most reasonable geographic substitutes for services provided by ACO participants—those other providers to whom patients could “practicably turn”—because PSAs reflect all those providers from whom most patients in a particular area have in fact sought services. The requirement that ACOs satisfy the market share limitation in each product market also minimizes vertical integration concerns by preventing ACOs from leveraging market power in one product market to gain higher payment rates in other product markets. This will ensure adequate competition in markets where physicians compete amongst themselves and where physicians compete with hospitals. Establishing market share limitations may also prove beneficial in deterring further consolidation in provider markets because providers will have

270. See Gloria Austin, CEO, Brown & Toland, Remarks at ACO Workshop, *supra* note 23, at 63 (stating that ten thousand beneficiaries may be needed for performance measurement purposes); Lawrence Casalino, Livingston Farrund Professor of Pub. Health & Chief, Div. of Outcomes and Effectiveness Research, Dep’t of Pub. Health, Weill Cornell Med. Coll., Remarks at ACO Workshop, *supra* note 23, at 63 (stating that five thousand beneficiaries would be insufficient for reliable hospital readmissions measurement).

271. *United States v. Phila. Nat’l Bank*, 374 U.S. 321, 359 (1963) (quoting *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961)).

272. See Thomas L. Greaney, *Chicago’s Procrustean Bed: Applying Antitrust Law in Health Care*, 71 ANTITRUST L.J. 857, 869–79 (2004) (describing the difficulties of geographic market analysis in health care); see also Adams & McChesney, *supra* note 118, 787–90 (recommending a framework for FTC to use in determining the geographic market for IPAs).

an incentive to keep their shares below the cap in order to avoid increasing their antitrust liability risk.

The nonexclusivity requirement, which is the only safety zone requirement addressing the unique risks posed by hospital ACOs, also helps mitigate the risks posed by concentration in the hospital marketplace and concerns related to vertical integration—the potential for an exclusive hospital member to translate its market power to other ACO members. ACOs with exclusive hospital members would have significantly greater market power because insurers could not contract with the hospitals directly if they felt the ACO was seeking unreasonable payment rates.²⁷³ Exclusivity would also force insurers to contract with all ACO participants, even if the insurer only needed access to a specialized service offered by one member.²⁷⁴ This concern is particularly salient with hospitals given the large number of specialized services offered and the high degree of concentration in the hospital sector. Finally, exclusivity can create barriers to entry of competitor ACOs because an incumbent ACO may have already reached an exclusive agreement with a provider that offers a unique and necessary service.

While the market share and nonexclusivity requirements deal with the concentration, horizontal integration, and vertical integration concerns, they fail to address the fourth major risk associated with hospital participation in ACOs: the potential for ACOs to turn hospitals into the dominant entities in the provider marketplace. As explained above, the basis of this concern is that ACOs are primarily expected to generate savings through lowering hospital services expenditures. Consequently, an ACO in which a hospital plays a dominant role may lack incentives to pursue cost savings, since any savings would likely come from the hospital's bottom line—a concern borne out in the results of the Physician Group Practice demonstration project.²⁷⁵ This same concern is not present with physician-only ACOs, since they can drive savings for their patient population through less hospital care without an

273. See Susan DeSanti, Dir., FTC Office of Policy & Planning, Remarks at ACO Workshop, *supra* note 23, at 79–80.

274. Cf. Berenson et al., *supra* note 21, at 702 (providing examples of hospital systems using unique services offered by one member medical center to negotiate higher rates for the entire hospital system).

275. See *supra* notes 249–51 and accompanying text.

associated decline in the volume of services rendered by their members.²⁷⁶

Adding a two-sided financial risk-sharing component to the safety zone for hospital ACOs would effectively address this fourth concern. Requiring two-sided financial risk sharing is important for two reasons: (1) it clearly evidences participants' intent to create efficiencies through integration and (2) it has a demonstrable record of driving efficiencies through decreased utilization and less hospital intensive care. With regard to the first reason, two-sided financial risk sharing is important because, as recognized by the Supreme Court in *Maricopa*²⁷⁷ and FTC and DOJ in the Guidelines,²⁷⁸ it demonstrates that parties to a joint venture have committed to act as a single economic agent and thus should be immune from Sherman Act Section 1 liability. In the context of hospital ACOs, two-sided financial risk sharing also mitigates concerns about positioning hospitals as the dominant player in the provider market because it ensures alignment of hospital and physician utilization incentives, which, as discussed above, are normally divergent.²⁷⁹ With the threat of reimbursement cuts if costs exceed expectations, hospitals would have a strong incentive to work with physician ACO members to contain costs.

Two-sided financial risk sharing is also more effective at driving efficiencies than one-sided risk-sharing payment methods like shared savings. As explained above, most providers in ACOs will be primarily reimbursed on a fee-for-service basis—a payment methodology that can drive providers to overutilize by rendering or prescribing unnecessary and costly treatment.²⁸⁰ While less troubling than pure fee-for-service reimbursement, one-sided risk-sharing systems are problematic because they raise greater overutilization concerns than two-sided risk-sharing systems since the lack of downside risk dulls disincentives against overutilization.²⁸¹ This is because risk-averse individuals “tend to be more concerned about

276. See Kocher & Sahni, *supra* note 257, at 2582 (predicting that if physicians “dominate” ACOs, hospitals will have fewer patients and lower revenue).

277. See *supra* note 135 and accompanying text.

278. See *supra* notes 168–70 and accompanying text.

279. See *supra* notes 44–46 and accompanying text.

280. See Blumstein, *supra* note 45, at 209.

281. See Saver, *supra* note 10, at 207; see also Greaney, *supra* note 196, at 2 (“Looking at the nation’s experience with preferred provider organizations, it is far from clear that the shared savings bonus model will effectively counteract the volume-increasing incentives of fee-for-service payment.”).

losing something of value than gaining the equivalent amount.”²⁸² For this reason, it is unlikely that ACOs that only use one-sided risk sharing will significantly lower health care expenditures because ACO participants will only restrain their utilization to the extent that their shared savings payments exceed the expected returns to overutilization.²⁸³ On the other hand, payment systems that involve two-sided risk sharing, such as capitation and bonus-and-withhold systems, have been shown in a variety of studies to decrease utilization and expenditures.²⁸⁴ For this reason, commentators, including some of the strongest proponents of ACOs, have suggested that CMS use regulatory incentives to encourage ACOs to engage in two-sided financial risk sharing.²⁸⁵

As explained above, rule of reason review attempts to determine whether the procompetitive efficiencies generated by a given restraint outweigh any associated anticompetitive effects.²⁸⁶ In establishing a safety zone from antitrust enforcement, FTC and DOJ are effectively determining that the procompetitive benefits of ACOs satisfying the safety zone requirements presumptively outweigh the harm to competition associated with allowing ACO members to jointly negotiate over price. Given that hospital ACOs pose greater risk of competitive harm than physician-only ACOs, FTC and DOJ should impose additional safety zone requirements for hospital ACOs in order to offset the additional risk of competitive harm. As the agencies say in the ACO Statement, “[t]he greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws.”²⁸⁷ With its

282. Saver, *supra* note 10, at 207.

283. More specifically, a rational provider would only restrain utilization if $R_L + E/S_L \geq R_H$, where, for a given stream of patients, R_L is the provider's reimbursement for a low utilization level, E/S_L is the provider's expected shared savings payment at the low utilization level, and R_H is the provider's reimbursement for a high utilization level.

284. See Manning et al., *supra* note 49, at 265–66. See generally Fred J. Hellinger, *The Impact of Financial Incentives on Physician Behavior in Managed Care Plans: A Review of the Evidence*, 53 MED. CARE RES. & REV. 294, 311 (1996) (reviewing the literature on the impact of managed care on utilization and finding that financial incentives for providers—primarily capitation—are a “key element” in managed care's success at controlling utilization).

285. See McClellan et al., *supra* note 13, at 990 n.5 (“[I]t may be advisable to encourage one-sided bonus models (such as shared savings) that transition over time towards models with greater accountability for costs and quality.”); Shortell et al., *supra* note 18, at 1295–96 (recommending that CMS adopt “tiered” payment structure for ACOs, under which ACOs that bear greater downside risk receive a larger portion of any savings to Medicare).

286. See *supra* notes 137–43 and accompanying text.

287. ACO Statement, *supra* note 24, at 67,027.

demonstrable record of decreasing utilization and expenditures, two-sided financial risk sharing is precisely such a requirement.

The key outstanding question, then, is whether the addition of a two-sided financial risk-sharing requirement would materially undermine the unique benefits of hospital participation in ACOs. The most significant concern is that the addition of a two-sided risk-sharing requirement would deter hospitals from participating in the ACO program and thus deprive prospective ACOs of hospitals' financial resources and administrative expertise. However, a financial integration requirement is unlikely to significantly deter hospital participation in ACOs for at least three reasons. First, hospitals have experience bearing limited risk under the current prospective payment system and thus have already implemented clinical and administrative practices necessary to operate profitably under such systems.²⁸⁸ This experience with risk bearing is a result of one of the two incentives created by prospective payment. While prospective payment creates a volume incentive for hospitals on the extensive margin, it also drives hospitals to control utilization on the intensive margin because they bear the risk of excess expenditures once a patient has been admitted. Second, hospitals are in a much stronger position to bear financial risk than physicians, who remain fragmented, since hospitals are generally larger and draw on more diverse sources of revenue.²⁸⁹ Finally, hospitals that elect not to participate in ACOs face the risk of substantial revenue declines since ACOs are expected to drive savings primarily through decreases in hospital services expenditures. Joining ACOs would give hospitals an opportunity to offset some of this declining revenue through shared savings payments.

The remaining two reasons for not treating hospital ACOs differently than physician ACOs for purposes of antitrust review—that hospitals are the most promising vehicle for generating savings in the health care system and that the market power of certain physician groups is not materially different than that of hospitals—also do not counsel against adding a two-sided financial risk-sharing requirement for hospital ACOs. The potential to drive efficiencies through decreases in provision of hospital services cuts both ways: since

288. For example, hospitals have been operating under the Medicare prospective payment system—a form of bundled payment—since the 1980s, whereas Medicare and most insurers still reimburse physicians on a fee-for-service basis. *See supra* notes 22, 45.

289. *Cf. Gaynor & Haas-Wilson, supra* note 224, at 148 (explaining that shift of risk from insurers to providers with the rise of capitation under managed care drove hospitals to consolidate in order to diversify against risk).

hospitals are likely to see the biggest decline in volume if ACOs are successful, they also have the greatest incentive to offset those potential revenue losses either by undermining ACO cost-saving efforts or using the additional market power associated with ACO membership to negotiate substantially higher prices. Similarly, the fact that certain physician groups have as much market power as hospitals is not so much an argument against increasing antitrust scrutiny for hospitals as it is an argument in favor of increasing antitrust scrutiny of physician groups with substantial market power.

Finally, it is worth noting that somewhat raising the antitrust scrutiny bar may have the salutary effect of ensuring that only those entities likely to be successful invest in formation of an ACO. Professor Lawrence Casalino, a strong proponent of ACOs, has recommended that FTC and DOJ use antitrust regulations to weed out

either sham organizations or well-meaning but incompetent organizations, who are only certain to fail. We don't want 80 percent of ACOs failing. On the other hand, I don't think we want 100 percent of ACOs succeeding. Then we're setting the bar too high. So I think the [antitrust scrutiny] bar . . . should be set in a place where people who sincerely want to do this are encouraged to try . . . but that the rate of success will be reasonably high.²⁹⁰

Given that financially integrated provider networks have a proven record of reducing costs, raising the antitrust scrutiny bar by including a two-sided financial risk-sharing requirement will make it more likely that only those entities likely to be successful at reducing expenditures will choose to participate in the Shared Savings Program. At the same time, by setting a higher bar for antitrust review of hospital ACOs that are not committed to both clinical *and* financial integration, FTC and DOJ will discourage providers from wastefully investing in formation of entities that are unlikely to achieve the efficiency goals of the ACO program.

D. The Dangers of "Pegging" FTC and DOJ Antitrust Review to Standards Set by Other Agencies

As discussed above, the Shared Savings Program participation rule and the antitrust enforcement policy for commercial ACOs are

290. Lawrence P. Casalino, Livingston Farrund Professor of Pub. Health & Chief, Div. of Outcomes and Effectiveness Research, Dep't of Pub. Health, Weill Cornell Med. Coll., Remarks at ACO Workshop, *supra* note 23, at 27.

highly interconnected. In particular, the ACO Statement provides that all commercial ACOs satisfying the Shared Savings Program participation requirements set out in the Rule will receive rule of reason review.²⁹¹ Commentators on the proposed Statement noted that this is among the first instances where FTC and DOJ's antitrust review standards are "peg[ged] . . . to standards created by a different [federal] agency."²⁹²

This Comment's analysis of the sufficiency of the antitrust safety zone for ACOs that include hospitals illustrates the potential pitfalls of FTC and DOJ tying their antitrust review standards to regulations issued by other agencies. As noted above, under CMS' proposed rule implementing the Shared Savings Program, all ACOs would have been required to engage in some degree of two-sided risk sharing during the first three years of the program.²⁹³ CMS eliminated the two-sided financial risk-sharing requirement in the final Rule, while FTC and DOJ left the ACO Statement largely unchanged.²⁹⁴ The safety zone set out in the ACO Statement was likely adequate under CMS' proposed rule, but it is inadequate under CMS' final Rule since, as the above analysis demonstrates, a financial integration requirement is critical to mitigating the unique competitive risks associated with hospital participation in ACOs. By tying the antitrust safety zone requirements to the Shared Savings Program Rule, the agencies effectively allowed CMS—an agency with a mission entirely different than antitrust enforcement—to dangerously lower antitrust review standards for ACOs, even in the absence of an official change in FTC and DOJ policy.

291. See *supra* note 197 and accompanying text.

292. See, e.g., Toby G. Singer & David R. Pearl, *A Not So Modest Proposal? The FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, COMPETITION POL'Y INT'L ANTITRUST CHRON. 3 (May 12, 2011), <https://www.competitionpolicyinternational.com/a-not-so-modest-proposal-the-ftc-doj-proposed-statement-of-antitrust-enforcement-policy-regarding-accountable-care-organizations-participating-in-the-medicare-shared-savings-program/>.

293. See *supra* note 93 and accompanying text.

294. FTC and DOJ state that there are two significant differences between the final ACO Statement and the proposed version: (1) the final ACO Statement applies to all entities eligible to participate in the Shared Savings Program, not just entities formed after March 23, 2010 and (2) the final ACO Statement does not contain language regarding a mandatory antitrust review program since CMS dropped the antitrust preclearance for high-share entities in the final Rule. See ACO Statement, *supra* note 24, at 67,026.

In response to substantial criticism from prospective ACO participants and other stakeholders,²⁹⁵ CMS significantly loosened the Shared Savings Program participation requirements in the final Rule.²⁹⁶ If the program fails to generate substantial interest from providers, the agency may face pressure to further loosen program requirements. This may mean, for example, that the agency could abandon its plan to require ACOs to engage in two-sided risk sharing after their initial three-year contract period (as it did with the initial contract two-sided risk-sharing requirement in the proposed rule). Some arguments for loosening the Rule may have merit on an individual basis, particularly from CMS' perspective since the agency's goal in drafting regulations is to make the Shared Savings Program as effective as possible, which necessarily entails choosing policies that will ensure there is robust participation in the program. However, under the ACO Statement, the Rule and the ACO Statement operate as a single regulatory structure and any changes to one must be analyzed in the context of the other. Consequently, FTC and DOJ must remain vigilant and revisit the ACO Statement each time CMS modifies the Rule to ensure that the ACO Statement adequately protects against the competitive risks posed by health care provider networks.

CONCLUSION

ACOs are a promising vehicle for remedying the continuing provider fragmentation in the United States health care system. Through formation of networks of providers, ACOs have the potential to improve care coordination and thus improve quality and reduce costs. However, these potential benefits also come with attendant risks, most notably the risk that as provider groups come together in ACOs and jointly negotiate with payers, they will be able

295. See Jane Norman, *Sebelius: HHS Will "Very Seriously" Consider Criticism of ACO Rule*, COMMONWEALTH FUND, <http://www.commonwealthfund.org/Content/Newsletters/Washington-Health-Policy-in-Review/2011/May/May-16-2011/HHS-Will-Very-Seriously-Consider-Criticism.aspx> (last visited Nov. 16, 2011).

296. In addition to eliminating the two-sided financial risk-sharing requirement in the first three years for ACOs opting for the Track 1 model, the final Rule reduces the number of quality measures used to monitor ACOs, increases the potential amount of shared savings payments, eliminates electronic health record use as a condition of program participation, and expands the number of entities eligible to participate in the program. For a table outlining key differences between the proposed rule and the final rule, see CMS, PROPOSED RULE VERSUS FINAL RULE FOR ACCOUNTABLE CARE ORGANIZATIONS IN THE MEDICARE SHARED SAVINGS PROGRAM, available at <http://www.cms.gov/ACO/Downloads/Appendix-ACO-Table.pdf>.

to extract significant price increases due to their enhanced bargaining leverage. This concern is particularly salient for ACOs that include hospitals, given the existing concentration in the hospital marketplace, the special concerns posed by horizontal and vertical integration between physicians and hospitals, and the risks associated with positioning hospitals as the dominant figure in the provider marketplace.

Under FTC and DOJ's antitrust enforcement regime for commercial ACOs, the antitrust enforcement environment for hospital ACOs would not be materially different than the environment facing physician-only ACOs. This represents a significant change from the Guidelines, under which multiprovider networks would be subject to more rigorous scrutiny than physician-only networks. While this Comment agrees with FTC and DOJ that the benefits associated with hospital participation in ACOs warrant a more lenient antitrust enforcement environment for hospital ACOs than under the Guidelines, it also argues that the safety zone requirements set out in the ACO Statement are insufficiently robust. In particular, it recommends that the agencies modify the safety zone to require hospital ACOs engage in two-sided financial risk sharing. In addition, this Comment urges FTC and DOJ to closely monitor the impact of future changes to CMS' Shared Savings Program Rule on the adequacy of the antitrust enforcement regime set out in the ACO Statement.

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