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On the Cusp of Historic Changes - What's Next for ACO Formation

Husch Blackwell attorneys participated in the public workshop on accountable care organizations (ACO) held in Baltimore, Maryland on October 5, 2010. The workshop was presented by the Federal Trade Commission (FTC), the Centers for Medicare and Medicaid Services (CMS) and the Office of the Inspector General for the Department of Health & Human Services (OIG). Leaders from all three agencies noted that we are on the cusp of historic changes to the way healthcare is delivered in the United States. All three presenters, Dr. Don Berwick for CMS, Jon Leibowitz for the FTC and Daniel Levinson for the OIG, recognized the opportunity for a sea change in the healthcare delivery system if all three agencies can work together with the provider community to overcome any current legal impediments to that change.

All three leaders concurred that the ACO structure contemplated in the Patient Protection and Affordable Care Act (PPACA) reflects neither the status quo, nor independent practice organizations or health maintenance organizations. However, to be effective, an ACO cannot be a one-size-fits-all system. There must be some flexibility in the systems to account for the location (rural versus urban), size and other factors.

Dr. Berwick said his agency's goals were the "three Bs – better care for the individual, better health for the population, and better systems to lower costs without causing harm." He foresees an ACO as a patient and family-centered organization that has shared decision-making, memory about the patient, teamwork among the patient and providers, reduction in waste, movement of resources to the patient and decreasing dependence on hospitals. Mr. Leibowitz spoke about the need to cast aside stereotypes. He cautioned that if ACOs stifle competition rather than invigorate it, the country will lose a great opportunity. Mr. Levinson emphasized that the healthcare fraud and abuse rules should not stand in the way of improving the quality of care while

lowering costs to the consumer. Levinson assured the audience that while his agency does not want to impede innovation, the OIG will continue to safeguard the integrity of new programs that are often vulnerable to a few bad actors.

Discussion ensued about whether the FTC will develop safe harbors for physicians and hospitals to work together in an ACO environment to share the risks and monetary benefits of coordinated care. The FTC is looking to develop safe harbors and an expedited review process for arrangements that fall outside the safe harbor parameters. Likewise, the OIG and CMS are working to develop safe harbors or other methods to avoid the strictures of the Stark Law and the Anti-Kickback Law. Following much discussion, the three agencies indicated that they are working frantically to develop relief mechanisms such as safe harbors or waivers for the Secretary of the Department of Health and Human Services (HHS) to implement within a short period of time because accountable care is a priority of the Obama Administration.

Throughout the workshop, the agencies remained silent about their particular views and proposals but expressed interest in receiving insight from a variety of organizations and persons. The first two of the three panel discussions were conducted by FTC officials and included representatives from various provider organizations (such as the American Medical Association and the American College of Cardiology), private healthcare providers (such as Fariview Health Service, TMC HealthCare and Weill Cornell Medical College), several insurance providers (CIGNA, BC/BS Massachusetts) and others, including one attorney and a representative of the St. Louis Area Business Health Coalition. These discussions focused primarily on antitrust issues. The last panel, which discussed fraud and abuse, Stark Law and Anti-Kickback Law issues, was organized by HHS officials and included representatives from Federation of American Hospitals, American Hospital Association, American Association of Medical Colleges, American Medical Group Association and American Academy of Nurse Practitioners.

Not surprisingly, the suggestions offered by each panelist reflected the views of his/her constituents. For example, insurance industry representatives are skeptical whether ACOs will be beneficial to quality of care and instead will result in decreased competition. One panelist noted that 79 percent of all physicians in private practice today work in groups of nine or fewer physicians – most include four or fewer. The panelist observed that the prevalence of small practice groups may make it difficult to develop ACOs. Other issues raised during the initial panel discussion included:

How to share cost containment benefits equitably when hospitals were subject to the brunt of the revenue loss

What should be done when a physician member of an ACO does not perform well or successfully contain costs?

What should the performance or cost containment measures include – clinical outcomes, patient experience measures or cost savings only – and should the measures be weighted?

Will the performance measures remain constant from year-to-year or adjust annually based on increased cost-savings incentives?

While no answers to the issues were forthcoming, the issues that were identified and discussed appeared to be appreciated by the agency representatives. The agencies want to work together to achieve the objectives of PPACA.

It was clear from the discussions that many questions need to be answered including:

Will providers measure performance differently than payors?

Must providers have electronic health records (EHR) before performance can be measured? One panelist noted that only 25 percent of all physicians have high speed internet access in their offices.

Even with the government assisting in the acquisition of EHR through the meaningful use process, it was estimated that 15 percent of the benefit for EHR was gained by the physician while 85 percent benefited third parties.

What metrics will be used to measure quality issues in specialties that Medicare does not cover, such as obstetrics and pediatrics?

How long can an ACO be in operation before it has to show cost-savings benefits?

How big does an ACO have to be to become profitable?

On the latter point, most of the panelists agreed that an ACO would require at least 5,000 patients to be successful. This suggestion led to a further discussion concerning the geographic size of the territory to be covered by an ACO in which several participants observed that many rural communities lack sufficient populations to satisfy this minimum.

The HHS panel discussion focused on waivers and the Secretary's waiver authority under PPACA. Two sections of the PPACA allow waivers -- §3021 (pilots designed to reduce expenditures while preserving or enhancing quality of care) and §3022 (Medicare Part A and B "Shared Savings Program"). Inspector General Levinson said that regulations will "be issued shortly" on the §3022 provision, which will focus on program safeguards, the application of the Stark Law and the Anti-Kickback Law principles to ACO and what changes are needed to accommodate ACOs. The discussion again focused on the use of waivers versus safe harbor provisions. There was also some suggestion that the OIG will issue broad guidelines under which each ACO will submit an application that will be approved or disapproved (waiver granted or not), much like an advisory opinion is solicited from the

OIG. OIG representatives were particularly interested in receiving feedback concerning the type of monitoring that should be conducted of ACOs, who should undertake the monitoring, and the role of information technology and EHR in monitoring ACOs. This commentary suggests that ACOs will be subject to the same OIG data mining scrutiny that other health care providers are experiencing currently.

Participants generally agreed that the ACO structure presents opportunities as well as challenges for physicians, hospital systems, other providers and patients. As contemplated by the agencies and panelists, ACOs will rely on primary care physicians to manage the ACO. Therefore, a critical mass of physicians and physician specialists will be needed to fund and support the infrastructure necessary to set up and run the ACO. In addition, organizational governance and structure will be important to help manage and monitor the core objectives of the ACO and care options. Hospitals have the necessary infrastructure to assist the primary care physicians, but ACOs require active physician participation to be successful.

Because the government will pay bonuses to participants based upon cost savings and most panelists agreed that the ultimate cost savings to be achieved under the new structure will come primarily from hospitals, hospitals should carefully consider how to accomplish the most beneficial savings. Acquiring physician practice groups to manage the ACO is not the answer, and preventing readmissions and other initiatives may negatively impact hospital financial results. Therefore, hospitals that participate in an ACO need to develop other sources of revenue within the ACO to offset losses.

The workshop raised more questions than answers. However, it was clear that the agencies involved have been working on the issues for some time and already have ideas about what the regulations and/or safe harbors need to provide to successfully implement the PPACA's directives. Since the regulations are expected to be issued soon, the agencies will have very little time to analyze the comments from the workshop to adjust their proposals.

For those interested, the recording and transcripts from the workshop have been posted by OIG along with Levinson’s prepared remarks.

What This Means To You

The overall sentiment among all of the agencies that participated in the workshop appeared to recognize that the rule of reason should be applied when evaluating ACOs.

Contact Info

If you have any questions about this or any other issue involving healthcare, please contact your Husch Blackwell attorney.

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