care organizations, or ACOs, as part of the Medicare Shared Savings Program.[5] Although the program is designed to serve Medicare patients, it is widely recognized that health care providers are more likely to form ACOs to treat Medicare beneficiaries if they can also do the same for commercially-insured patients.[6]

While many aspects of health care reform generated considerable public and political debate, the promotion of ACOs through t

be achieved through integration, while at the same time protecting patients against anticompetitive harm.

I would like to begin by briefly describing the criteria that ACOs formed after March 2010

to qualify for the Shared Savings Program, ACO participants must make a minimum three-year commitment to CMS and have more than 5,000 beneficiaries.[11]

While the potential types of ACOs may be diverse, the goals underlying their formation are clear. ACOs are intended, through provider cooperation and new incentives, to save money, generate efficiencies, and improve patient care. Under the Program, ACOs and their participants will share financial rewards for reducing health care spending below CMS benchmarks while at the same time meeting CMS-prescribed quality goals.

Although providers will still be paid on the traditional Medicare fee-for-service basis, ACOs will be able to retain, and share with their members, a portion of the money saved when costs fall below a benchmark set by CMS.[12] The proposed CMS regulations provide for two different models for sharing savings. The first is the ñone-sidedò model under which the ACO may share savings, up to 52.5%, with the Medicare program, but is not liable for sharing any losses.[13] The other is the ñtwo-sidedò model where the ACO may share a greater amount of the savings, up to 65%, but is also liable for sharing any losses.[14] An ACO has two options as part of its three-year commitment to the Program: (1) use the one-sided model for two years and the two-sided model in the third year, or (2) use the two-sided model for all three years.[15] The first option is likely to be most attractive to newly-formed ACOs so that they can develop expertise before assuming the financial risk of the two-sided model.

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[11] § 1899(b)(2)(B).
[12] § 1899(a)(1)(B)(i).
[13] Medicare Shared Savings Program, 76 Fed. Reg. 19,641-47 (April 7, 2011) (to be codified at 42 C.F.R. pt. 425.4-425.7).
[14] *Id.*
[15] *Id.*

The expectation is that the Shared Savings Program will eliminate the incentives present in a typical fee-for-service model for providers to order unnecessary tests and procedures while the quality requirements will ensure that patient health is not sacrificed to cut costs.

To achieve these goals and, at the same time qualify for ACO status and the Shared Savings Program, potential ACOs and their participants must show that they meet various requirements laid out in the CMS regulations. Specifically, provider networks must show that they have various components in place to qualify for ACO status. These include:

> coordinated care among providers and a willingness to be held accountable for the quality, cost, and care of the ACOôs patients;
>
> a common leadership and management structure that includes shared clinical and administrative systems;
>
> the implementation of quality standards with a means to correct and discipline poor performance by members;
>
> the capacity to collect and report to CMS various quality and cost measures; and
>
> a formal legal structure that allows for the sharing of savings.[16]

II. Antitrust Concerns Raised by ACOs

So, what are the competition concerns raised by ACOs that have triggered so much debate in the antitrust community? There are two key concerns. One is that by encouraging collaboration among otherwise independent providers, ACOs will become a vehicle for providers to fix prices for their services. Price fixing is a per se violation of the antitrust laws, eliminating the need to prove competitive harm. In the last decade, the

[16] §§ 1899(b)(2)(B)-(G).

FTC has stopped a number of physician groups that have come together for little more than jointly setting rates.[17]

The other concern is that the formation of ACOs will harm consumers by creating market power in a relevant geographic market or by allowing market power to be used in new ways. Already, in anticipation of the Shared Savings Program, hospitals are looking to acquire competitors and are using ACOs as a justification.[18] In a recent successful challenge by the FTC to a hospital merger in Toledo, Ohio, the defendant hospitals cited the need to be prepared for the new law as a rationale for the transaction.[19] Significantly, the court rejected this argument, properly recognizing that a merger is not necessary to achieve the efficiencies associated with ACOs.[20]

But market power concerns do not just arise at the hospital level. Another significant concern is that a large share of specialists in a particular practice area may join a single ACO, resulting in that ACO possessing market power in that specialty. The FTC is keenly aware of this potential problem outside the ACO context. For instance, just two months ago, a hospital in Spokane, Washington called off its acquisition of two local cardiology groups after the FTC and the Washington Attorney General expressed concerns that the transaction would give the hospital market power in cardiology.[21]

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[17] The FTC brought approximately 30 enforcement actions against physicians groups between 2000 and September 2010. *See* Overview of FTC Antitrust Actions in Health Care Services and Products (Sept. 2010), *available at* http://www.ftc.gov/bc/110120hcupdate.pdf.

[18] *See, e.g.*, Vince Galloro, *Picking Up Speed: Health Reform Among the Drivers Cited for Recent Uptick in Health Care Mergers and Acquisitions*, Modern Health Care, Jan. 17, 2011, at 22; Robert Pear, *Consumer Risks Feare*

Statement, however, to accommodate the need for expedited reviews, market share will be assessed using the ACOôs Primary Service Area (ñPSAò), defined as ñthe lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service.ò[25]

Now, although a PSA serves as a proxy for a relevant geographic market, it does not necessarily represent a properly defined antitrust market.[26] It focuses on where the sellerôs customers originate rather than where customers would turn in the event of a price increase.[27] But, it is still a useful tool for evaluating potential anticompetitive effects.[28]

To provide transparency and ease the regulatory burden, the Policy Statement establishes the following guidelines for participation in the Shared Savings Program. Any ACO with PSA shares under 30% for all common services falls within the ñsafety zoneò and can apply directly to CMS to participate in the Shared Savings Plan without obtaining prior approval from the antitrust agencies.[29] Additionally, as a check on potential market power, for hospitals and ambulatory surgery centers to fall within the safety zone, they must be non-exclusive to the ACO.[30]

For ACOs with PSA shares between 30% and 50%, an antitrust review is not necessary before applying to CMS, but they may request a review if they want some comfort that they are unlikely to cause competitive harm given the competitive dynamics

[25] *Id.* at 21,897.
[26] *Id.* at 21,896 n.22.
[27] *See U.S. Dep't of Justice & Federal Trade Comm'n*, Horizontal Merger Guidelines § 4.2.1 (rev. 2010).
[28] If there is a belief that the PSA shares misrepresent a particular ACOôs actual market impact, parties are encouraged to come forward and present additional ir 8w361.27 9f(e f)-5(or)-3(w)5 BT1 0 0l r377.35

at the time of the request.[31] To provide additional guidance, the Policy Statement also warns against certain conduct that has the potential to be anticompetitive, including anti-steering provisions, exclusive dealing arrangements, tying, and the sharing of pricing information for the treatment of patients outside the ACO.

ACOs with a PSA share greater than 50% in any particular service trigger a mandatory antitrust review, which will be completed within 90 days.[32] These ACOs must submit certain categories of documents relating to competition and business strategy to the antitrust agencies, which will then determine whether the ACO is likely to cause competitive harm.[33] A letter from the reviewing agency indicating that it has no present plans to challenge the ACO is required to qualify for the Shared Savings Program.[34]

IV. The Policy Statement is ! ! . Similar Arrangements

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I am comfortable with this approach because CMSôs requirements for participation in the Shared Savings Program generally satisfy the agenciesô criteria for clinical integration.

a. Clinical Integration

As I discussed previously, to qualify for the Shared Savings Program, ACOs must meet a number of requirements, including having common management, coordinated care, cost and quality reporting, practice protocols, common information technology, and the ability to discipline members. These requirements are consistent with the types of characteristics that the FTC has, in the past, found to be strong indicia of clinical integration acceptable for providers to negotiate prices jointly.[37]

For example, in an advisory opinion issued s pl

Another example is what happened in Grand Junction, Colorado, back in the late 1990s. There, the FTC challenged the creation of a single organization comprised of almost all of the doctors in Grand Junction that jointly bargained with insurers. The proposed organization lacked any indicia of clinical integration necessary to avoid per se treatment and, as a result, drew FTC scrutiny.[40]

The FTC worked with the physicians to create a settlement that ended the anticompetitive pricing practices, but allowed doctors to be part of legitimate collaborations involving the use of a community-wide electronic health records system, common practice protocols, and physician peer review. As a result of these reforms, the quality of care improved dramatically while the cost of treating patients, which had been 30% higher than elsewhere in the state prior to the FTCôs investigation, fell well below the national average.[41] In fact, Grand Junction has been

integration.[44] But, to be sure, the FTC continued to monitor MedSouthôs activities for five years to ensure that it fulfilled its promise of lowering costs and improving care. In 2007, the FTC issued a follow-up opinion noting the success of the program at achieving its goals.[45]

Outcomes like the ones in Grand Junction and Denver suggest that the FTC has been on the right track. Now, CMSôs ongoing data collection and monitoring regarding ACO costs and quality will provide an opportunity to assess whether collaborations meeting the CMS requirements for clinical integration really do achieve the anticipated positive results on a more widespread basis.

So, while the Policy Statement does represent a shift in approach because it dispenses, at least in some cases, with a more individualized antitrust review, this shift is appropriate. CMSôs requirements are consistent with, and build upon, the FTCôs enforcement principles regarding health care collaborations, particularly when considered together with the Policy Statement. The Policy Statement is also preventive in nature ð it is designed to stop anticompetitive arrangements before they can cause harm.

b. Mergers/Dominant Providers

I also want to note that the Policy Statement does not change the FTCôs approach to reviewing mergers that occur within the ACO context or its treatment of dominant providers. Mergers will continue to be evaluated using the criteria outlined in the Horizontal Merger Guidelines. I believe it is vitally important that the FTC continue to enforce the antitrust laws