January 1, 2012 marked the statutory deadline for the Medicare Shared Savings Program (the “Program”) to be established under the Patient Protection and Affordable Care Act. With the two-fold goal of increasing quality while reducing costs in serving Medicare fee-for-service beneficiaries, the Program encourages health care providers to form Accountable Care Organizations (“ACOs”). Through a well-coordinated effort, federal agencies met the deadline and the first participant ACOs are scheduled to start in the Program on April 1, 2012. As health care providers are in the process of setting up ACOs, it is an appropriate time to review some antitrust considerations related to these arrangements.

In general, ACOs are networks formed through collaboration agreements between health care providers that may otherwise be competitors. ACOs may include physicians and nurses, networks of physician groups, “integrated delivery systems” of hospitals and their employed physicians, and partnerships of hospitals and physicians. Such networks must meet certain requirements to qualify as ACOs, such as applying for the Program and agreeing to other terms for a three-year period. A participating ACO that successfully meets quality requirements and creates cost savings will be able to share in those savings. ACOs that fail to meet quality and cost requirements may be penalized.

While providers working together may ultimately improve both patient care and costs, the ACO structure encouraged by the Act has created concern because many potential ACOs will simultaneously serve both Medicare and privately insured patients. Aware that joint price negotiations with private market payers could open the door to per se illegal price-fixing and market-allocation agreements among competitors, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) issued welcomed guidance for health care organizations seeking to avoid liability under antitrust laws while benefiting from Program participation. Although this guidance offers some protection under federal antitrust laws, it is not a prescription for complete immunity.

The October 2011 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program addressed many competition issues relating to ACOs, which were left unanswered by previous policy statements. As a preliminary note, the Policy Statement applies to certain collaborations among independent providers and provider groups that have been approved to participate in the Program or are eligible for and intend to participate in it. But it does not apply to mergers or
single, fully integrated entities. It creates an “antitrust safety zone” for ACOs meeting certain criteria. ACOs operating outside of the safety zone are provided with specific practices to avoid and a voluntary expedited review process is available for new ACOs. Additionally, two controversial provisions from the April 2011 proposed statement were altered for the final Policy Statement.

The Policy Statement explains when rule of reason treatment will be given to ACOs for joint price negotiations instead of per se illegal treatment. For ACOs that use the same structure and processes used in the Program to serve commercial markets, the FTC and DOJ will analyze joint price negotiations under the broader and more lenient rule of reason analysis instead of treating them as per se illegal. Under the rule of reason treatment, antitrust enforcement agencies weigh the procompetitive efficiencies against the likely anticompetitive effects of a collaboration to determine the legality of conduct. Eligibility requirements and continued federal monitoring of performance data that are part of the Program justify this more flexible approach.

Beyond receiving rule of reason treatment, some ACOs also may fall within the antitrust safety zone for organizations the FTC and DOJ will not challenge, absent extraordinary circumstances. Factors considered in determining whether an ACO falls within the safety zone include: (1) the ACO’s share of services (such as physician specialties, major diagnostic categories for inpatient facilities and outpatient categories) within (2) each ACO participant’s Primary Service Area (PSA). When an ACO participant provides the same services as other ACO participants, the ACO must have a combined share of 30 percent or less in each common service in each participant’s PSA in order to qualify for the safety zone. The availability of the safety zone may differ depending on the type of service involved and whether an ACO participant is exclusive or non-exclusive to the ACO. The zone may be extended by a limited exception for some rural providers and may be further limited for ACOs in which any participant holds more than a 50 percent share in its PSA.

The Agencies emphasize that falling outside of the safety zone does not necessarily mean that the ACO poses competitive concerns. However, ACOs must ensure that they are avoiding conduct such as improperly sharing competitively sensitive information (e.g. prices) that could lead to collusion and reduce competition in providing services outside of the ACO. Additionally, ACOs with high market share or market power may raise competitive concerns in four situations detailed in the Policy Statement that may prevent private payers from receiving better quality service and lower prices for their enrollees.

Two aspects of the final Policy Statement differ from the version proposed in April 2011 in ways that are beneficial to providers. First, the proposed mandatory antitrust review of ACOs was eliminated in the final version. Instead, newly formed ACOs may seek voluntary antitrust review that the Agencies will complete in 90 days. Second, unlike the earlier draft statement, the new Policy Statement does apply to ACOs formed before the enactment of the Act.

The Act does not include a preemption provision for antitrust activities so states may still apply their own antitrust laws to ACOs formed under the Act. This could result in a different analysis than that outlined in the Policy Statement and thus should be taken into consideration in the ACO’s formation and implementation of its business activities.

The Policy Statement does not provide blanket immunity for eligible ACOs against antitrust claims. However, it clarifies how health care providers may form integrated patient care delivery systems without exposing them to antitrust enforcement actions when they operate in both the Program and the commercial market.

To be eligible for the Program’s second start date on July 1, 2012, health care organizations must begin the application process by submitting a Notice of Intent by February 17, 2012.

Even if your organization decides to not pursue the Program, but rather decides to pursue forming and implementing an “ACO” solely for the commercial market, you still must be aware of potential antitrust concerns involving joint negotiations among competitors. We at Porter Wright have direct experience with these issues and representation before the FTC, including representation of a clinically integrated organization consisting of eight hospitals and more than 1,600 physicians in over 500 medical groups. Please contact any of our attorneys listed on this alert to discuss how we may help your organization.