

**Keynote Address by Commissioner Edith Ramirez  
Federal Trade Commission**

**11th Annual Loyola Antitrust Colloquium  
Loyola University Chicago School of Law  
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**“Antitrust, Accountable Care Organizations, and  
the Promise of Health Care Reform”**

Good afternoon. Thank you for inviting me to speak to you today. It is a pleasure to be part of your Colloquium.<sup>1</sup> My remarks today focus on the role of antitrust in ensuring that the health care reform efforts currently underway fulfill their true promise. Part of the impetus behind health care reform is to lower the overwhelming costs of health care. Currently, health care expenditures in the United States are a staggering 18 percent of GDP, and they are expected to rise sharply in the coming years.<sup>2</sup> If the current trend continues, by 2040 health care costs could account for more than a third of total output in the U.S. economy.<sup>3</sup> And, of course, as spending on health care increases, it has a ripple effect on American standards of living as families are forced to devote even more of their paychecks to cover health care costs.

To expand coverage, improve quality, and help stem the tide of rising health care costs, Congress passed the Patient Protection and Affordable Care Act, which President Obama signed into law in March 2010.<sup>4</sup> The Act’s primary tool to slow the rising rate of health care costs and improve patient outcomes is the promotion of collaboration among doctors, hospitals and other health care providers through the formation of accountable

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<sup>1</sup> The views expressed in these remarks are my own and do not necessarily reflect the views of the Commission or any other Commissioner.

<sup>2</sup> Council of Economic Advisors, *The Economic Case for Health Care Reform* (June 2009) at 2, available at [http://www.whitehouse.gov/assets/documents/CEA\\_Health\\_Care\\_Report.pdf](http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf).

<sup>3</sup> *Id.*

<sup>4</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-48 (2010).

care organizations, or ACOs, as part of the Medicare Shared Savings Program.<sup>5</sup>

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.<sup>6</sup>

While many aspects of health care reform generated considerable public and political debate, the promotion of ACOs through the Shared Savings Program enjoyed solid bipartisan support and was largely without controversy—except in antitrust circles. Antitrust enforcers recognize that provider collaboration represents an innovative way to seek to lower health care costs and improve the quality of care. We of course do not want to stand in the way of those goals. At the same time, we want to ensure that the financial savings and improved patient outcomes that could result from these collaborative efforts are not lost because of increased provider concentration and coordination.<sup>7</sup>

To balance these competing interests, antitrust enforcement must allow ACOs the opportunity to achieve the efficiencies and improvements in health care delivery that may

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<sup>5</sup> Title XVIII § 1899(b)(1), to be codified at 42 U.S.C. § 1395jjj *et seq.*

<sup>6</sup> Federal Trade Comm'n & U.S. Dept. of Justice, Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21,894 (April 19, 2011) (hereinafter "Policy Statement"), *available at* <http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf>; Am. Medical Ass'n, Statement of the Am. Medical Ass'n to the Federal Trade Comm'n, the Centers for Medicare & Medicaid Servs. & the Office of Inspector General of Health and Human Servs. Re: Accountable Care Organizations (Sept. 27, 2010).

<sup>7</sup> There is considerable empirical evidence that consolidation among health care providers can lead to higher prices and lower quality of care. *See, e.g.,* Patrick S. Roman & David J. Balan, *A Retrospective Analysis of the Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare*,<sup>7</sup> FTC Bureau of Economics Working Paper No. 307 (Nov. 2010), *available at* <http://www.ftc.gov/be/workpapers/wp307.pdf>; Robert Berenson, Paul Ginsburg, & Nicole Kemper, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*, *Health Affairs* (April 2010); William B. Vogt and Robert Town, *How Has provider Consolidation Affected the Price and Quality of Hospital Care?*, Synthesis Project No. 9, Robert Wood Johnson Foundation (Feb. 2006).

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 will be required to meet to qualify for the Shared Savings Program. I will then elaborate more fully on the antitrust concerns ACOs may raise, followed by a discussion of how the Federal Trade Commission and Department of Justice aim to address those concerns.

## **I. Overview of ACOs**

Some commentators have referred to ACOs as an “elusive unicorn” because everyone has a sense of what an ACO would look like, but no one has actually seen one.<sup>8</sup> The fact is that we will not know precisely what form ACOs will take until the Shared Savings Program begins; they could come in many different shapes and sizes. The agency responsible for implementing the Program, the Centers for Medicare and Medicaid Services (“CMS”) has identified some possibilities. They include:

- (1) group practices of physicians, physicians assistants, and nurses;
- (2) networks of physicians groups, such as independent practice associations (“IPAs”);
- (3) integrated delivery systems such as hospitals and their employed physicians; and
- (4) partnerships of hospitals and physicians.<sup>9</sup>

Under the statute, CMS has leeway to determine what an appropriate ACO might be, and use that flexibility to encourage innovative care and payment models.<sup>10</sup> Regardless of the form,

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<sup>8</sup> Jenny Gold, “Accountable Care Organizations, Explained,” *available at* <http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained>.

<sup>9</sup> Title XVIII § 1899(b)(1).

<sup>10</sup> *Id.*

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.<sup>11</sup>

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.<sup>12</sup> The proposed CMS regulations provide for two different models for sharing savings. The first is the “one-sided” model under which the ACO may share savings, up to 52.5%, with the Medicare program, but is not liable for sharing any losses.<sup>13</sup> The other is the “two-sided” model where the ACO may share a greater amount of the savings, up to 65%, but is also liable for sharing any losses.<sup>14</sup> 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.<sup>15</sup> 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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<sup>11</sup> § 1899(b)(2)(B).

<sup>12</sup> § 1899(a)(1)(B)(i).

<sup>13</sup> 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).

<sup>14</sup> *Id.*

<sup>15</sup> *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 ACO's 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.<sup>16</sup>

## **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

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<sup>16</sup> §§ 1899(b)(2)(B)-(G).

FTC has stopped a number of physician groups that have come together for little more than jointly setting rates.<sup>17</sup>

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.<sup>18</sup> 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.<sup>19</sup> Significantly, the court rejected this argument, properly recognizing that a merger is not necessary to achieve the efficiencies associated with ACOs.<sup>20</sup>

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.<sup>21</sup>

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<sup>17</sup> 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>.

<sup>18</sup> 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 Feared as Health Law Spurs Mergers*, N. Y. Times, Nov. 20, 2010, at A1.

<sup>19</sup> See, e.g., Paul Barr, *Acquisition Hindsight; FTC: Sales Gives Promedica Too Much Clout*, Modern Health Care, Jan. 10, 2011, at 14.

<sup>20</sup> *Federal Trade Comm'n v. Promedica Health Sys., Inc.*, Case No. 3:11 CV 47, 2011 WL 1219281, at \*41 (N.D. Ohio March 29, 2011).

<sup>21</sup> See Statement of Richard Feinstein, Director, Federal Trade Comm'n Bureau of Competition, on Provident Health and Services' Abandonment of its Plan to Acquire Spokane Cardiology and

### III. Proposed Policy Statement

With those concerns in mind, how do the antitrust agencies intend to deal with ACOs? At the end of March, the FTC and the DOJ announced their Proposed Statement of Antitrust Enforcement Policy Regarding ACOs (“Policy Statement”).<sup>22</sup> The Policy Statement represents a joint effort by the FTC and DOJ, in coordination with CMS, to ensure that ACOs have an opportunity to fulfill their potential while at the same time recognizing that competition must be preserved to accomplish those goals.

The proposed Policy Statement, currently open to public comment, clarifies the competition analysis that the antitrust agencies will use when reviewing ACOs applying to participate in the Shared Savings Program. If a group meets CMS’s ACO criteria for participating in the Shared Savings Program, and uses the same governance, leadership, and clinical and administrative processes for its private business, then the collective actions of the ACO, including joint rate negotiations, will be subject to rule of reason, rather than per se, treatment.<sup>23</sup>

Under a rule of reason analysis, the antitrust agencies evaluate whether the ACO is likely to have substantial anticompetitive effects and whether the efficiencies it generates outweigh those effects.<sup>24</sup>

The first step in determining whether an ACO is likely to raise competitive concerns is an evaluation of its share in individual specialties or common services. This step addresses one of the major concerns related to ACOs—enhanced market power. In a typical antitrust analysis, the geographic market is very fact dependent. Under the Policy

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Heart Clinics Northwest in Spokane, Washington (April 8, 2011), *available at* <http://www.ftc.gov/opa/2011/04/providence.shtm>.

<sup>22</sup> Policy Statement, 76 Fed. Reg. at 21,894.

<sup>23</sup> *Id.* at 21,896.

<sup>24</sup> *Id.* at 21,895.

Statement, however, to accommodate the need for expedited reviews, market share will be assessed using the ACO's Primary Service Area ("PSA"), defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service."<sup>25</sup>

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

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 "safety zone" and can apply directly to CMS to participate in the Shared Savings Plan without obtaining prior approval from the antitrust agencies.<sup>29</sup> 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.<sup>30</sup>

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

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<sup>25</sup> *Id.* at 21,897.

<sup>26</sup> *Id.* at 21,896 n.22.

<sup>27</sup> *See U.S. Dep't of Justice & Federal Trade Comm'n*, Horizontal Merger Guidelines § 4.2.1 (rev. 2010).

<sup>28</sup> If there is a belief that the PSA shares misrepresent a particular ACO's actual market impact, parties are encouraged to come forward and present additional information.

<sup>29</sup> *Id.* at 21,897.

<sup>30</sup> *Id.*

at the time of the request.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup> 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.<sup>34</sup>

#### **IV. The Policy Statement is Consistent with the FTC's Prior Treatment of Similar Arrangements**

So, how does the Policy Statement fit in with the FTC's current enforcement policies? Under the FTC's current policy, to avoid per se condemnation, otherwise competing health care providers wishing to negotiate rates jointly are required to show either clinical integration or substantial shared financial risk to establish that the collaboration is a legitimate, efficiency-enhancing integration.<sup>35</sup>

The Policy Statement presumes that an ACO participating in the Shared Savings Program that operates in the same way for commercially insured patients is clinically integrated and that its joint price setting is reasonably necessary.<sup>36</sup>

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<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 21,897-98.

<sup>34</sup> *Id.*

<sup>35</sup> See U.S. Dep't of Justice & Federal Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care Statements 8-9 (rev. 1996) (hereinafter "Health Care Statements").

<sup>36</sup> 76 Fed. Reg. at 21,896.

I am comfortable with this approach because CMS's requirements for participation in the Shared Savings Program generally satisfy the agencies' 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.<sup>37</sup>

For example, in an advisory opinion issued to TriState Health Partners in 2009, the FTC permitted a proposed physician-hospital organization in Hagerstown, Maryland to contract jointly with payors.<sup>38</sup> The FTC cited the potential for lower costs and improved patient care through, among other things, the implementation of an integrated web-based health records system, mandatory quality standards, and performance monitoring as evidence that the joint fee negotiations were ancillary to its coordinated care objectives.<sup>39</sup>

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<sup>37</sup> See Health Care Statements 8-9; Federal Trade Comm'n & U.S. Dep't of Justice, *Improving Health Care: A Dose of Competition* (July 2004). Notably, CMS concluded that "[i]t is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the antitrust criteria on clinical integration." 76 Fed. Reg. 19258, 19542.

<sup>38</sup> Letter from Markus Meier, Assistant Director, Bureau of Competition, Federal Trade Comm'n, to Christi J. Braun (April 13, 2009) (TriState Health Partners, Inc. Advisory Opinion from FTC Staff).

<sup>39</sup> *Id.* Similarly, in *Greater Rochester IPA*, the FTC permitted competing physicians in Rochester, New York to engage in joint negotiations with payors because it found those negotiations were ancillary to their efforts to improve the quality of care and lower costs through the adoption of a shared electronic clinical-information system, the monitoring of individual and collective performance, and the implementation of minimum quality standards and uniform practice protocols. Letter from Markus Meier, Assistant Director, Bureau of Competition,

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.<sup>40</sup>

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 FTC's investigation, fell well below the national average.<sup>41</sup> In fact, Grand Junction has been recently identified as a model for health care reform.<sup>42</sup>

In 2002, the FTC conducted its own experiment. FTC staff issued an advisory opinion approving a clinical integration program proposed by MedSouth, Inc., an independent practice association in Denver, Colorado.<sup>43</sup> The program, which included the implementation of clinical protocols and a web-based health records system, as well as physician oversight and reporting, largely met the FTC's standards for clinical

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Federal Trade Comm'n, to Christi J. Braun & John J. Miles (Sept. 17, 2007) (Greater Rochester Independent Practice Ass'n Advisory Opinion from FTC Staff).

<sup>40</sup> *In the Matter of Mesa County Physicians Indep. Practice Ass'n, Inc.*, 127 FTC 564 (1999) (consent order).

<sup>41</sup> Nicholas Riccardi, *Grand Junction a Microcosm of Efficient Health Care*, Los Angeles Times, April 14, 2009, at A4.

<sup>42</sup> See, e.g., Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, The New Yorker, June 1, 2009, at 36.

<sup>43</sup> Letter from Jeffrey W. Brennan, Assistant Director, Bureau of Competition, Federal Trade Comm'n, to John J. Miles (February 21, 2002) (MedSouth, Inc. Advisory Opinion from FTC Staff).

integration.<sup>44</sup> But, to be sure, the FTC continued to monitor MedSouth's 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.<sup>45</sup>

Outcomes like the ones in Grand Junction and Denver suggest that the FTC has been on the right track. Now, CMS's 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. CMS's requirements are consistent with, and build upon, the FTC's enforcement principles regarding health care collaborations, particularly when considered together with the Policy Statement. The Policy Statement is also preventive in nature—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 FTC's 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 vigorously to prevent anticompetitive acquisitions and the

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<sup>44</sup> *Id.*

<sup>45</sup> Letter from Markus Meier, Assistant Director, Bureau of Competition, Federal Trade Comm'n, to John J. Miles (June 18, 2007) (MedSouth, Inc. Follow-up Advisory Opinion from FTC Staff).

abuse of market power. ACOs should not, as the FTC's successful challenge in *Promedica* shows, be used to justify otherwise anticompetitive transactions or conduct.

**V. Conclusion**

Let me close by saying that, in the past, the FTC has successfully identified problematic collaborations while permitting those collaborative arrangements that show the most promise for improved patient outcomes and cost savings. I believe that the new ACO guidelines will continue that tradition and ensure that the potential benefits of ACOs—reduced costs and improved quality—are not lost as a result of anticompetitive behavior.

Thank you.