August 2014

Wolters Kluwer Law & Business White Paper

Focus on Quality, Coordination of Care Leads to Quick Changes for U.S. Health Care Delivery—But Can ACOs Shake Antitrust Concerns?

Inside

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Sec. 3022 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) required the Secretary of HHS to establish the Medicare Shared Savings Program (MSSP). The goal was to encourage health care providers and suppliers to create Accountable Care Organizations (ACOs)—groups of providers and suppliers that band together to accept joint responsibility for the quality and cost of care delivered to their patients. These ACOs would agree "to be held accountable for improving the health and experience of care for individuals and improving the health of populations while reducing the rate of growth in health care spending," according to a fact sheet created by CMS' Medicare Learning Network to summarize the final rule provisions for ACOs. ACOs would improve the patient experience and, because better care has been shown to be more cost-effective, they also would help save money for the Medicare program.

Since the implementation of the ACO model in 2011, the quality and coordination of care for Medicare beneficiaries have improved and access to care has increased. Because of the experimental nature of the ACO, as well as the start-up costs of offering coordinated care, however, some health care providers are still leery about taking the plunge. Nevertheless, early results and projections have shown that the benefits of adopting ACOs—for beneficiaries and the nation as a whole—could be worth the initial risk of implementing the model.

The ACA's MSSP rewards ACOs with incentives for meeting certain performance measurements. The collaboration required between independent providers to create ACOs, however, necessarily raises the possibility of antitrust violations. In October 2011, the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) issued a policy statement that included safety zones for ACOs "that are highly unlikely to raise significant competitive concerns" to help providers forming ACOs ensure that they are compliant with the antitrust laws. This white paper provides an overview on ACOs and coordinated care, and then considers the policy statement and how it affects ACOs more than two years after its release.

ACOs: Bringing Coordinated Care to the Forefront

ACOs are groups of doctors, hospitals, and health care providers who join together voluntarily with the goal of providing high-quality coordinated care to Medicare beneficiaries. With proper coordination, health care providers can "work together to treat an individual patient across care settings—including doctor's offices, hospitals, and long-term care facilities," according

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to the CMS fact sheet. The coordination of care plays an indispensable role in eliminating waste and ensuring that patients, especially the chronically ill, "get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors," CMS explained.

ACO Requirements

Under the final rule, ACOs are required to establish a governing body that represents both the providers and the Medicare beneficiaries. The organizations also must engage in "routine self-assessment, monitoring, and reporting" of the care it delivers, utilizing the data to "continually improve the care delivered to their Medicare beneficiaries," according to the fact sheet. ACOs are also subject to a monitoring plan under which data regarding claims, spending, and quality is analyzed. Site visits are performed under the monitoring plans, as well as beneficiary surveys and audits, if deemed necessary.

Cost and quality of care are inherently tied. The final rule creating ACOs establishes the quality measures under which ACOs are evaluated and "link[s] quality and financial performance . . . set[ting] a high bar on delivering coordinated and patient-centered care by ACOs." ACOs are required to report quality measures to CMS, and feedback is to be given by the ACO to its providers to sustain continuous improvement in the quality of care, according to the CMS fact sheet. The quality standards established by CMS, the *2013-2014 version* of which can be found on the CMS website, often includes measures such as readmissions, use of electronic health records, preventive care and screening for high blood pressure, body mass index, and influenza, among other health issues.

Shared savings incentives are paid by CMS to ACOs that achieve specific savings goals established by CMS. The incentive payments received are based both on the savings earned by the ACO or any losses incurred. Because of the varying levels of experience and willingness to share losses among ACOs, there are two tracks available that serve as entry points for the organizations—the first allows the ACO to share savings only with CMS for the length of its first agreement, while the second allows the ACO to receive a higher share of savings, while also being responsible for any losses incurred during its first agreement period.

MSSP

CMS's MSSP was created on October 20, 2011, to facilitate the cooperation necessary among providers to reach quality and cost-saving goals. When ACOs experience success in cutting costs while still meeting performance standards in the provision of quality care, they are eligible to a share of the savings achieved for Medicare. According to the fact sheet, the types of health care providers and suppliers who are eligible to participate in the MSSP include:

- ACO professionals (*i.e.*, practitioners meeting the statutory definition) in group practice arrangements:
- Networks of individual practices of ACO professionals:
- Partnerships or joint ventures arrangements between hospitals and ACO professionals:
- Hospitals employing ACO professionals: or
- Other Medicare providers and suppliers as determined by the Secretary.

The providers and suppliers granted MSSP eligibility under the Secretary's discretion include certain critical access hospitals, federal qualified health centers (FQHCs), and rural health clinics (RHCs). All Medicare-enrolled providers that are in good standing also are eligible to participate as in an ACO, as long as they are not used for the purposes of assigning patients to the ACO.

Pioneer ACO Model

The Pioneer ACO Model was implemented by the CMS Innovation Center on January 1, 2012, to support organizations with more experience in offering coordinated, patient-centered care. Distinct from the MSSP, the model was developed to test the payment arrangement of shared savings and shared losses, offering "higher levels of reward and risk than in the Shared Savings Program" during the first two performance years, according to CMS. In the third year, the Pioneer ACOs that showed savings in the initial period would be eligible to participate in a population-based payment model, under which payments are made per-beneficiary per month. This population-based model would essentially replace the fee-for-service payment system with prospective monthly payments.

With the patient experience being "one of the central focuses" of the Pioneer ACO Model, beneficiaries maintain full benefits received under traditional, fee-for-service Medicare, "as well as the right to receive services from any healthcare provider accepting Medicare patients." Quality measures that mirror those in the MSSP are also used to monitor the

quality of care provided by Pioneer ACOs, as well as beneficiary satisfaction.

Advance Payment Model

Acknowledging that physician-owned and rural providers participating in the MSSP might need increased start-up support, CMS implemented the advance payment model. An initiative used to determine whether upfront payments would increase participation in the MSSP, the advance payment model gives a selected number of participants the opportunity to receive advance payments, which will be recouped by CMS from the ACOs' shared savings, according to a CMS fact sheet on the advance payment model. The advance payment model also sheds light on whether upfront payments would contribute to improved care for Medicare beneficiaries, increasing the amount of savings for the Medicare program.

The advance payment model is available to ACOs participating in the MSSP that do not include inpatient facilities and earn less than $50 million in total annual revenue or do include inpatient facilities that are critical access hospitals and/or Medicare low-volume rural hospitals and earn less than $80 million in total annual revenue. Applications are submitted by eligible ACOs for participation in the advance payment model, and the scoring system favors organizations that have the least access to capital, serve rural populations, and serve a significant number of Medicaid beneficiaries.

Three types of advance payments are available to these ACOs: (1) an upfront, fixed payment; (2) an upfront, variable payment based on its number of historically-assigned beneficiaries; and (3) a monthly payment that varies in amount based on the ACO's historically-assigned beneficiaries, according to the advance payment model fact sheet. The advance payments are recouped by CMS through the ACOs' shared savings based on an agreement between the ACOs and CMS, with any remaining balance paid by the ACO's shared savings for the subsequent performance year, until the end of the ACO's first initial agreement period. Any advance payments left unpaid at the end of the full initial agreement period are forgiven, unless the ACO does not complete the initial agreement period (in which case full recoupment is sought by CMS).

ACO Participation and Access to Care

Thirty-two initial Pioneer ACOs were announced in December 2011, and in April 2012, the first 27 ACOs under the MSSP were announced. The first batch of ACOs included more than 10,000 physicians, 10 hospitals, and 13 smaller physician-driven organizations, Wolters Kluwer reported (see First ACOs announced under Shared Savings Program, April 23, 2012). At that point, more than 1.1 million Medicare beneficiaries were receiving high-quality coordinated care from these organizations.

In July 2012, 89 more ACOs had been added to the MSSP, bringing the total to 154 and adding 1.2 million beneficiaries to the number of those served by ACOs. January 2013, saw the addition of 106 new ACOs, including 15 advance payment model ACOs, bringing high-quality coordinated care to up to 4 million more Medicare beneficiaries, according to a report from HHS. Again, in December 2013, 123 new ACOs were formed, and 1.5 million Medicare beneficiaries were added to the tally of receiving care from ACOs.

The coordination of care plays an indispensable role in eliminating waste and ensuring that patients, especially the chronically ill, "get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors."

A December 2013 report by Premier, Inc. showed that ACO participation nearly quadrupled over 18 months, with nearly 500 ACOs in existence throughout the country. Hospital participation in ACOs was at about 4.8 percent in spring 2012, increasing to 18 percent at the time of the report. And the number is expected to grow, as 76.5 percent of respondents in Premier's survey of 101 hospitals in 35 states said that they expected their hospitals to participate in the future.

Hesitation Among Providers

Not all health care providers are eager to jump on the bandwagon, however. Despite significant increase

in ACO participation, of the 50 percent of the respondents in Premier's survey who stated that they would participate by the end of 2013, only about 25 percent actually did so by the time of the report. The study also showed that large hospitals moved more quickly than small hospitals in joining ACOs, and nonrural and integrated delivery network hospitals were more likely to participate than rural and "stand-alone" hospitals.

Another late-2013 survey by Purdue Healthcare Advisors showed that 45 percent of hospital executives had no plans to implement an ACO-like model in the near future. The responses showed that hospital executives who are interested in ACOs are waiting for more stable and mature ACO models before joining, with the numbers breaking down as detailed in the report:

- 52 percent feel that there is too much unknown and are waiting for stronger evidence and a consistency of successful models;
- 49 percent feel their hospital is too small for an ACO-like model;
- 26 percent cite that, currently, the financial investment outweighs any potential benefit;
- 13 percent feel the performance benchmarks established by CMS are not realistic for their hospital; and
- 4 percent are concerned that transitioning to an ACO model would be too overwhelming for the staff.

Ultimately, hospital executives "are struggling with finding solutions for lower reimbursements and increased costs, while still maintaining an acceptable level of quality care," according to Purdue.

Costs Not as High as Projected

The costs of forming an ACO and getting it off the ground are also a deterrent for some health care providers, especially considering the risk of loss. "The average first 12 months [startup] cost per ACO of $2,000,000 is [a] strong statement about the high level of risk ACOs are willing to take to transform care in their community, said the *National Association of ACOs (NAACOs)*. The average startup costs ranged from $300,000 to $6.7 million, with the average falling at the $2 million mark, according to a survey by NAACOs. All-in-all, NAACOs said, "the average ACO will risk $3.5 million plus any feasibility and pre-application costs," estimating that "ACOs on average will need $4 million of startup capital until there is a chance for any recoupment of savings.

Cost of Care

The final rule states that Medicare will continue its practices under the fee-for-service payment system, paying "individual providers and suppliers for specific items and services," according to the fact sheet. A notable change comes by way of shared savings incentives paid by CMS to ACOs whose spending falls below the benchmark set by CMS.

The January 2013 report from HHS announced that the growth of spending per beneficiary in 2011 and 2012 has slowed, bringing projections of spending growth to GDP+0 for 2012-2022, a number that is "unprecedented in the history of the Medicare program," according to the report. If sustained, HHS reports that Medicare will be able to sustain "its commitment to seniors and persons with disabilities today and well into the future."

State of ACOs

CMS detailed the current state of health care delivery reform in a January 2014 *fact sheet*. According to fact sheet, more than 360 organizations are participating as Medicare ACOs, giving more than 5.3 million beneficiaries access to high-quality, coordinated care. Since the implementation of the MSSP, ACOs have saved $128 million in net savings for the Medicare trust fund. "While ACOs are designed to achieve savings over several years, not always on an annual basis," said CMS in a January 2014 *press release*, the first 12 months of ACO data shows that nearly half the ACOs that began operations in 2012—54 of 114—had lower expenditures than expected. Of the 54, 29 generated shared savings of more than $126 million, CMS reported.

As of *May 2014*, 338 ACOs were participating in the MSSP, covering 4.9 million assigned beneficiaries in 47 states, the District of Columbia, and Puerto Rico. An additional 23 participated in the Pioneer ACO program. Only 1 percent of MSSP participants, or five ACOs, utilized a two-sided risk model. More than half of all ACOs (57 percent) included networks of individual practices; 39 percent included group practices; and 49 percent involved hospitals that were not critical access hospitals. When the first ACO performance period began in April 2012, *27 ACOs* were participating in the MSSP, less than one-twelfth of the May 2014 figure.

Preliminary results also show that the 23 ACOs participating in the Pioneer ACO model have generated gross savings of $147 million in their first year. Nine out of the total 23 had significantly lower spending

growth, compared to Medicare fee-for-service, while still exceeding the quality reporting requirements.

Antitrust Concerns for ACOs

To receive shared savings payments, ACOs must have per capita costs for beneficiaries that are below specified benchmarks. The benchmarks are estimates of what total Medicare Part A and B expenditures would have been for a particular ACO's beneficiaries had the ACO not existed, even if some ACO beneficiaries received services outside the ACO. The ACO also must meet certain minimum savings rates and yearly quality standards with respect to *33 quality measures*. The shared savings an ACO receives is a percent of the difference between the estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, and the benchmark for the particular ACO. A one-sided risk model allows for a maximum sharing of 50 percent of savings, but not losses, only during the entire length of the first agreement period. A two-sided risk model provides for the sharing of up to 60 percent in savings, as well as losses, in all three years. Payments in the one-sided model are capped at 7.5 percent of an ACO's benchmark, while payments in the two-sided model are capped at 10 percent of the benchmark. The shared savings information is detailed in a *Final Rule* published November 2, 2011 (76 FR 67802).

Antitrust Enforcement Policy

Generally, *market allocation and price-fixing agreements* violate antitrust laws. Market allocation refers to the allocation of specific customers, types of customers, products, or territories among competitors; competitors agree to sell only to allocated customers or groups and refrain from selling to customers or groups allocated to other competitors. Price fixing is an agreement among competitors to charge the same price for goods or services. This characterization poses a potential problem for ACOs, which necessarily involve the collaboration of providers who may be considered competitors. To address antitrust concerns by providers interested in forming ACOs, the FTC and the DOJ (the Agencies) *issued* a *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (*policy statement)* on October 20, 2011. With one exception, the policy statement applies to all ACOs eligible for participation in the MSSP, regardless of whether they were formed before or after the date of enactment of the ACA. It includes ACOs that serve commercially insured patients, in addition to Medicare beneficiaries; however, it does not apply to mergers.

Rule of Reason Analysis

When competing health care providers that have engaged in a joint price agreement are financially or clinically integrated and the agreement is "reasonably necessary to accomplish the procompetitive benefits of the integration," the Agencies will apply a rule of reason analysis. The analysis determines whether any anticompetitive effects are outweighed by the procompetitive effects. The Agencies determined that they will apply the rule of reason to ACOs participating in the MSSP that use the same clinical and administrative processes and governance and leadership structures to serve patients in commercial markets. They concluded that ACOs' pricing agreements with private payers are typically reasonably necessary to allow the ACOs to improve health care delivery. The Agencies were comfortable making these determinations because CMS' eligibility criteria for ACOs to enter the MSSP, such as a leadership and management structure that includes clinical and administrative processes and reporting on quality and cost measures, were generally consistent with the Agencies' own discussion of clinical integration in their *Statements of Antitrust Enforcement Policy in Health Care*. Of particular importance was CMS' monitoring of quality improvement and cost reduction by individual ACOs.

ACOs' pricing agreements with private payers are typically reasonably necessary to allow the ACOs to improve health care delivery.

Safety Zones

The Agencies have established a safety zone for ACOs that are highly unlikely to raise anticompetitive concerns, focusing only on physicians, inpatient facilities, and outpatient facilities, rather than other types of providers, such as clinical laboratories and nursing homes. Specifically, the safety zone criteria involve three categories of

services: physician specialties, major diagnostic categories (MDCs) for inpatient facilities, and CMS-defined outpatient categories for outpatient facilities.

ACOs fall into the safety zone when independent ACO participants that make up the ACO and provide a common service have a combined share of 30 percent or less of each common service in each participant's primary service area (PSA), if at least two participants provide that service to participants from that PSA. A PSA is "the lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]." Each independent physician solo practice, fully integrated physician group practice, inpatient facility, and outpatient facility has its own PSA; each inpatient facility has a separate PSA for inpatient services, outpatient services, and physician services provided by its physician employees. Furthermore, to fall within the safety zone, hospitals and ambulatory surgical centers (ASCs) must be nonexclusive to the ACO, meaning that they are allowed to contract with private payers through entities other than the ACO. In an interview with Wolters Kluwer, *Ashley Fischer*, a partner at *McDermott Will & Emery*, noted, however, that ACOs may encounter difficulties meeting safety zone thresholds in every specialty.

ACOs qualify for a "rural exception" when the inclusion of certain physicians causes the share of a common service to be greater than 30 percent in any participant's PSA provided that the ACO includes only one physician or physician group practice per specialty on a nonexclusive basis for any county that includes one or more "isolated rural" or "other small rural" zip code. The exception also applies to rural hospitals on a nonexclusive basis. Despite this exception, Fischer observed, "there will be some specialties in rural areas with only a few providers, and including just a few of them can result in a high PSA share."

A "dominant participation limitation" applies where a nonexclusive ACO participant has a greater than 50 percent share in its PSA for a service that no other ACO in its PSA provides. The ACO, however, cannot require a private payer to exclusively contract with the ACO or limit its ability to contract with other ACOs or provider networks.

ACOs Outside the Safety Zone

Although an ACO's failure to meet safety zone requirements does not automatically indicate that it is anticompetitive, the Agencies suggest that ACOs falling outside of the safety zone avoid certain conduct to evade an anticompetitive label. For example, ACOs should refrain from including the improper sharing of competitively sensitive information, such as pricing information, that could lead to an increase in prices or a reduction in the quality or availability of health care services. The Agencies also warn that ACOs with high PSA shares or other possible indicia of market power should avoid discouraging private payers from incentivizing patients to choose certain providers; tying sales of ACO services to a private payer's purchase of services from other providers; discouraging ACO participants from contracting with private payers outside the ACO through exclusive ACO contracts; and restricting private payers' ability to make cost, quality, efficiency, and performance information similar to that used in the MSSP to its health plan enrollees.

Expedited Voluntary Antitrust Review

ACOs that had not yet signed or negotiated contracts with private payers as of the date of enactment of the ACA and have not yet begun participating in the MSSP may request expedited 90-day voluntary antitrust review from the Agencies. ACOs are instructed to submit requests to both Agencies before they enter the MSSP; the Agencies will determine whether the FTC or the DOJ will perform the review. ACOS must submit:

- an application and supporting documentation, including, for example, a sample of each type of participation agreement documents discussing business strategies regarding competition in the Medicare and commercial markets and the level and nature of competition among ACO participants;
- information sufficient to show the common services that two or more ACO participants provide to patients from the same PSA;
- the PSA of each participant, along with either the PSA share calculation or other data demonstrating the ACO's current competitive significance;
- restrictions that prevent participants from obtaining other participants' pricing data for services not contracted through the ACO;
- the identity of the five largest commercial health plans or other private payers for the ACO's services; the identify of other ACOs in any market in which the ACO will provide services; and
- any other documentation relevant to its impact on competition.

The reviewing Agency will advise the ACO that it does not likely raise competitive concerns, potentially

raises competitive concerns, or likely raises competitive concerns. The Agencies reserve the right to take further action when it appears that an ACO's formation or conduct may be anticompetitive.

Activity Since Policy Statement

On April 10, 2013, the FTC/DOJ ACO Working Group released a summary of its activities from October 2011 through March 2013. During that time period, only two organizations submitted requests for expedited voluntary antitrust review. The first applicant withdrew its request after being informed that it was ineligible for such review because it did not intend to operate in a commercial market, although the reviewing Agency offered to provide informal advice. Subsequently, the first applicant was accepted into the MSSP. The second applicant withdrew its request without explanation prior to review. As of the date of the summary, it had not participated in the MSSP.

The Working Group responded to 33 questions regarding participation in the MSSP; 25 of them related to PSA share calculations involved in safety zone analyses.

Policy Impact

It is difficult to determine how well the review process is working, when so few ACOs or potential ACOs have taken advantage of it. Although the Agencies' policy statement essentially offers ACOs a safe harbor in the form of safety zones, the guidance does not hold the weight of law. Indeed, although courts adjudicating antitrust matters may take the Agencies' guidance into consideration, they are not required to rely on it in issuing decisions. Therefore, it is possible that an ACO may meet safety zone requirements or receive a review statement suggesting that it does not likely raise competitive concerns and still receive a negative ruling in a court of law. It appears, though, that ACOs may be relying on safety zones in performing anticompetition analyses.

In her interview with Wolters Kluwer, Fischer expressed a desire for the Agencies to expand their policy statement to apply to "purely commercial ACOs," provided they would meet CMS' eligibility requirements for the MSSP, including utilization of "the same governance and leadership structures and clinical and administrative processes as ACOs that do participate." She also would like to see guidance on hospitals' ability to clinically integrate in commercial ACOs and contract jointly solely on that basis.

Conclusion

So far experiencing a successful implementation, ACOs are expected to continue showing results well within the projections for the first year of the program. Medicare and its beneficiaries are not the only ones reaping the benefits of the initiative—the ACOs themselves are seeing rewards. "We are delighted to be participating in the Shared Savings Program because of its goal to reduce costs while simultaneously increasing the quality of care and services we provide to our patients and community," said Dr. John B. Chessare, president and CEO of the Greater Baltimore Medical Center HealthCare system, in the CMS press release. "The Shared Savings Program is a tangible reminder of the historic transformation taking place in our health care system and we are pleased to be a part of it."

ACOs should refrain from including the improper sharing of competitively sensitive information, such as pricing information, that could lead to an increase in prices or a reduction in the quality or availability of health care services.

The Agencies continue to stand behind their policy statement, despite providers' concerns about mixed messages of collaboration versus antitrust enforcement. In a June 2013 keynote address to the 2013 National Summit on Provider Market Power Catalyst for Payment Reform, FTC Commissioner Julie Brill advised that providers engaged in "legitimate collaborative activities" had little to fear from the Agency. "Far from being a barrier to procompetitive collaboration envisioned in the ACA," she noted, "antitrust aligns naturally with the goals of ACOs." While there has been little news recently of Agency antitrust action against ACOs, analysts have noted an increase in FTC crackdowns on health care mergers. Brill, herself, stated that the Agency had increased enforcement activity related to hospital acquisitions of physician groups where a number of

specialists in a particular area join a single hospital, giving the hospital too much market power in that specialty area. She suggested that it might behoove providers to enter into ACO arrangements to avoid antitrust issues raised by mergers, emphasizing that ACO participants must coordinate care, but are not required or even encouraged to consolidate.

David Balto, a former FTC policy commissioner testified on September 19, 2013, before the House Committee on the Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law. In his opinion, "the most difficult issue the agencies must grapple with in the formation of these ACOs is market power, not integration." He argued that clinically integrated physician-sponsored ACOs could provide competitive alternatives to markets dominated by hospitals. That being said, he noted that the FTC had not taken enforcement action against a group of physicians for exercising market power since 1994 and suggested that the agency should pay more attention to this area. He cautioned, "the ACA and the need to control healthcare costs should not be the basis for approving an otherwise problematic merger among healthcare payors."