CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
July 2012 (1)

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Lona Fowdur & John M. Gale
Economists Incorporated

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I. INTRODUCTION

The Accountable Care Act ("ACA") has brought to the fore the concept of Accountable Care Organizations ("ACOs").[2] These organizations comprise networks of otherwise unaffiliated providers that can obtain approval from the Centers for Medicare & Medicaid Services ("CMS") to become jointly responsible for the coordinated care of an assigned Medicare patient population. Per their agreement with CMS, ACOs are eligible to participate in the Medicare Shared Savings Program ("MSSP"). The program entitles participants to share in the Medicare savings they generate if they are able to lower the cost of care for their assigned Medicare patient population, and if they are able to perform adequately along a range of pre-determined quality metrics. Such ACOs would also be permitted to negotiate collectively with private providers and thereby extend the potential savings from care-coordination to commercially insured patients.

As such, it would seem that in passing the ACA, legislators took note of the potential efficiencies that could be realized through affiliations between provider groups. Providers, on the other hand, have sought such efficiencies, even prior to the enactment of the ACA, both through negotiations with managed care plans—for example under pay-for-performance systems—and through formal consolidations in the form of mergers and acquisitions.

Antitrust regulatory agencies at the U.S. Department of Justice and the Federal Trade Commission ("the Agencies") remain concerned, however, that affiliations between provider groups may lead to market power and price increases. Such concerns could be warranted if affiliations between provider groups lead to an increase in the providers' negotiating power vis-à-vis managed care plans. For example, if there were no equivalent alternative to a group of providers and a managed care plan were unable to offer a product without the group, it is possible that the group could extract higher payments for their services than they otherwise could. The Agencies aim to safeguard against such outcomes, but they also recognize the need for integration in order to achieve efficiencies. Consequently they have provided some guidance to provider groups as to how they will evaluate affiliations.

Provider groups need to recognize the Agencies' stance on antitrust regulation as they consider affiliations with other groups, whether under the banner of an ACO, in joint-negotiations with commercial payers, or in the context of formal integrations through mergers and acquisitions. In this article we provide an overview of ACO formation to date, survey similar payment systems outside of CMS's MSSP initiatives, and briefly review the Agencies' policies in regards to ACO formation and recent merger activity.

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[1] Lona Fowdur is Senior Economist and John Gale is Vice President of Economists Incorporated in Washington, DC.

[2] The ACA was passed in March 2010 and upheld in most part by the Supreme Court in June 2012.

II. ACCOUNTABLE CARE ORGANIZATIONS—MSSP PARTICIPANTS

Under the shared savings arrangement with CMS, approved ACOs receive bonuses depending on the savings they generate relative to a benchmark.[3] CMS calculates this benchmark on the basis of the per capita costs of Medicare beneficiaries assigned to the ACO participants in each of the three years preceding the formation of the ACO. For example, ACOs starting in 2012 would have 2009, 2010, and 2011 as their benchmarking years. As such, an ACO's bonus is unaffected by whether the ACOs' per capita Medicare costs were historically high or low.

A pre-condition for an ACO to share in MSSP savings, however, is that the ACO must demonstrate that it has met a pre-determined set of quality thresholds. These are the same for all ACO types (detailed below) and span 33 measures across four key domains: patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk populations.

Another distinguishing feature of an ACO in the MSSP is that patients are free to use the service of providers outside of the ACO (unlike preferred provider organizations ("PPOs"), for example) where patients have a financial incentive to use in-network services since they incur higher co-pays for out-of-network services.

CMS currently offers three types of ACO programs. These are:

1. The Medicare Shared Savings Program ("MSSP")

Under this program, Medicare fee-for-service providers can form an ACO and share in the potential savings they generate by coordinating care for their assigned Medicare patient population.[4]

In January 2012, CMS began accepting applications from provider groups to form ACOs that would participate in the MSSP and four months later CMS released a list of 27 ACOs that were approved for participation in the program, effective April 1, 2012.[5] The April 2012 announcement also indicated that CMS was reviewing 150 additional applications for a July 1, 2012 start date.[6] On July, 9 2012, CMS announced that 89 of these applications had been approved.[7] The later announcement estimated that a total of 2.4 million Medicare patients would be served by ACOs participating in the MSSP.

2. The Advance Payment Initiative

This program is an initiative meant only for certain eligible participants in the MSSP that may not be able to participate in the program because of their limited capital resources.[8] Through this program, approved ACOs receive advance payments, which they can use toward the upfront infrastructure costs of coordinating care.

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[3] *See* Medicare Shared Savings Program Frequently Asked Questions, *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/FAQ.html.

[4] For more information, *see* http://www.cms.gov/sharedsavingsprogram.

[5] *See* CMS Press Release, April 10, 2012.

[6] *Id.*

[7] *See* CMS Press Release, July 9, 2012.

[8] For more information, *see* http://innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html.

CMS announced that five ACOs are participating in the Advance Payment ACO Model, effective April 1, and that it was reviewing about 50 applications from ACOs seeking to participate under this model beginning July 1, 2012.[9]

3. The Pioneer ACO Program

This ACO model constitutes an initiative that CMS is testing over a period of three years to determine whether organizations with greater experience offering coordinated care under an ACO structure would be able to operate under a population-based payment system.[10] In particular, in the first two performance years (which began in January 2012) the Pioneer model tests payment arrangements whereby, as in the MSSP, payments would be calibrated based on savings relative to previous expenditures, but with higher levels of risks and rewards. Specifically, such ACOs would be eligible for a higher share of the savings, but would also be liable to pay back a higher amount to CMS if they increase spending above projections. In the third year of the program, those Pioneer ACOs that demonstrated savings in the first two years would be eligible to move to a population-based payment system whereby they would receive a prospective per-beneficiary monthly payment that would replace some or the entirety of the fee-for-service payment entitlement.

Thirty-two participants were selected from an applicant pool in December 2011 to participate in the Pioneer ACO program. CMS is no longer accepting applications for ACO participation under this model, but if the model demonstrates success, it could eventually be extended to more participants.

ACO Antitrust Risk

Participants in the CMS-sponsored ACO programs need to be cognizant of possible antitrust risks. While CMS no longer requires a clearance letter or a mandatory review from the Agencies in order to consider an ACO application, it is committed to providing data to the Agencies that will assist them in monitoring the competitive effects of ACOs.[11] Such data would allow the Agencies to challenge ACOs if the Agencies consider them to be anticompetitive.

In order to provide greater clarity to potential ACO participants, the Agencies have released a joint statement addressing their antitrust enforcement policies ("ACO Policy Statement").[12] The statement clarifies the circumstances under which the Agencies will apply the rule-of-reason to evaluate the competitive impact of an ACO. Under such treatment, the Agencies consider whether an ACO's pro-competitive effects outweigh any potential

[9] *See supra* note 4. It is unclear how many of these applications were approved.

[10] For more information, *see* http://innovations.cms.gov/initiatives/aco/pioneer/.

[11] Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, Federal Trade Commission/ U.S. Department of Justice, 76 Fed. Reg. 67,026 (November 18, 2011), p. 1 (*hereinafter* ACO Policy Statement).

[12] *Id.* The statement explains that the Agencies' enforcement policies apply to all independent providers and groups seeking to form ACOs, but not to proposed mergers or fully integrated groups that will continue to be evaluated under the Agencies' Horizontal Merger Guidelines. *See* U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines, August 19, 2010, (*hereinafter* Joint Merger Guideline), *available at* http://www.justice.gov/atr/public/guidelines/hmg-2010.pdf.

anticompetitive effects. The Agencies expect that pro-competitive benefits could be achieved via sufficient clinical integration that would, in turn, facilitate the realization of efficiencies.

For now the Agencies have determined that CMS's eligibility criteria for ACO formation are broadly consistent with sufficient clinical integration and that fulfillment of these criteria is likely to generate bona fide arrangements between provider groups.[13] As a result, the Agencies have determined that as long as the ACO fulfills CMS's eligibility criteria and uses the same governance, leadership, and administrative processes to serve patients in the commercial market, the ACO's joint negotiations with private payers will be treated under the *per se* criterion.

The ACO Policy Statement does imply, however, that a *per se* analysis would not always be needed. In particular, the statement defines an antitrust safety zone whereby ACOs would be considered highly unlikely to raise significant competitive concerns.[14] ACOs would fall in the safety zone if their share of each relevant service component offered by more than one provider is 30 percent or less within each participant's primary service area ("PSA").[15] These service components span three separate service categories, namely physician specialties, major diagnostic categories for inpatient services, and outpatient categories for outpatient services.[16] In addition, to fall within the safety zone, all hospitals and outpatient facility participants must be non-exclusive to the ACO.[17] For ACOs that fall outside of the safety zone, the ACO policy Statement provides some guidance including a description of the types of behavior to avoid and the process for an expedited 90-day review whereby the Agencies would evaluate the competitive impacts of the ACO under the rule-of-reason.[18]

Other Potential Sources of Risk

Since ACO participation in the CMS-sponsored MSSP is still a relatively new phenomenon, it is impossible to anticipate all the risk factors that providers considering ACO formation should take into account. It is clear, however, that the most significant motivator for Medicare providers to join the program is the opportunity to share in savings. Until such savings

[13] ACO Policy Statement, p. 5. CMS's eligibility criteria for the shared savings program include: (1) a legal structure that allows receipt and distribution of shared savings, (2) a leadership and management structure that includes clinical and administrative processes, (3) process to promote evidence-based medicine and patient engagement, (4) quality and cost-measures reporting, and (5) coordinated care for beneficiaries.

[14] *Id.,* p. 6.

[15] A PSA comprises the lowest number of zip codes from which the provider participant draws at least 75 percent of its patients.

[16] *Id.,* p. 7.

[17] *Id.,* p. 8-9. Where one or more PSA shares exceeds 30 percent, an ACO may still fall in the antitrust safety zone if it qualifies for a rural exception, i.e., where one physician or physician group per specialty is located in a rural zip code (per the CMS definition for such zip codes) and is included on a non-exclusive basis. An ACO could also be in the antitrust safety zone if it includes a dominant participant with a greater than 50 percent share in its PSA for a service that none of the other ACO participants provide in that PSA, the dominant participant is non-exclusive to the ACO, and the dominant participant does not require a private payer to contract exclusively with the ACO.

[18] *Id.,* p. 11. The ACO statement explains that all ACOs should avoid conduct that could facilitate collusion among ACO participants in the sale of competing services outside of ACOs and that, in addition, ACOs outside of the safety zone should avoid practices that impede private payers from encouraging patients to use providers outside of the ACO, practices that are tantamount to tying of sales or of exclusive contracting, and practices that could curtail a payer's ability to provide cost and quality information to patients.

actually materialize for existing groups, several others may end up taking a wait-and-see approach, especially since the upfront costs of delivering care under an integrated system may be substantial.

III. ACO-TYPE ARRANGEMENTS BETWEEN PROVIDERS AND COMMERCIAL INSURERS

Since before legislation of the ACA, and aside from CMS-sponsored ACOs, several providers and provider groups have been engaged in ACO-type negotiations based on the premise of incentive-based payments and quality improvement (sometimes referred to as Pay for Performance ("P4P")).[19] As early as 2010, a survey of health plans found that 96 percent of the plans reported having incentive-based plans either in operation or in development for physicians.[20] About 40 percent of the plans had pay-for-performance programs in place for hospitals and another 13 percent had programs ready to go or in development.[21] A large percentage of plans had either already implemented or were planning to implement ACO payment models or "patient-centered medical homes" which provide the care coordination needed for ACOs.[22] A more recent study by Leavitt Partners (2012) identified 221 distinct organizations across four states that were operating under ACO-type arrangements in June 2012.[23] The study highlights that while the care coordination and payment models vary widely across the organizations, they are all engaged in testing various delivery models that promote patient health while lowering cost.

For example, Integrated Healthcare Association in California incorporates 228 medical groups representing 40,000 physicians and 8 million health plan members. Aetna, Blue Cross Blue Shield, Cigna, Health Net, PacifiCare, and Western Health Advantage participate along with major California hospital systems. A second example is the Anthem Bridges to Excellence initiative, which was developed by a coalition of large employers and is operational in 13 states with 9,642 physicians in 1,838 practices. Other examples include the Blue Cross Blue Shield of Michigan program, Rewarding Results, which provides incentives to hospitals and the Physician Group Incentive Program that includes 40 contracted physician organizations with more than 4,000 practices and 11,274 physicians (about one-half PCPs and one-half specialists). [24]

The advantage of ACO-type arrangements between providers and commercial payers is that they can be structured to best respond to the idiosyncratic needs and commercial realities of dissimilar markets. In particular, providers and payers can negotiate on the delivery systems, quality measures, and reward mechanisms that would be most conducive to better cost and quality outcomes.

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[19] *See* J. Cromwell, M. Trisolini, *et al., Pay for Performance in Health Care: Methods and Approaches,* RTI INTERNATIONAL, (June 2011) (*hereinafter* Cromwell, Trisolini *et al.*) *available at* https://www.rti.org/pubs/bk-0002-1103-mitchell.pdf.

[20] *See* Med-Vantage, *2010 National P4P Survey*, p. 2.

[21] *Id.*, p. 3.

[22] *Id.*, p. 9.

[23] Leavitt Partners Accountable Care Intelligence Team, *Growth and Dispersion of Accountable Care Organizations: June 2012 Update, available at* http://leavittpartners.com/accountable-care-organization-intelligence/.

[24] *See* Cromwell, Trisolini *et al., supra* note 19, pp. 16-17, 22.

Antitrust Risks of ACO-Type Arrangements with Commercial Payers

ACOs enrolled in the MSSP have the ability to negotiate jointly with commercial payers, and the Agencies have indicated that the competitive effects of such negotiations will be analyzed under the rule-of-reason. Hence, all of the currently effective ACOs are potential candidates for joint negotiations with managed care plans, and if their Medicare service shares fall in the antitrust safety zone, they will be unlikely to face antitrust challenges.

ACO-type arrangements outside of the CMS-sponsored programs may face greater antitrust scrutiny because the Agencies generally condemn joint agreements on price or service terms between competing provider groups. As a result, complete avoidance of antitrust risk may only be possible for negotiations between already integrated provider groups and managed care plans. Provider groups that are not already sufficiently integrated can obtain some guidance towards joint negotiations from the Agencies 1996 Statement of Antitrust Enforcement Policy in Health Care.[25] That statement established that where providers share substantial financial risk or pursue meaningful clinical integration, they would likely produce efficiencies to the benefit of consumers. The 1996 statement specifies the criteria upon which the Agencies would make such determinations.

IV. MERGERS AND ACQUISITIONS

Many standalone providers are unlikely to have sufficient service scope, network size or patient volume to achieve meaningful savings through the process of coordinating care. This is especially true since the primary driver of savings from integrated care is coordination across the broad range of service types that patient populations need and across sufficient patient volume to justify the non-trivial costs of setting up and maintaining an integrated care delivery platform. It is unsurprising, therefore, that providers have been seeking formal integrations through mergers and acquisitions, both between hospital groups and with physician practices. Aside from greater service scope and added patient volume, formal integrations are appealing because of the undoubtedly greater ease to pursue coordinated care objectives under one provider organization as opposed to several.

Antitrust Risks of Mergers and Acquisitions

The Agencies' enforcement policies in regards to mergers and acquisitions are distinct from those pertaining to ACOs and joint negotiations between otherwise unaffiliated provider groups. In particular, the Agencies evaluate mergers and acquisitions under their Joint Merger Guidelines.[26]

In a recent speech, FTC Chairman Jon Leibowitz indicated that the 2007-2011 timeframe had produced about 333 hospital mergers nationwide, about one-third of which were reported to the FTC under Hart-Scott-Rodino.[27] Of those, as Chairman Leibowitz pointed out, about one-tenth received Second Requests and four were challenged in court. The FTC's challenges reveal

[25] U.S. Department of Justice & Federal Trade Commission, Statements of Antitrust Enforcement Policy in Health Care (1996), *available at* http://www.justice.gov/atr/public/guidelines/0000.htm.

[26] *See supra* note 19.

[27] *See* Remarks of FTC Chairman Jon Leibowitz, Antitrust in Healthcare Conference, American Bar Association/ American Health Lawyers Association, Ritz-Carlton Hotel, Pentagon City, VA, May 3, 2012.

that the FTC is generally concerned about concentration in the market for acute care services (and some specialty services like obstetrics) as well as the reduction of the number of provider alternatives for such services. In the case of the FTC's challenge of OSF Healthcare System's proposed acquisition of Rockford Health System in Rockford, Illinois, the FTC also defined a market for primary care physician services and computed the merging parties' share of full-time-equivalent physicians. It is possible that the FTC will continue to use such share calculations in their future analyses of proposed mergers between hospitals and of hospital acquisitions of physician practices.

The Joint Merger Guidelines do allow for an efficiency justification for proposed mergers and acquisitions.[28] Providers need to demonstrate, however, that the consolidation will lead to benefits that would be unattainable but for the proposed consolidation. For example, merging parties may need to demonstrate how a formal integration could lead to better economic alignment between provider groups working towards the goal of coordinating care, how the integration might deliver patient volumes sufficient to generate scale economies, or how smaller and less efficient groups could benefit from a larger provider's expertise at being able to manage sizeable groups of physicians and patients.

V. CONCLUSION

Affiliations between provider groups constitute a strengthening trend that will likely continue as the market responds to the recent health care legislation and as providers form strategic alliances in order to reduce costs and manage uncertainties going forward. While it is unclear which types of affiliations will prove most effective, provider groups need to factor the antitrust risks of each possible affiliation structure into their decision-making. Given that many types of affiliations are only just getting off the ground, there is little precedent on the basis of which to gauge what the Agencies' enforcement policies will be, but so far it appears that the Agencies will be receptive to efficiency arguments in their evaluations of the competitive effects resulting from the various affiliation types.

[28] *See* Horizontal Merger Guidelines, *supra* note 19, § 10.