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In Search of Antitrust Guidance and Safe Harbors for Accountable Care Organizations

Gregory J. Pelnar[1]

I. INTRODUCTION

An Accountable Care Organization ("ACO") is "an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it."[2] The Affordable Care Act of 2010 ("ACA") encourages the formation of ACOs to provide medical care to Medicare beneficiaries and, if they meet quality thresholds, to share in the cost savings they achieve for the Medicare program. One hope is that ACOs will reduce the fragmentation of care across providers who have little, if any, communication with one another about the health status of their common patients, resulting in low-quality care (*e.g.*, duplication of tests, prescriptions with adverse interactions, and unaddressed health problems that "fall through the cracks" because the patient's other physician was supposed to address them). A still greater hope is that the hoped-for improvement in coordination of care will lower health care costs.

The Centers for Medicare & Medicaid Services ("CMS") plans to establish a "Shared Savings Program" ("SSP") by January 1, 2012. The statutory requirements for an organization to participate in the SSP include: (1) a minimum of 5,000 assigned Medicare beneficiaries; (2) an agreement to participate for at least three years; and (3) defined processes to promote evidence-based medicine, coordinate care, and report the data necessary for the evaluation of quality and cost. The statute specifies a number of organizations that may become an ACO: physicians and other professionals in group practices or in networks of practices; partnership or joint venture arrangements between hospitals and physicians and other professionals; hospitals employing physicians or other professionals; and other organizational forms that the Secretary of Health and Human Services ("HHS") may deem appropriate. The CMS is in the process of determining how the program will be implemented, including requirements for an organization to qualify as a Medicare ACO and how any savings generated will be measured and shared.[3]

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[2] Centers for Medicare & Medicaid Services (CMS), Medicare "Accountable Care Organizations" Shared Savings Program – New Section 1899 of Title XVIII: Preliminary Questions & Answers, CMS Office of Legislation, *available at* http://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf.

[3] A healthy dose of skepticism as to any reported savings from the SSP is warranted for a number of reasons, not the least of which is that SSP participants can be expected to invest in obtaining more easily obtainable benchmarks. Regulatory capture and "gaming the system" are widely recognized phenomena. The evidence from Medicare's Physician Group Practice (PGP) Demonstration, discussed in more detail below, reinforces such skepticism, as only 4 of the 10 participating PGPs earned performance payments in the second year of the program

The Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ"), meanwhile, are in the process of attempting to devise antitrust guidance, including safe harbors, for the ACOs participating in the SSP and, since those ACOs are expected to contract with health insurers in the private ("commercial") sector, the safe harbors may cover commercial ACOs as well.[4] FTC Commissioner J. Thomas Rosch notes that the formation of ACOs raises three antitrust concerns:

1) ACOs run the risk of illegal price fixing if they engage in joint price negotiations with private payers…
2) ACOs may be able to exercise market power, particularly in rural markets, and thereby increase health care costs…
3) There is also a risk that ACOs could facilitate collusion by participants when operating outside the venture.[5]

The FTC, CMS, and Office of the Inspector General ("OIG") for the Department of Health and Human Services held a joint workshop on October 5, 2010 to solicit the views of interested parties. Regarding antitrust guidance and safe harbors, FTC Chairman Jon Leibowitz posed the question: "[H]ow can we design rules for ACOs that are flexible enough to allow the health care community to collaborate to improve quality and decrease costs but obviously not to create undue market concentration and not to affectively end up fixing prices?"[6]

II. POTENTIAL GUIDANCE AND CANDIDATES FOR SAFE HARBORS

The FTC and DOJ have provided antitrust guidance to health care providers in the past.[7] One type of guidance is the specification of antitrust safe harbors or safety zones (*i.e.*, sets of conditions under which the FTC and DOJ are unlikely to challenge the arrangement on antitrust grounds). An arrangement that fails to satisfy the safe harbor conditions, however, is not necessarily anticompetitive (*i.e.*, unlawful) and will not necessarily be challenged by the antitrust authorities.

The formation of ACOs capable of generating coordination of care benefits is expected to be very costly. There is some concern that health care providers will be unwilling to undertake that substantial investment without assurance that they will not be violating the antitrust laws. Thus, there is a demand for antitrust safe harbors for ACOs. On the other hand, the antitrust

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and "the 4 PGPs earning performance payments … exhibited favorable cost trends prior to the Demonstration—trends that might have continued had the Demonstration not occurred." Kathleen Sebelius, *Report to Congress: Physician Group Practice Demonstration Evaluation Report* (2009), p. 62, *available at* http://www.cms.gov/reports/downloads/RTC_Sebelius_09_2009.pdf.

[4] The health care services offered by Medicare and commercial ACOs may differ somewhat since some services generally not demanded by Medicare beneficiaries, such as pediatrics and obstetrics, may not be included in a Medicare ACO but may need to be included in a commercial ACO.

[5] J. Thomas Rosch, *Theoretical and Practical Observations on Cartel and Merger Enforcement at the Federal Trade Commission*, remarks before the George Mason Law Review's 14th Annual Symposium of Antitrust Law, Washington, DC (February 9, 2011), pp. 7-8, *available at* http://www.ftc.gov/speeches/rosch/110209georgemasoncartelsmergers.pdf.

[6] FTC-CMS-OIG, Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws Transcript (October 5, 2010, 9:00a.m. EST), p. 14, *available at* http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopAMSessionTranscript.pdf.

[7] *See*, *e.g.*, Statement 8 of DOJ & FTC, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996), *available at* http://www.justice.gov/atr/public/guidelines/1791.pdf.

authorities have repeatedly made the point that the antitrust laws do not pose any barrier to the creation of innovative provider organizations that generate net benefits to consumers.[8] As long as the pro-competitive benefits of the organization outweigh its anticompetitive effects, and if there is no less restrictive alternative, the arrangement is likely to pass a rule of reason analysis. Nevertheless, providers reportedly are wary and would prefer reassurance in the form of antitrust safe harbors.

To achieve their purpose, any safe harbors would have to be neither too simple nor too complex. They would have to be simple enough that providers seeking to form pro-competitive ACOs will not be deterred from undertaking those investments for fear of antitrust prosecution, but the safe harbors also would need to be complex enough to exclude ACOs whose positive competitive impacts were less clear-cut and that needed to be evaluated on a case-by-case basis under a rule of reason analysis.

The simplest, though not the wisest, safe harbor would include any and all ACOs approved by CMS for participation in the Shared Savings Program. In other words, if an ACO was approved by CMS, the FTC and DOJ should not challenge it on antitrust grounds. There are a number of problems with such a safe harbor. First, assuming antitrust concerns are not irrelevant to CMS, it simply shifts the antitrust concerns from the FTC and DOJ to the CMS—or from the agencies with considerable antitrust expertise to one with lesser such expertise. Second, it is generally believed that ACOs participating in Medicare's Shared Savings Program will also operate in the commercial sector. Even if the CMS takes into consideration antitrust concerns in deciding whether to approve an ACO for participation in the SSP, the CMS cannot be expected to take into consideration the antitrust implications of the ACO's operations in the commercial sector. Moreover, the FTC and DOJ have devoted considerable thought to issues of clinical and financial integration, and have offered guidance for when such integration does or does not raise antitrust concerns.[9] Suppose the CMS implicitly or explicitly adopts a lower integration threshold than the FTC-DOJ experience suggests will yield net benefits for consumers. Should the antitrust agencies ignore their own experience?

Antitrust guidance and safe harbors ideally should be based on solid economic theory and strong empirical evidence. Careful attention must be paid to factors that could impact whether the market power possessed by an ACO, if any, more than offsets the benefits to the ACO's patients in the form of higher quality care. Such factors may include the ACO's scale (market share), scope, degree of integration, exclusivity, contract terms, restriction on payer access to cost and quality data, ancillarity of joint negotiations with payers, and policy for admitting members.

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[8] For example, the FTC's Director of the Bureau of Competition, Richard Feinstein, testified before a congressional subcommittee that, "the antitrust laws do not stand in the way of collaborations among providers that improve health care quality and lower costs." *See*, Richard A. Feinstein, *Antitrust Enforcement in the Health Care Industry*, Prepared Statement of the Federal Trade Commission, U.S. House of Representatives, Committee on the Judiciary, Subcommittee on Courts and Competition Policy (December 1, 2010), p. 11, *available at* http://www.ftc.gov/os/testimony/101201antitrusthealthcare.pdf. Similarly, Christine Varney, Assistant Attorney General of the DOJ's Antitrust Division, remarked that "antitrust is not an impediment to the formation of innovative, integrated health care delivery systems and genuine increases in provider efficiency." *See*, Christine A. Varney, *Antitrust and Health Care*, Remarks as Prepared for the American Bar Association/American Health Lawyers Association Antitrust in Healthcare Conference, Arlington, VA (May 24, 2010), pp. 11-12, *available at* http://www.justice.gov/atr/public/speeches/258898.pdf.

[9] *See*, *e.g.*, Gregory J. Pelnar, *Are Clinically Integrated Physician Networks Candy-Coated Cartels?*, 10(1) CPI ANTITRUST CHRON., (October 2010).

Yet, it is not just each factor in isolation that is important to an assessment of the competitive impact of an ACO, but the interaction among each factor as well.

A. Market Share

If an ACO is to benefit consumers through improved coordination of care, it must be sufficiently large that much of a patient's care occurs within the "vertical silo" of the ACO. If an ACO's cost and quality are to be reliably monitored, the ACO also must be sufficiently large to generate robust performance measures. On the other hand, if an ACO is to produce a net benefit for consumers, it must not be so large that its market power effects swamp those benefits. Whether ACOs can be large enough to produce coordination of care benefits, yet small enough that the market power effect does not outweigh those benefits, remains to be seen.

It is sometimes stated or implied that a firm with, say, a 30 percent market share is too small to be able to exercise market power and thus a 30 percent market share safe harbor is warranted. For example, the DOJ and FTC's 1996 *Statements of Antitrust Enforcement Policy in Health Care* ("*1996 Statements*") contains several safe harbors for physician network joint ventures. For example, the DOJ and FTC state that, absent extraordinary circumstances, they will not challenge "an exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 20 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market"; nor will they challenge "a non-exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 30 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market."[10]

The theoretical and empirical basis for these market share thresholds is left unspecified. Maybe the FTC's and DOJ's experiences with clinical and financial integration show that non-exclusive provider networks with market shares of 30 percent or less have generated net benefits for their patients. If so, a 30 percent market share safe harbor may be reasonable. However, the antitrust authorities appear to have conducted few retrospective studies of physician network joint ventures so it remains an open question whether these market share thresholds can be supported by economic evidence.

Then there is the practical question of how to calculate the market share. ACOs will offer a range of services. Should market shares be calculated by physician specialty and, if so, does each market share have to be less than the same threshold? And since patients may be willing to travel further to see particular specialists than to see their primary care physician, for example, the geographic market for each physician specialty may differ. Although the FTC has considerable experience in delineating hospital antitrust markets, its track record in successfully challenging hospital mergers has not been good, although that may be changing. Perhaps the relatively recent innovation in defining hospital geographic markets—the willingness-to-pay approach pioneered by Capps, Dranove, & Satterthwaite (2003) and others—offers a promising approach for delineating geographic markets of ACOs.[11]

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[10] DOJ & FTC, *supra* note 7, pp. 64-65 (footnotes omitted).

[11] *See*, Cory Capps, David Dranove & Mark Satterthwaite, *Competition and Market Power in Option Demand Markets*, 34 RAND J. ECON. 737 (2003). For a less technical discussion, *see* David Dranove & Andrew Sfekas, *The Revolution in Health Care Antitrust: New Methods and Provocative Implications*, 87 MILBANK QRTL'Y 607 (2009).

Some have argued that market shares understate the extent to which an organization may be able to exercise market power. Blue Shield of California offers three reasons:

First,

> [p]articularly in California, the market shares of providers located in the same area as Kaiser facilities often are greatly understated because Kaiser's large network is included when their market shares are calculated, notwithstanding that Kaiser is a closed provider system that is not available to contract with competing network health plans.

Second,

> network health plans must gain advanced permission from the Department of Managed Health Care to transfer members from a provider that is being terminated from the network, but these providers often insist, and sometime persuade the Department, that alternative providers are not adequate substitutes, leaving the health plan with no choice but to deal with the incumbent provider.

Third,

> market share screens may not provide adequate protection when a provider network with multiple facilities and/or physicians uses its status as the only provider in some areas to require payers to contract on an 'all-or-nothing' basis that includes providers in other areas where the network has a much smaller market share.[12]

But even suppose the recent willingness-to-pay methodology produces reliable geographic markets for ACOs and a 30 percent market share safe harbor is adopted. In small communities and rural areas, an ACO with even a 30 percent market share may be too small to generate significant coordination of care benefits. In fact, the American Medical Association (AMA) argues that ACOs may be natural monopolies in such localities, and that states should regulate them accordingly—thereby making them immune from the federal antitrust laws under the state action doctrine.[13]

On the other hand, market share has important interaction effects with other factors that may affect the net benefits produced by ACOs. For example, the competitive impact of exclusivity is more worrisome when market share is relatively high. Likewise, some contract terms, such as a most-favored-nation clause, are more likely to raise competitive concerns when the market share of one of the contracting parties is relatively high. Therefore, inclusion of a sufficiently low market share threshold in any safe harbor would contribute to keeping it relatively simple.

In sum, it would be easy for the FTC and DOJ to specify an antitrust safe harbor based on some numerical market share cutoff, as they did for physician network joint ventures in their *1996 Statements*, but theoretical and empirical support for whatever market share threshold the antitrust authorities chose for ACOs would be lacking. But if the FTC and DOJ specify safe

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[12] Blue Shield of California, Comments Relating to Workshop Regarding Accountable Care Organizations (November 4, 2010), p. 2, *available at* http://www.ftc.gov/os/comments/aco/101104bsc.pdf.

[13] AMA, Statement to the FTC, CMS & OIG Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and the Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws (September 27, 2010), p. 9, *available at* http://www.ftc.gov/os/comments/aco/100927ama.pdf.

harbors, they will have to somehow exclude ones with dominant market positions (*i.e.*, those whose formation leave consumers and payers with a paucity of health care provider choices). Thus, market share thresholds, while imperfect, would likely be part of any safe harbors due to their relative simplicity and the relative clarity they offer to providers, yet such thresholds could frustrate the achievement of coordination of care benefits.

B. Scope

The Affordable Care Act, as discussed above, specifies a number of organizations that can be ACOs, including physicians in group practices or networks of practices, hospital-physician partnerships or joint ventures, and hospitals with physician employees. The statute also permits other organizational forms to be ACOs if approved by the HHS Secretary.

A Medicare ACO, at a minimum, will be comprised of a group of primary care physicians ("PCPs"); together these physicians need to be responsible for the care of at least 5,000 Medicare beneficiaries. Unless the PCPs are employed by a hospital, in order to achieve coordination of care benefits, they will need to partner with specialist physicians (*e.g.*, cardiologists) to whom they can refer their patients requiring such care. The partnership may be either formal (*i.e.*, the specialist becomes a member of the ACO) or informal (*i.e.*, ACO members agree to refer their patients to certain specialists who are not part of the ACO for certain medical conditions). Similarly, they may choose to partner, either formally or informally, with disease management specialists who can monitor the PCPs' patients with a specific medical problem, such as diabetes. Other potential ACO participants include surgical centers, nursing homes, pharmacists,[14] and health insurers. And, of course, physicians attempting to form an ACO may seek to partner with a hospital to provide some or all of these specialized services, or a hospital with physician-employees may attempt to set up an ACO itself.[15]

The participation of hospitals in ACOs, especially hospitals with large market shares, has generated much antitrust concern. One concern is that such hospitals will be able to strengthen their dominance by forming ACOs around themselves and inhibiting the development of competing ACOs. Another concern is that a hospital in an ACO may have perverse incentives because, if the ACO is successful in raising the quality of patients' care, its patients should undergo fewer (and shorter) hospitalizations and the hospital will see a decline in demand for its services. In other words, a large portion of any savings produced by ACOs may result from a decline in the demand for hospital services.[16] Although the ACO may receive a portion of the savings generated, the hospital itself may find itself worse off depending on how the shared savings payments are distributed among the ACO's members. One possibility is that hospitals

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[14] The National Community Pharmacist Association argues that pharmacists can play an important role in improving patient health, as evidenced by the success of the Asheville Project undertaken by the city of Asheville, N.C., to provide education and personal oversight to employees with chronic health problems. National Community Pharmacists Association, Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and the Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws (September 27, 2010), *available at* http://www.ftc.gov/os/comments/aco/100927ncpa.pdf.

[15] For a discussion of physician- versus hospital-led ACOs, *see* Robert Kocher & Nikhil R. Sahni, *Physicians Versus Hospitals as Leaders of Accountable Care Organizations*, NEW ENGL. J. MED. 2579 (December 30, 2010).

[16] A similar argument can be made that, if an ACO is successful in improving patient care, demand for the services of specialist physicians may also fall, thereby creating perverse incentives for physician specialists participating in an ACO as well. Thus, ACOs may have difficulty attracting physician specialists on an exclusive basis.

may buy up physician practices to gain access to a greater portion of the shared savings. Another possibility is that ACOs with hospital partners will have less incentive to achieve such savings.

Regarding the latter possibility, the experience of ACO prototypes with hospitals in Medicare's Physicians Group Practice ("PGP") Demonstration deserves attention.[17] Medicare recently completed a five-year pilot program involving ten ACO prototypes.[18] Savings in excess of a 2 percent benchmark were shared roughly 80-20 between the PGP and Medicare, conditional on attaining certain quality standards focusing on high-cost, high-volume disease conditions. Some results for the first four years have been publicly reported and show that 4 of the 6 PGPs with hospitals (excluding academic medical centers) failed to receive any shared savings payments, while the other two received payments in the third and fourth years.[19] Although drawing any conclusions from such a small pilot program is hazardous, the results do not provide much support for the hope that ACOs with hospitals will generate significant cost savings—with the possible exception of academic medical centers.[20]

Other competitive concerns about the scope of an ACO include the possibility that ACO members may (1) gain access to competitively sensitive information about their competitors outside the ACO and (2) agree to coordinate their behavior in their provision of services outside of the ACO. An example of the former would be an insurer that is part of an ACO that contracts with other payers, thereby giving it access to the others' competitively sensitive information. An example of the latter would be two independent hospitals belonging to the same ACO mutually deciding what services each will offer outside the ACO.

In sum, while coordination of care benefits may climb as the scope of an ACO increases, the tradeoff is that an ACO may become so large as to inhibit the development of competing ACOs. Such concerns would be particularly acute for ACOs with dominant hospitals. Although the Affordable Care Act identifies a number of organizational forms that can become ACOs, including hospitals, those organizational forms should not automatically fall within an antitrust

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[17] *See*, Sebelius, *supra* note 3; CMS, Medicare Physician Group Practice Demonstration: Physicians Groups Continue to Improve Quality and Generate Savings Under Medicare Physician Pay-for-Performance Demonstration (December 2010), *available at* https://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Fact_Sheet.pdf; and John K. Iglehart, *Assessing an ACO Prototype – Medicare's Physician Group Practice Demonstration*, NEW ENGL. J. MED. 198 (January 20, 2011).

[18] The participants consisted of two academic medical centers with hospitals, two free-standing group practices with no hospital, five integrated delivery systems with hospitals, and a network model with a hospital.

[19] In contrast, both academic medical centers had hospitals and received shared savings payments—one in all four years and the other in three years. Also, both PGPs that did not include a hospital received shared savings payments in at least one year—one receiving such payments all four years and the other only in the second year.

[20] However, there are a number of reasons why ACOs may not be successful at academic medical centers either, including the incentives of department chairs to continue operating on a decentralized model, the lack of standardization of clinical care because clinical faculty members may have their own way of diagnosing and treating patients, and the fact that, for many clinical faculty members, care for patients is a part-time activity that detracts from their research activities. *See*, John A. Kastor, *Accountable Care Organizations at Academic Medical Centers*, NEW ENGL. J. MED. e11(1) (February 2, 2011), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1013221. Also, the cost of implementing an electronic medical record system capable of assisting in the coordination of care at an academic medical center may be enormous. For example, Johns Hopkins does not have a single integrated medical record platform throughout its system and implementing one "would require the single largest (non-physical-plant) investment in our history." Scott A. Berkowitz & Edward D. Miller, *Accountable Care at Academic Medical Centers – Lessons from Johns Hopkins*, NEW ENGL. J. MED. e12(1) (February 2, 2011), p. e12(2), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1100076.

safe harbor. Another concern is that participants in an ACO may gain access to their competitors' competitively sensitive information or may agree among themselves on the provision of their services outside the ACO. Yet, if the antitrust safe harbors impose too detailed restrictions on the composition of ACOs, the FTC and DOJ will be accused of smothering innovation in the provision of health care services.

C. Degree of Integration

The FTC and DOJ have wrestled with the question of how "integrated" physician practices must be to have their joint negotiations with payers analyzed on a rule of reason basis rather than judged a *per se* violation of Section 1 of the Sherman Act.[21] Initially, the antitrust agencies required "financial integration" (*i.e.*, the sharing of financial risks) because it would incentivize providers to change practice patterns. An example of financial integration would be providers joining together to negotiate a capitation contract with a payer (*i.e.*, a fixed payment per patient rather than a fee for each service provided to the patient). In the face of criticism that such a standard was too strict, the agencies reconsidered and allowed "clinical integration" as well. Whether the agencies' guidance on what constitutes clinical integration is also too narrow (or too vague) is hotly disputed. While some payers argue that at least some clinically integrated physician joint ventures are essentially cartels more interested in securing higher rates from payers than on improving patient care, the AMA has countered that "few if any clinical integration programs will ever recover their initial investment."[22]

Although some large provider organizations, such as the Cleveland Clinic and Mayo Clinic, may serve as ACOs by themselves, many ACOs are expected to be organized as joint ventures of independent provider organizations. A major difference between ACOs and some earlier physician network joint ventures is the payment mechanism. Although there were some experiments with capitation, the dominant payment system remains fee-for-service. The formation of ACOs is intended to facilitate a movement away from fee-for-service contracts, which are believed to reward overutilization of services, and towards other payment systems such as shared savings, capitation, partial capitation, and bundled payments. To counter the ACO's incentive for the underutilization of services created by these alternative payment mechanisms, CMS and private payers will attempt to monitor the quality of care provided by ACOs.

These alternative payment mechanisms result in at least some financial risk being shifted to the ACO. Thus, to some extent, the members of an ACO will be financially integrated. The extent of the financial integration will depend at least in part on the structure of the payment system, such as whether the ACO bears both upside and downside risk or only upside or only downside. For example, the PGP Demonstration subjected participants only to upside risk (ignoring the cost of participating, including startup costs) because they would receive a portion of the shared savings if some benchmark was exceeded, but they would bear no penalty for not achieving the benchmark.[23] In contrast, under full capitation, an ACO would bear both upside

[21] *See*, *e.g.*, Pelnar, *supra* note 9.

[22] AMA, *supra* note 13, p. 6.

[23] If participation costs are program-specific in the sense that they do not produce any benefits outside the program, then those costs may subject participants to downside risk since they will be unable to recoup those costs unless they generate sufficiently high savings. Chester Speed of the AMA testified that participants in the PGP Demonstration incurred costs of about $1 million to participate. FTC-CMS-OIG Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil

and downside risk—if costs of patient care exceed the contracted amount it bears the entire loss but if patient care costs fall far below the contracted rate it keeps the entire savings. Therefore, the extent to which an ACO is financially integrated will depend on the details of the payment system. In the case of Medicare ACOs, the extent of financial integration in an ACO will depend, in part, on the details of how savings are shared—the greater the savings shared with the ACO, the greater the financial integration of its members. Likewise, financial integration of commercial ACOs will depend on the types of contracts they negotiate with health insurers.[24]

Yet, an ACO can be financially (or clinically) integrated and still engage in anticompetitive behavior. Consider an ACO that contracts with a private payer to share any savings above a particular benchmark given a certain fee-for-service price list. The ACO bears only upside risk. However, even if it never generates any savings to be shared, the fact that the ACO members are jointly negotiating with the private payer may enable it to exercise market power and demand higher fees. The ACO may fail to obtain the savings for any number of reasons (*e.g.*, incompetence, bad luck), but also succeed in extracting higher fees for physician services. From the ACO's perspective, that may constitute success, but from an antitrust perspective, the ACO is simply a collection of providers engaged in price-fixing.

Therefore, the antitrust authorities may need to consider fazing out safe harbor protections for ACOs which year after year fail to improve the quality of patient care or generate health care savings but are successful in extracting higher rates from payers via joint negotiations, regardless of the extent to which they are financially or clinically integrated.[25]

D. Exclusivity

In its advisory opinions to physician network joint ventures, the FTC has shown a preference for non-exclusive arrangements (*i.e.*, a provider organization can be a member of more than one network or can contract separately with payers). Non-exclusive arrangements are expected to curb the exercise of market power by, among other things, facilitating the entry of competing provider networks. However, whether non-exclusivity leads to more competitive outcomes than exclusivity is not obvious, at least for organizations with sufficiently small market shares.

Exclusivity would provide a number of significant benefits to an ACO. It would give ACO members a strong incentive to work for the ACO's success.[26] If an ACO's members are

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Monetary Penalty Laws Transcript (October 5, 2010, 1:30p.m. EST), p. 10, *available at* http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopPMSessionTranscript.pdf.

[24] The AMA argues that sufficient financial integration should exist in the case of any contract between an ACO and a payer that employs any of the following: capitation, substantial withholds (15-20 percent range), percentage of premium, global fees or all-inclusive case rates, cost and utilization targets, or any other pay-for-performance reimbursement model that involves risk. *See*, AMA, *supra* note 13, p. 4.

[25] Though focused on hospital-physician integration rather than ACOs, the empirical results of Cuellar & Gertler (2006) are worth noting. They find that "integration has little effect on efficiency, but it is associated with an increase in prices, especially when the integrated organization is exclusive and occurs in less competitive markets." They conclude that their evidence supports "efforts by antitrust policymakers to more closely scrutinize hospital-physician integration" and advise that, "public programs, such as Medicare and Medicaid, should reconsider their policies that promote hospital-physician integration." Alison Evans Cuellar & Paul J. Gertler, *Strategic Integration of Hospitals and Physicians*, 25 J. HEALTH ECON. 1 (2006), pp. 1 & 26.

[26] The AMA notes that clinical integration programs today tend to be non-exclusive, but these non-exclusive clinical integration programs have not done well commercially. *See*, AMA, *supra* note 13, p. 6.

able to participate in other provider networks, the ACO becomes just another network to which the member belongs.

Exclusivity would also prevent free-riding by ACO members. For example, an ACO may develop a particularly successful process for improving the health status of patients with a particular condition. In the absence of exclusivity, the ACO's physician group that treats the condition could contract outside the ACO with private payers—in effect, the physician group would be both a member, and competitor, of the ACO.

A third rationale for exclusivity would be the administrative complexity of running a physician network participating in multiple ACOs, with the likely result being an impairment in coordination of care. Each ACO may have a different electronic medical records system for coordinating care, and the different systems are unlikely to be interoperable. Moreover, if different ACOs advocate somewhat different patterns of care for the same medical condition, a physician's treatment of a particular patient may depend on what ACO that patient has been assigned (with or without the patient's knowledge).

The benefits of exclusivity may be stronger for primary care physicians than for specialists due to problems of scale. For some widespread health problems such as diabetes, demand for the specialist's services may be met from the ACO's patient base. However, specialists of relatively rare conditions may find an ACO's patient base insufficient to provide a steady stream of patients. Unless they can participate in an ACO on a non-exclusive basis, they may refuse to participate in any ACO because no single ACO would be able to supply the number of patients they need for their practices to survive and flourish.

Exclusivity also would not necessarily impede the formation of competing ACOs. If a subset of physicians in an ACO becomes frustrated with its operation, they could leave and either join another ACO or form their own.[27] The key is that the physicians own their own practices (*i.e.*, are not employees of the ACO itself) and thus can take their patients with them if they choose to exit the ACO. However, the competitive implications of exclusivity are more worrisome in the case of ACOs formed by consolidating physician practices. For example, if a hospital buys up physician practices to form an ACO and makes those physicians its employees, those physicians would have an exclusive arrangement with the ACO and, although they could quit their employment, they would not have a patient base to take with them to a competing ACO.

Exclusivity could also cause a competitive problem in the case of some specialized services. For example, since a market may have only one or two children's hospitals, if one joined an ACO on an exclusive basis, it may be difficult for pediatricians and obstetricians to form a competing ACO.

In sum, any antitrust safe harbor should not contain a blanket exclusion of exclusive ACOs, but also should not include exclusive ACOs with sufficiently large market shares.

E. Contract Terms with Payers

Some contract terms may raise sufficient competitive concerns that their inclusion in ACO-payer contracts may warrant forfeiture of safe harbor protection. Examples may include

[27] The ease of doing so would depend on the specific contractual terms agreed to among the ACO participants when organizing the ACO.

most-favored-nation ("MFN") clauses,[28] clauses conditioning prices or discounts on whether the payer contracts with any of the ACO's competitors,[29] and (at least according to some commentators) all-or-nothing contract terms effectively tying services offered by the ACO with the services offered by ACO members outside of the ACO. However, such contract terms are unlikely to be obtained by ACOs that do not possess large market shares. Therefore, including a relatively low market share threshold in the safe harbors may obviate the need to include restrictions on contracts with payers in the safe harbors as well.

F. Payer Access to Cost and Quality Data

The formation of ACOs is being encouraged to lower health care costs and improve patient care. Some payment mechanisms, such as full capitation, have been criticized for creating at least short-term incentives for providers to skimp on patient care. Therefore, Medicare will not only monitor cost savings associated with ACOs, but the quality of patient care as well.

Private payers are concerned about similar incentive problems if they contract with ACOs. Since it often takes time for untreated or under-treated medical conditions to lead to serious health problems, skimping on care may produce short-run savings over the life of the ACO-payer contact, but produce a subsequent explosion in the cost of treating those patients. As a result, private payers want access to the ACO's data on costs and quality of care and are concerned that some ACOs may deny them such access. They argue that any safe harbors should include a requirement that the ACO share cost and quality of care data with payers.

G. Ancillarity of Joint Negotiations with Payers

Some payers have accused some clinically integrated physician practices of basically being cartels. In other words, the practices are jointly negotiating with payers even though the success of the clinical integration activities undertaken by the practices in no way hinges on the ability to jointly negotiate with payers. In the case of ACOs, this is less likely to be a problem. ACO members must jointly negotiate capitated payments, all-inclusive rates, and so on because the negotiated rate is for an entire spectrum of care provided across ACO members. On the other hand, safe harbor protection could be phased out for ACOs that successfully obtain higher fee-for-service rates without a corresponding improvement in patient care.

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[28] The DOJ has recently challenged Blue Cross Blue Shield of Michigan's use of MFN clauses in its contracts with hospitals in Michigan, alleging that the MFN clauses have "reduced competition in the sale of health insurance in markets throughout Michigan by inhibiting hospitals from negotiating competitive contracts with Blue Cross' competitors" and "have reduced competition by (1) reducing the ability of other health insurers to compete with Blue Cross, or actually excluding Blue Cross' competitors in certain markets, and (2) raising prices paid by Blue Cross' competitors and by self-insured employers." *U.S. v. Blue Cross Blue Shield of Michigan*, complaint (October 18, 2010), p. 1, *available at* http://www.justice.gov/atr/cases/f263200/263235.pdf.

[29] The DOJ has recently challenged United Regional Health Care System's maintenance of its monopoly power by entering into contracts with payers that "effectively prevent insurers from contracting with hospitals and other health-care facilities that compete with United Regional by requiring the insurers to pay a substantial pricing penalty if they also contract with United Regional's competitors" and the effect of this 13 percent to 27 percent pricing penalty is "to make the cost of including a competing hospital or other health-care facility in an issuer's network prohibitively expensive and not commercially viable, and to exclude equally-efficient rivals." *U.S. v. United Regional Health Care System*, complaint (February 25, 2011), p. 2, *available at* http://www.justice.gov/atr/cases/f267600/267651.pdf.

H. Open-Door Policy

Hospitals have been the target of antitrust lawsuits if they deny staff privileges to a physician.[30] However, courts have generally sided with the hospitals since there are strong pro-competitive reasons for hospitals not to grant staff privileges to any physician who asks. Likewise, an ACO, especially one with a large market share, may face an antitrust challenge alleging boycott or refusal to deal if it excludes a provider who wants to join and is willing to abide by the ACO's rules. Yet, like hospitals, ACOs have strong efficiency reasons for not having an open-door policy for any provider who wants to join. Such a policy would complicate the ACO's already challenging objective of reducing fragmentation of patient care. Also, like hospitals, ACOs have a strong incentive to weed out physicians with poor risk-adjusted patient outcomes and, even better, prevent them from joining the ACO in the first place. Thus, any safe harbor should not require an ACO to have an open-door policy for any provider who wants to join and is willing to abide by its rules.

III. CONCLUSION

In order to produce consumer benefits such as less fragmented care, ACOs will have to be sufficiently large that at least a significant number of patients are willing to obtain care from within the ACO's vertical silo. Yet, if ACOs are too large, they will exercise market power, driving health care costs up rather than down.

While potential ACO members would like the antitrust authorities to provide guidance (and, in particular, safe harbors) for forming ACOs, it is not obvious how to craft such guidance. Of course, it is easy to craft safe harbors that are so narrow that market power is unlikely to be a problem, but ACOs meeting such criteria may be unable to produce coordination of care benefits for consumers—thereby defeating the purposes of ACOs in the first place. Likewise, it is easy to craft safe harbors that are so broad that ACOs will have great flexibility for implementing strategies for improving care quality, but what is to stop them from also implementing strategies that drive up health care costs as well? Perhaps the antitrust authorities should evaluate all ACOs on a case-by-case basis applying rule of reason analysis and offer providers considering forming an ACO the following guidance:

> There is nothing special about health care as it relates to the application of the antitrust laws. If you are going to form an ACO, make sure that your patients obtain a net benefit and don't engage in more restrictive activities than needed to produce those net benefits.

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[30] See, *e.g.*, William J. Lynk & Heather R. Spang, *The Balance of Power in Hospital Staff Privileges Disputes*, 52 ANTITRUST BULL. 371 (2007).