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Accountable Care Organizations: More Guidance, but at what Cost?

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Recognizing that clinical and financial integration among health care providers can lead to efficiencies that will benefit patients, the Patient Protection and Accountable Care Act of 2010 (ACA) delegated to the Centers for Medicare and Medicaid Services (CMS) the authority to approve accountable care organizations (ACOs) to participate in the Medicare Shared-Savings Program. ACOs are comprised of different types of health-care providers (e.g., teams of doctors, hospitals, and other health care providers) who join together to coordinate and improve care for Medicare patients. The benefits of ACOs to their participating providers are twofold: (1) the ability to share in the savings they create; and (2) the ability to jointly negotiate with commercial payers to provide health care services. To obtain approval from CMS to participate in the Shared Savings Program, ACOs must clinically integrate their providers in ways so they are likely to meet CMS's quality and cost-savings standards.

Purpose

As stated in its Regulation Summary, CMS's goals with respect to the Medicare Shared Savings Program are: "[b]etter care for individuals; better health for populations; and lower growth in expenditures." More succinctly, CMS is asking ACOs to improve the quality of health care services they provide while at the same time developing efficiencies to keep costs down. These are lofty goals to be sure, as one often associates higher quality with higher prices.

How can ACOs achieve CMS's high goals? CMS hopes that ACOs will bring physician groups, hospitals, and other providers together in ways that create efficiencies in the delivery of care, permitting them to provide improved care at lower costs. If this proves true, ACOs will share in the savings they create, i.e., ACOs will make a return on their investment. ACOs that meet CMS's criteria will also be permitted to negotiate with commercial health plans, a key benefit to ACOs.

Antitrust Concerns

That ACOs are comprised of competing providers raises antitrust concerns because those providers will likely compete with one another outside the ACO. Although providers do not compete on price to participate in Medicare, they do compete on price to participate in commercial payers' networks. ACOs negotiating contracts with commercial insurers on behalf of provider participants that otherwise compete with each other is normally problematic. Indeed, the antitrust laws treat many agreements between competitors to set prices through joint negotiations with commercial insurers as per se illegal without analyzing their actual effect on competition.

Recognizing both the benefit of having ACOs provide quality care to Medicare beneficiaries and the potential anticompetitive effects of allowing ACOs to negotiate fee-for-service contracts with commercial payers, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (together, the Agencies) issued the *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (Proposed Statement). The Proposed Statement's purpose is to provide health care providers the antitrust clarity and guidance they need to form procompetitive ACOs that will participate in both Medicare and commercial markets.

Clinical and Financial Integration

The Agencies provided general antitrust guidance to provider-controlled contracting networks, such as IPAs, PPOs, and PHOs that contract with commercial insurers as a group, in their 1996 *Statements of Antitrust Enforcement Policy in Health Care*. In Statements 8 and 9, the Agencies explain that they will evaluate joint price agreements among competing health care providers in these types of networks under the rule of reason if the providers are financially or clinically integrated and joint negotiations of prices are reasonably necessary to accomplish the procompetitive benefits of the integration. The 1996 Statements provide a general roadmap for provider groups to follow to achieve clinical or financial integration sufficient to warrant a rule-of-reason analysis. That guidance is quite general,

however, and it resulted in many provider networks requesting formal advisory opinions from both the FTC and the DOJ, thus substantially increasing their up-front integration and compliance costs.

The Proposed Statement, however, gives providers forming ACOs to participate in the Medicare Shared Savings program with a blueprint to follow to ensure that they are clinically integrated without the need to obtain an FTC Staff Advisory Opinion or DOJ Business Review Letter—at least with respect to whether their jointly negotiating prices with commercial insurers constitutes a per se violation. This additional clarity benefits both CMS, which needs ACOs to achieve its goals for reducing Medicare costs, and ACOs that will contract with both Medicare and commercial health plans. Indeed, the Proposed Statement in many scenarios streamlines the compliance process for start-up ACOs, thus reducing up-front integration costs.

Importantly, the Proposed Statement provides that if an ACO meets CMS's eligibility criteria for participation in the Shared-Savings Program, the Agencies, without undertaking an in-depth analysis, will deem the ACO sufficiently integrated so that its joint negotiations are not per se violations of the antitrust laws. The more important CMS eligibility requirements are:

1. A formal legal structure that allows ACOs to receive and distribute payments for shared savings;
2. A leadership and management structure that includes clinical and administrative processes;
3. Processes to promote evidence-based medicine and patient engagement;
4. Processes to report on quality and cost measures; and
5. Coordinated care for beneficiaries.

Notably, ACOs that implement the same governance and leadership structure and participate in the same types of clinical integration activities with respect to their dealings with commercial insurers as in participating in the Medicare Shared Service Program can contract jointly with commercial health plans without worrying about per se illegality.

If the ACO meets these requirements, the question turns to whether the ACO will have the ability to exercise market power by increasing prices. The Proposed Statement provides a streamlined procedure for assessing this question under the rule-of-reason standard. For every service that the ACO provides through two or more providers, it must calculate the ACO's market share of that service in the primary service area (PSA) of each ACO provider offering that service. If none of those market shares exceeds 30 percent, the ACO is in an antitrust safety zone, and the Agencies will not challenge it except in "extraordinary circumstances." But if any of the ACO's market shares exceeds 50 percent (with minor exceptions), the ACO must obtain an antitrust review letter from the FTC or Antitrust Division stating that the agency has no intention of challenging the ACO. ACOs with market shares between 31 and 50 percent need not obtain a review letter, but the Proposed Statement suggests that they not engage in certain types of exclusionary conduct. The Proposed Statement's bright-line safety zone is markedly different from Statement 9's treatment of multiprovider networks (most akin to ACOs), which includes no antitrust safety zone.

Conclusions and Concerns

CMS has provided a blueprint for provider groups to clinically integrate and the Agencies have provided a streamlined procedure for assessing an ACO's market power under the rule-of-reason. With this specific guidance, provider groups should be racing to form ACOs, right? Not necessarily. The up-front costs of formation and compliance may be prohibitive.

In its proposed rule, CMS estimates that it will cost $1.8 million to form and then operate an ACO for one year. Professional associations and other organizations, however, are skeptical of CMS's estimates. In fact, the American Hospital Association (AHA), on May 13, 2011, released its own detailed study that analyzes the start-up investment required to form an ACO. In the AHA's study, the cost to start and manage an ACO for one year ranges from $11.6 million for a 200-bed, single-hospital system, to $26.1 million for a 1200-bed, five-hospital system.

Provider groups, hospitals, and other health care professionals considering whether to form an ACO must also account for compliance costs. In addition, ACOs that initially fit within the Proposed Statement's antitrust safety zone will be required to develop procedures to ensure that they maintain their safety-zone status. This will require ACOs to calculate each of their participants' PSA market shares regularly, as they lose their safety-zone protection if any participant's market share for any common service increases above the safety zone's 30 percent threshold. Regularly collecting and analyzing the data necessary to compute the PSAs could prove costly.

Prospective ACO participants are rightfully concerned about the up-front costs of forming, and the ongoing implementation costs of maintaining, an ACO, especially in light of the potentially small financial return on these investments. Despite providing relatively bright-line integration criteria, CMS may have underestimated the financial burden that forming an ACO will have on provider groups. If CMS is committed to the ACO model as a means of enhancing the quality of care while reducing Medicare costs, it should consider eschewing the complex details of the regulations in favor of cost-effective measures that are attractive to provider groups and that address CMS's regulatory concerns.