



Federal Trade Commission

Accountable Care Organizations: What Exactly Are We Getting?

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before the

ABA Section of Antitrust Law Fall Forum
Washington, DC

November 17, 2011

I.

The Patient Protection and Affordable Care Act (the “Act”), also known as “ObamaCare,” was signed into law by the President on March 23, 2010.¹ One of the reforms in the Act is the Medicare Shared Savings Program, which promotes the formation and operation of Accountable Care Organizations (“ACOs”) to serve Medicare fee-for-service beneficiaries. Under this provision, “groups of providers . . . meeting the criteria specified by the [Department of Health and Human Services] may work together to manage and coordinate care for Medicare .

* The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor, Darren Tucker, for his invaluable assistance in preparing this paper.

¹ The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). This Act was amended a few days later by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

. . beneficiaries through an [ACO].’’² An ACO can share in a portion of any savings it creates if it also meets certain quality performance standards published by the Centers for Medicare and Medicaid Services (“CMS”). The Act requires that ACOs that wish to participate in the Shared Savings Program enter into an agreement with CMS for at least three years and agree to accept at least 5,000 beneficiaries assigned by CMS.

ACOs may be formed from a variety of entities, including networks of individual practices, partnerships, hospitals, and other health care professionals. Some ACOs are expected to be newly-formed joint ventures among previously independent, competing entities. It is expected that most health care providers that form ACOs for Medicare beneficiaries will also seek to use the ACO structure for their commercially-insured patients.

The final regulations provide for two “tracks” for ACOs: the “one-sided” track and the “two-sided” track.³ Under the one-sided track, an ACO receives up to 50% of any savings but is not subject to sharing in losses. Under the two-sided track, an ACO receives up to 60% of any savings but must absorb a portion of expenses that exceed a certain benchmark. An ACO participating in the two-sided track can reduce its liability for losses by hitting certain health care quality benchmarks. An ACO can have only one agreement period under the one-sided model; after that, it must agree to shared losses as well as shared savings. CMS has estimated that 1 to 5 million Medicare beneficiaries will be aligned with 50 to 270 ACOs during the first four years of the Shared Savings Program.

² Affordable Care Act § 3022 (to be codified as 42 U.S.C. § 1395jjj).

³ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, -- Fed. Reg. -- (2011) (to be codified at 42 C.F.R. pt. 425), *available at* http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf [hereinafter Final CMS Regulations]. The proposed regulations are available at 76 Fed. Reg. 19,528 (Apr. 7, 2011).

The antitrust agencies recognize that the formation of ACOs raises a number of antitrust concerns, in particular that ACOs run the risk of price fixing if they engage in joint price negotiations, and that they may be able to exercise market power, particularly in rural markets.⁴ These concerns are heightened when ACOs are negotiating with private payors. After all, Medicare sets its own rates and providers must either take or leave them.

To address these antitrust concerns, last month the FTC and DOJ issued a joint enforcement Policy Statement specific to ACOs.⁵ The Policy Statement is intended to describe the standards under which the antitrust agencies will review ACOs that participate in both the Medicare and commercial markets. The final Policy Statement was preceded by a draft Policy Statement that was released for public comment in the Spring.⁶ As I will describe later, the final Policy Statement differed in a number of respects from the draft Policy Statement as a result of input from the public.

The final Policy Statement provides that the antitrust agencies will evaluate an ACO under the rule of reason if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.

It may seem odd that a key aspect of the antitrust analysis of ACOs turns on the satisfaction of certain eligibility criteria of another federal agency that lacks antitrust

⁴ There is also a risk that ACOs could facilitate collusion by participants when operating outside the venture.

⁵ Fed. Trade Comm'n & Antitrust Div. of U.S. Dep't of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, -- Fed. Reg. -- (2011) [hereinafter Final Policy Statement].

⁶ 76 Fed. Reg. 21,894 (Apr. 19, 2011) [hereinafter Draft Policy Statement].

enforcement authority or expertise. After all, the FTC and DOJ have previously described the circumstances under which they will accord rule of reason treatment for provider networks.

Nevertheless, the antitrust agencies viewed CMS's proposed eligibility criteria as generally consistent with the indicia of clinical integration described in the Health Care Statements.⁷ In addition, it would have been unwieldy for Shared Savings Program applicants to have to satisfy distinct clinical integration requirements from CMS on the one hand and FTC and DOJ on the other. I should also note that staff at the FTC and DOJ worked closely with staff at CMS to ensure that CMS's clinical integration requirements would incorporate the antitrust agencies' perspectives.

II.

On its face, the Shared Savings Program sounds promising: using financial incentives to reduce costs and improve the quality of care. Who could be against that? Nevertheless, I am skeptical that ACOs will actually lead to any net health care cost savings. The available evidence suggests that the cost savings to Medicare will be very small to nonexistent, and there is a substantial risk that any reduction in Medicare expenditures will simply be shifted to payors in the commercial sector.

The Congressional Budget Office projected that Medicare would save \$5.3 billion over ten years from the formation of ACOs.⁸ Over the same period, total Medicare spending is

⁷ U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care at Statement 8 (1996), *available at* <http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm> [hereinafter Health Care Statements].

⁸ Congressional Budget Office, Budget Options Volume I: Health Care at 72-74 (Dec. 2008), *available at* <http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf>. In a more recent analysis, CMS estimated \$470 million in Medicare savings in the first four years of the program. *See* Final CMS Regulations, *supra* note 3, at Table 8.

projected to be over \$7 trillion.⁹ Thus, the cost savings from ACOs, assuming that these organizations are actually effective in improving quality and containing costs, represent less than one tenth of one percent of expected Medicare expenditures over the next decade. In other words, even under the most optimistic scenario, the savings to Medicare from the ACO program are no more than a rounding error.

Yet even the CBO's modest cost savings projections are likely overstated. CMS has been running what is known as the Physician Group Practice (PGP) Demonstration for the last several years.¹⁰ The PGP Demonstration created incentives for physician groups to coordinate care delivered to Medicare patients, rewarded them for improving the quality and cost of services, and created a framework for collaboration with other providers – in other words, they've done a trial run of the ACO program. The results were nothing to crow about. While all participating physician groups improved the quality of their services based on certain benchmarks, the cost savings were, in CMS's own words, "minimal."¹¹ Even after five years of the project, a majority of the participating practice groups did not achieve any cost savings.¹² In addition, the practice groups that did hit cost savings targets had, again according to CMS, "exhibited favorable cost trends prior to the Demonstration – trends that might have continued had the Demonstration not

⁹ 2011 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds at Table III.A1 (2011), *available at* <https://www.cms.gov/reportstrustfunds/downloads/tr2011.pdf>.

¹⁰ Secretary of Health and Human Services, Report to Congress: Physician Group Practice Demonstration Evaluation Report (2009) [hereinafter PGP Report]; Centers for Medicare & Medicaid Services, PGP Demonstration Fact Sheet (July 2011); Centers for Medicare & Medicaid Services PGP Demonstration Summary Results (undated). All of these materials are at <https://www.cms.gov/demoprojectsevalrpts/md/itemdetail.asp?itemid=CMS1198992>.

¹¹ PGP Report, *supra* note 10, at 9; *see also id.* at 9 ("Ignoring performance payment offsets, Actual Expenditures were \$120 per person or 1.2 percent less than Target Expenditures per beneficiary for the combined 10 PGPs in PY2."); *see also id.* at 17 ("The effect of the Demonstration on promoting expenditure savings is less certain.").

¹² PGP Demonstration Summary Results, *supra* note 10.

occurred.”¹³ In other words, CMS acknowledged that the reduction in Medicare expenditures at these practice groups might have occurred even absent the financial incentives of the project. I should also mention that ACOs in the Shared Savings Program will have smaller financial incentives to reduce costs than providers in the PGP Demonstration had.¹⁴

There is also a substantial risk that any reduction in costs due to the Shared Savings Program will simply be borne by commercial payors. The commercial sector already effectively subsidizes providers accepting Medicare and Medicaid payments for certain services. The ACO program may exacerbate this trend by causing providers to shift more of their costs to commercially insured patients in order to qualify for the Medicare cost-reduction bonuses. This cost shifting may be facilitated by the enhanced market power of some ACOs in the commercial market. One recent study showed that this is precisely what happened in California as independent practice associations flourished there.¹⁵ In short, even if ACO participants demonstrate that they are lowering costs to Medicare, that will say nothing about the net changes in health care costs for the country as a whole.

My skepticism about ACOs and similar organizations is nothing new. It actually dates back to 1996, when the Health Care Statements were amended to provide an antitrust safe harbor for joint negotiations by competing providers when there was thought to be sufficient clinical integration. This amendment was in addition to the antitrust safe harbor that had previously existed for providers that were considered sufficiently financially integrated.

¹³ PGP Report, *supra* note 10, at 14.

¹⁴ PGP Demonstration participants could receive a rebate of up to 80% of the cost savings, while ACOs will only receive up to 50% for participation in the one-sided model or 60% in the two-sided model.

¹⁵ Robert A. Berenson, Paul B. Ginsburg & Nicole Kemper, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*, 29 Health Affairs 699 (2010).

I thought then, as an antitrust practitioner who frequently represented health care providers, that the 1996 amendments creating a safe harbor for competing providers who were merely clinically integrated were the biggest loophole in the antitrust laws I had seen.¹⁶ For one thing, there was a good deal of joint venture case law to the effect that sufficient financial integration provided efficiencies that would justify shielding from antitrust liability potential competitors who were joint venturers.

For example, in its 1982 *Maricopa* decision, the Supreme Court held that agreements among competing physicians regarding the fees they would charge health insurers for their services constituted *per se* unlawful horizontal price fixing.¹⁷ But the Court distinguished the medical groups from joint ventures in which the participants had pooled their resources and agreed to “share the risks of loss as well as the opportunities for profit,” thereby becoming “a single firm competing with other sellers in the market.”¹⁸ As an example, the Court suggested that a group of providers that offered “complete medical coverage for a flat fee . . . would be perfectly proper.”¹⁹ In addition, there were clear, concrete guidelines in the Health Care Statements as to the forms of financial integration that the agencies will find acceptable.

¹⁶ Health Care Statements, *supra* note 7, at Statement 8.

¹⁷ *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 356-57 (1982); *see also Goldfarb v. Va. State Bar*, 421 U.S. 773, 787 (1975); *see also North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008) (upholding a Commission opinion that a group of independent competing physicians violated Section 5 of the FTC Act by orchestrating a price agreement among its physicians, negotiating price terms in payor contracts on behalf of its physicians, and refusing to deal with payors except on collectively agreed-upon terms).

¹⁸ *Maricopa*, 457 U.S. at 356.

¹⁹ *Id.* at 357. The Court also drew a contrast to the blanket license arrangement in *BMI*, which the Court described as “entirely different from the product that any one composer was able to sell by himself.” *Id.* at 355 (citing *Broadcast Music, Inc. v. Columbia Broadcasting Sys., Inc.*, 441 U.S. 1 (1979)).

In contrast, there is no joint venture case law for clinical integration, and Statement 8 of the Health Care Guidelines offers only a “bloppy” assortment of indicia of clinical integration without ever saying what the precise requirements are. Subsequent Advisory Opinions issued by Commission staff provide little help in decoding the circumstances in which clinical integration by competing providers might be sufficient to justify joint negotiations with payors.²⁰ To the contrary, I felt those Advisory Opinions were about as clear as mud. And I said so in some remarks I made as a Commissioner in 2007 and 2008.²¹ I opined then that competing providers would be well advised to employ substantial financial carrots and sticks if they wanted to engage in joint negotiations with antitrust impunity. That brings us up to the enactment of health care reform last year.

I regard ACOs as a form of clinical integration. The Affordable Care Act does not require that competing providers adopt any financial carrots or sticks in order to participate in the Medicare Shared Savings program as an ACO. Instead, the Act requires a leadership and management structure that includes clinical systems, promotion of evidence-based medicine, and reporting of quality and cost data – all hallmarks of clinical integration.

²⁰ The advisory opinions are available at <http://www.ftc.gov/bc/healthcare/industryguide/opinionguidance.htm>.

²¹ J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, Enforcement Strategies in the Health Care Industry, Remarks Before the ABA 6th Annual Washington Healthcare Summit 8-9 (Nov. 17, 2008), *available at* <http://www.ftc.gov/speeches/rosch/081117abahealthcaresummit.pdf> (“If a clinical integration program includes a very strong system of rewards and punishment, I personally think it could be successful. But to be on the safe side I have counseled that there be some significant degree of financial integration for a physician group seeking to justify joint contracting on the basis of clinical integration.”); J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, Clinical Integration in Antitrust: Prospects for the Future, Remarks at the 2007 Antitrust in Health Care Conference 17 (Sept. 17, 2007), *available at* <http://www.ftc.gov/speeches/rosch/070917clinic.pdf> (“the incentives for physicians to create efficiencies with clinical integration are not nearly as obvious or direct as the incentives with financial integration”).

To its credit, CMS issued regulations providing for both financial carrots and sticks to ACOs. As I previously mentioned, two tracks will be available for the initial agreement period. The first track, which I expect will be more popular, includes shared savings only. The second track includes both shared savings *and* shared losses. An ACO can have only one agreement period with just shared savings; after that, it must agree to shared losses as well as shared savings. In other words, for most ACOs, the financial sticks will not kick in until 2016 or later. And even then, the degree of risk-sharing or withholds required by CMS will be less than that generally required by the FTC or DOJ in giving competing providers a pass to negotiate jointly on the ground that the providers are sufficiently “financially integrated.” But the CMS regulations are a step in the right direction.

III.

Next, I’d like to address some of the concerns that were raised about the FTC and DOJ’s draft ACO Policy Statement. I think it’s fair to say that the final Policy Statement differs in a number of significant ways from the draft Policy Statement and that public comments led to many of the changes.

Perhaps the most fundamental objection to the draft Policy Statement was that the mandatory review by the FTC and DOJ of certain proposed ACOs was an impermissible subdelegation of authority from CMS to the FTC and DOJ. Under the subdelegation doctrine, courts have placed limits on the ability of federal agencies to transfer their statutory authority to outside entities, including other federal agencies.²² That doctrine was implicated by the draft CMS regulations and the draft Policy Statement because the antitrust agencies would be making

²² See generally Richard D. Raskin, Ben J. Keith & Brenna E. Jenny, *Delegation Dilemma: Can HHS Require Medicare ACOs To Undergo Pre-Clearance by the Antitrust Agencies?*, Health Law Reporter (BNA), June 23, 2011.

the final determination of whether an ACO was eligible to participate in the Shared Savings Program, even though the Affordable Care Act did not expressly authorize CMS to delegate its authority to the FTC or DOJ.

The final CMS regulations and antitrust Policy Statement eliminate mandatory antitrust review at the FTC and DOJ. As a result, the FTC and DOJ will not be able to block an ACO from participating in the Shared Savings Program. That does not mean, however, that participants in the Shared Savings Program have antitrust immunity or that CMS is blind to antitrust considerations. To the contrary, the FTC is committed to challenging anticompetitive ACOs, and CMS will assist us to the extent possible. For example, CMS will be providing the FTC with aggregated ACO claims data and the applications of newly formed ACOs, both of which should help our staff identify ACOs that are exercising market power or not achieving efficiencies. In addition, if an ACO is found to violate the antitrust laws, CMS can kick that ACO out of the Shared Savings Program. The FTC will be vigilantly monitoring complaints about ACOs and will take whatever enforcement action may be appropriate.

Given that some potential applicants to the Shared Savings Program will want antitrust comfort before participating in the Program, the antitrust agencies, upon request, will provide an expedited review for newly formed ACOs. These voluntary reviews will be similar to the usual Advisory Opinions our staff issue, except that we have committed to making an assessment within 90 days after all of the materials have been submitted. ACOs or proposed ACOs that do not seek voluntary review can still rely on the final Policy Statement to understand the agencies' enforcement approach with regard to ACOs participating in the commercial sector and to take steps to reduce their antitrust exposure.

As an aside, I am more than a little curious as to how many requests for voluntary review we will receive.²³ After all, how many merging companies would voluntarily notify the government about their acquisition in the absence of the HSR Act? On the other hand, providers may see the benefits from a voluntary review, given the antitrust agencies' stated interest in this area and the potential for future enforcement action.

Another concern with the draft Policy Statement was that it did not apply to all ACOs. There was language in the draft Policy Statement indicating that it applied only to ACOs formed after March 23, 2010, the date the Affordable Care Act was signed into law. Long-existing providers argued they too should receive the benefit of rule of reason treatment and the safety zone. We agreed.

As a result, the final Policy Statement applies to *all* ACOs that participate in the Shared Savings Program, regardless of when they were formed. Thus, rule of reason treatment and the safety zone apply to all ACOs participating in and meeting the requirements of the Shared Savings Program, not just the ones formed after March 23, 2010. The only exception is that the voluntary review process is limited to “newly formed” ACOs, i.e., those formed after March 23, 2010. The reason for this exception is that FTC and DOJ Advisory Opinions are available only to evaluate *prospective* conduct.

A third common complaint about the draft Policy Statement was that the criteria adopted by the FTC and DOJ were too burdensome and expensive. Specifically, providers complained about the use of PSA data on the ground that the information is too difficult and expensive to gather. PSA refers to a Primary Service Area, which is defined as “the lowest number of postal

²³ Under the mandatory review system initially proposed, the antitrust agencies estimated that 38 to 200 ACOs would have been subject to antitrust review. *See* Draft Policy Statement, *supra* note 6, at 21,901.

zip codes from which the [ACO participant] draws at least 75 percent of its [patients].”²⁴

Although a PSA does not necessarily constitute a relevant antitrust geographic market, it is designed to serve as a screen for evaluating potential competitive effects of proposed ACOs. The draft Policy Statement required ACOs to calculate PSA shares as part of the mandatory review, as well as to determine whether they fell within the safe harbor.

The final version of the Policy Statement continues to rely on PSA data. From my perspective, this was correct. PSA data are a reasonable and reliable means by which to make preliminary assessments of ACOs without having to go through the rigors of a full-blown geographic market analysis. I was also persuaded to keep PSAs because the complaining providers were unable to identify a better alternative.

Nevertheless, the final Policy Statement does reduce the burden of calculating PSAs in three respects. First, because the antitrust review is no longer mandatory, the need to calculate PSA shares is similarly no longer mandatory; although, providers may decide to calculate these shares as part of their internal antitrust review. Second, providers have the option of providing “data that show the current competitive significance of the ACO or ACO participants” in lieu of PSA shares.²⁵ Third, the definition of a PSA is much simpler. It no longer requires the zip codes to be contiguous, and each physician or physician group will have to determine just one PSA for its entire practice, instead of for each specific service. Likewise, a hospital will only have to determine three PSAs – for inpatient services, outpatient services, and physician services – instead of for each specific service.

Providers also complained that the clinical integration requirements in CMS’ draft regulations were too onerous. Many groups – especially doctor groups – asserted that their

²⁴ Final Policy Statement, *supra* note 5, § IV.A.

²⁵ *Id.* § IV.B.2.

interest in the Shared Savings Program had been dashed by formalistic, redundant, and expensive requirements that offered little benefit for patients. This was not, strictly speaking, an FTC or DOJ issue, but it did touch on an important aspect of our enforcement policy. As I previously mentioned, satisfaction of CMS' clinical integration requirements entitles ACOs to rule of reason treatment if they operate in commercial markets in basically the same way as in Medicare markets.

In response to these concerns, the final CMS regulations eliminated a number of requirements, with the goal of giving providers greater flexibility. Nevertheless, the requirements are still intended to mirror the requirements of FTC Advisory Opinions and the Health Care Statements. In addition, the Policy Statement was revised to make clear that rule of reason treatment will not apply if an ACO does not actually implement the required processes or otherwise meet the CMS eligibility criteria, or if the ACO is accepted for, but never participates in the Shared Savings Program.

A final concern with the draft Policy Statement was that the various PSA thresholds were too low and would result in unwarranted scrutiny of unproblematic ACOs. Providers pointed in particular to the 50 percent PSA threshold for triggering mandatory review, which was intended to be a "valuable indication of the potential for competitive harm."²⁶ Providers argued that shares of this magnitude by a physician joint venture did not necessarily indicate market power and objected to the triggering of mandatory review based on a single practice of a multi-practice ACO having a PSA share in excess of 50 percent.

²⁶ Draft Policy Statement, *supra* note 6, § IV.B.

This criticism did not resonate with me. The mandatory review threshold not only exceeded the market power thresholds in the Health Care Statements,²⁷ but also the market power thresholds found in recent court decisions. Indeed, insurers (who arguably are the direct victims if ACOs facilitate the exercise of market power or engage in anticompetitive practices) argued that the PSA thresholds were too lax. In light of this, I was skeptical about applying lower requirements for ACOs, particularly for those in the one-sided track.

In any event, the role of PSAs is diminished in the final Policy Statement, making this debate somewhat moot. As I previously mentioned, the final Policy Statement omits a mandatory review provision. As a result, the 50 percent cutoff is gone.²⁸ The most important PSA threshold that remains is a 30 percent threshold for the safety zone. The Health Care Statements, by contrast, have *no* safety zone for clinically integrated health care providers. Accordingly, the 30 percent cutoff for the safety zone strikes me as extraordinarily generous to providers, at least for those participating in the one-sided track.

IV.

Whatever one thinks about the health care reform legislation from 2010, it's hard not to be skeptical about the prospects of the Medicare Shared Savings Program. CMS' own pilot program was far from a success, and there is a significant risk that, like Medicare and Medicaid generally, any purported cost savings from the program will be offset by higher costs to payors in the commercial market. Against the very meager prospects for cost savings, there is a very

²⁷ Statement 8 of the Health Care Statements defines the thresholds for market power as 20 percent if the relevant providers are integrated and contract exclusively as an integrated entity, and 30 percent if they are integrated but not exclusively so. *See* Health Care Statements, *supra* note 8, at Statement 8.

²⁸ There is still a 50 percent PSA threshold for the dominant participant limitation, under which providers with a 50 percent PSA share must be non-exclusive to the ACO for the ACO to fall within the safety zone. *See* Final Policy Statement, *supra* note 5, § IV.A.2.

real risk that some ACOs will be formed with an eye toward creating or exercising market power. The net result of the Shared Savings Program may therefore be *higher* costs and *lower* quality health care – precisely the opposite of its goal. Sociologist Robert K. Merton, who popularized the concept of the law of unintended consequences,²⁹ would no doubt get a chuckle out of this state of affairs.

²⁹ Robert K. Merton, *The Unanticipated Consequences of Purposive Social Action*, 1 *American Sociological Review* 894 (1936).