ADVERTISEMENT

DuaneMorris®

ACCOUNTABLE CARE AND CLINICAL INTEGRATION:
What Every CEO Should Consider Now

The Patient Protection and Affordable Care Act (the "Act"), signed into law by President Obama in March, provided for a number of noteworthy healthcare reforms, including provisions establishing a Medicare pilot project for the creation of accountable care organizations ("ACO").

What Is an ACO?

An ACO is an organization that:

1. is legally organized to receive and distribute shared savings;
2. has at least 5,000 Medicare beneficiaries and sufficient primary-care physicians to serve these enrollees;
3. has agreed to participate in the program for at least a three-year period;
4. collects sufficient information concerning ACO providers such that the U.S. Secretary of Health and Human Services may determine how best to assign Medicare beneficiaries to the ACO and what constitutes shared savings;
5. has a leadership and management structure that includes clinical and administrative information systems;
6. has the guidelines and information systems to (a) promote evidenced-based medicine, (b) collect and report the necessary data to evaluate quality and cost measures, and (c) coordinate care; and
7. can demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

The model is intended to promote efficiencies by encouraging healthcare providers to integrate by employing new financial incentives to collaborate on the care of a patient, while at the same time promoting increased quality outcomes. Any savings generated from the delivery of coordinated care would be shared with the providers on a predetermined formula. These assumed savings are anticipated to be derived from, at a minimum, doctors and hospitals sharing patient information electronically and providing care according to common protocols rooted in evidence-based medicine. In the absence of new safe harbors, exceptions and or waivers to the Stark, anti-kickback antitrust laws, it appears providers seeking to become an ACO may need to be "clinically integrated."

What Is Clinical Integration?

ACOs appear to have been established without deep consideration of the existing laws, which may make it difficult to effectuate the desired affiliations needed to form an ACO. The collaboration of competitors invariably presents antitrust issues, and shared savings may be hard to implement given the specific anti-kickback and Stark prohibitions. A recent joint meeting of officials from the Federal Trade Commission ("FTC") and the Centers for Medicare & Medicaid Services ("CMS") considered some of these issues, leaving an impression that certain exemptions would be considered to foster the growth of ACOs. However, without further clarification from the FTC, the elements of clinical integration—which were established by the FTC in 1996—may be worth reviewing when considering what must be done to establish an ACO. Competitors may collaborate and potentially avoid antitrust exposure if these competitors are clinically integrated. Applied to ACOs, and in the absence of new "approved" affiliation arrangements, clinical integration would likely be necessary for competitors to collectively negotiate provider agreements with insurers.

To avert a per se violation of antitrust laws, consider reviewing past FTC opinions, noting that antitrust analysis is fact-intensive and based on the specific marketplace dynamics.

What Should be Considered Now?

Proposed models of ACOs are untested, the methods of payment and savings sharing are in the development phases, and certain laws may need to be changed. It is unknown what, if any, role Medicare beneficiaries may have in shaping the ACO delivery model.

One trend that CEOs may want to monitor is the role of the Medicaid programs in each state and their inclination to support ACO development. The impetus for providers to consider ACOs appears driven by proposed changes in Medicare reimbursement, which will not take place until 2012. Medicaid changes are evolving now, with some states moving to capitation and ultimately to ACOs. CEOs may want to keep in mind that the ACO structure considered to comply with state Medicaid programs should also comply with Medicare guidelines.

CEOs may also want to consider:

1. developing electronic medical records and other information systems to enable an ACO provider to share information, monitor clinical compliance with established clinical benchmarks and calculate the savings generated from collaborative patient care;
2. creating an evolving vision of the healthcare provider's role in ACO development—as a leader or collaborator;
3. implementing a physician/hospital collaboration strategy, particularly for the relationships with primary-care physicians; and
4. staying current on new legal developments regarding ACOs, especially with respect to antitrust, Stark and anti-kickback changes to accommodate ACOs.

From a 40,000-foot view, the "biggest loser" in the implementation of ACOs could be the insurers. Large, established ACOs with significant numbers of private and public patients could create insurance vehicles that they own and control, potentially cutting out the insurer or HMO. CEOs may want to consider which, if any, local insurers would make good partners now—before the scramble for insurance partners begins.

If you have a question on this material or would like to discuss legal services, please contact us at **healthcare@duanemorris.com**.

Duane Morris LLP is an international full-service law firm of more than 700 lawyers, approximately 35 of whom advise a wide range of healthcare organizations on all aspects of corporate matters, mergers and acquisitions, regulatory compliance and enforcement, reimbursement, litigation, labor and employment, real estate and taxation matters.

C. Mitchell Goldman is a partner in Duane Morris' Health Law Practice Group. He has been advising members of the U.S. Senate and their staffs on health insurance reform issues. He focuses his practice on the finance and corporate aspects of healthcare delivery.

Gregory A. Brodek is a partner in Duane Morris' Health Law Practice Group. He concentrates his practice exclusively in the area of healthcare law and represents hospitals, physicians, physician groups and integrated delivery systems on a wide variety of regulatory, compliance, and reimbursement issues in the United States.

Originally published as a special supplement to Modern Healthcare Magazine, October 2010.