Government Workshop Weighs Impact of Antitrust, Anti-kickback and CMP Laws on ACOs

The Federal Trade Commission (FTC), the Centers for Medicare and Medicaid Services (CMS), and the Department of Health and Human Services (HHS) Office of Inspector General (OIG), hosted a multi-stakeholder workshop recently to address two specific legal issues related to accountable care organizations (ACOs) – antitrust, and fraud and abuse. The workshop featured panel discussions involving health care industry representatives, legal experts and regulators who focused on how current laws may be obstacles in the formation of ACOs.

CMS Administrator Dr. Donald Berwick emphasized that ACOs should not operate as health care financing mechanisms, but rather as delivery systems, and that the transition from the current fee-for-service delivery system to one focused on accountability (both clinical and financial) would be difficult. His views were echoed by FTC Chairman Jon Leibowitz and HHS Inspector General Daniel Levinson, who both stated that current laws should not stand in the way of improving health care delivery but rather be considered in a different context. All pledged their commitment to cooperation and flexibility to ensure that ACOs are allowed to grow.

The Patient Protection and Affordable Care Act (PPACA) defines an ACO as an organization of health care providers that agrees to be accountable for the quality, cost and overall care of the Medicare beneficiaries assigned to the ACO. This accountability will be measured by the ACO providers’ ability to cooperate across the patient care spectrum in ways sufficient to achieve cost savings, while simultaneously improving the quality of care delivered. Many legal experts believe that existing antitrust laws, the Anti-Kickback Statute, Stark and the Civil Monetary Penalty (CMP) laws, will have a chilling effect on the ability of competing health care providers to come together and cooperate in ways that are fundamental to the formation and success of ACOs. Fortunately, the PPACA also gives HHS the express authority to issue fraud and abuse waivers to ACOs and organizations defined as “health care innovation zones” as necessary.

Under current antitrust laws competing, independent providers are barred from negotiating jointly with payors, unless the providers integrate with one another in a way that meets either the existing financial integration or clinical integration safe
harbors. Under the financial integration safe harbor, competing, independent providers are permitted to negotiate jointly with payors if the providers share a certain level of financial risk under the reimbursement arrangement (e.g., global capitation payments or risk pools). Under the clinical integration safe harbor, providers must demonstrate a certain level of clinical integration such as shared quality improvement measures, shared protocols and other shared performance metrics. Workshop panelists discussed the expansion of these safe harbors and the creation of new ones that would allow independent providers in ACOs to negotiate jointly not only with CMS under the Shared Savings Program, but also with commercial payors.

Federal regulators indicated that they are exploring an antitrust safe harbor based on market share, as well as implementing a possible expedited review process for ACO activities that fall outside existing antitrust safe harbors. Some participants proposed that federal regulators base any safe harbors or waivers on an ACO’s ability to meet the objectives of improving care and population health, rather than focusing on specific infrastructure components or governance structures (e.g., requirements that electronic health records be a component of ACO development). Workshop panelists agreed that ACOs should commit to data-sharing and transparency before qualifying for any antitrust safe harbor or exemption. Others commented that any safe harbor protection being considered for ACOs should have the same criteria for commercial payors as for Medicare.

Participants expressed concerns about the Medicare Shared Savings Program and its potential to cause further, anti-competitive consolidation in the market. Given that the bulk of the savings under the program likely will be generated from reduced hospital admissions, and shared largely by physicians, hospitals may have an incentive to buy up and integrate with physician practices as a way to share in the savings and offset admissions declines. Whether ACO-driven consolidation represents a dangerous development for the commercial insurance market was a specific concern. Several panelists, including payor and employer representatives, raised concerns that ACOs ultimately would consolidate around players who are already dominant in their markets, in many areas favoring hospital-led organizations with a large base of employed physicians. Others noted, however, that the PPACA permits physicians to form ACOs without hospitals, which could mitigate this concern.

From a fraud and abuse perspective, the civil monetary penalty law (CMP) is perhaps the most significant legal impediment to the growth and success of ACOs. The CMP makes it illegal for hospitals to pay physicians to reduce or limit services to Medicare beneficiaries. The Stark and Anti-kickback laws also prohibit certain types of financial arrangements between referring providers. Collectively these laws, without further expansion of existing safe harbors or the creation of additional ones, could impede the ability of ACO providers to share financial risk and distribute achieved savings. Workshop panelists discussed the need to either finalize the already existing proposed shared savings safe harbor or create new safe harbors that would encourage information and risk sharing among ACO providers.

Federal regulators will be collecting written statements from stakeholders on the many issues discussed during the workshop, and proposed regulations regarding ACOs are expected by the end of the year. Whether the regulations will address the many issues
and concerns that were raised during the workshop remains unclear. Drinker Biddle has been closely monitoring CMS’s development of the regulations and has been meeting with agency officials to discuss ACO implementation. The firm will continue to provide insight as these issues progress.

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