

HEALTH REFORM IMPACT

What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Report from the Accountable Care Organization Workshop

October 15, 2010

Introduction

On October 5, 2010, the Federal Trade Commission ("FTC"), the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services' Office of Inspector General ("OIG") jointly hosted a workshop on the legal issues and potential impediments associated with developing Accountable Care Organizations ("ACOs"). The workshop began with a speech by CMS Administrator Don Berwick, M.D., M.P.P. highlighting his triple aim for healthcare: better care for individuals, better health for populations and reduced per-capita costs without harm to the beneficiaries. Berwick emphasized the need for cooperation among healthcare providers and a regulatory structure that will allow and encourage such cooperation. The morning session featured two FTC-moderated panels on ACOs and antitrust issues. During the first of two afternoon sessions, Vicki Robinson, Senior Advisor for Health Care Reform from the OIG, and Troy Barsky, Director, Division of Technical Payment Policy from CMS, moderated a panel ("HHS Panel") of leaders from various industry associations.¹

Background

Section 3022 of the Patient Protection and Affordable Care Act ("PPACA") requires the creation of the Medicare "shared savings program," which allows qualified groups of providers and suppliers to work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO.² ACOs that meet quality performance standards established by the Secretary of Health and Human Services ("the Secretary") will be eligible to receive a share of the savings that they have generated for the Medicare program. The Secretary must establish the shared savings program no later than January 1, 2012.

Because PPACA does not provide many details about forming ACOs or what requirements will apply to them, and because shared savings arrangements can potentially run afoul of the current fraud and abuse laws, as well as antitrust laws, the industry has been eagerly awaiting the implementing regulations that will impact the structure and function of ACOs. The Secretary has been given broad

¹ The represented trade groups included the Federation of American Hospitals, the American Hospital Association, the Association of Health Insurance Plans, the National Association of Community Health Centers, the Medical Group Management Association, the American Medical Group Association, the American Academy of Nurse Practitioners and the AARP. Public comments are [available here](#).

² For more information about Section 3022 of the Patient Protection and Affordable Care Act, please [click here](#).

waiver authority under Section 3022 of PPACA to waive anti-kickback, self-referral and civil monetary penalty ("CMP") laws with regard to ACOs.

FTC Panel Discussions

In introductory remarks to the morning session, FTC Chairman Jon Leibowitz stated that ACOs provide the opportunity to effectuate healthcare reform and that the FTC's goal is to ensure that regulation both encourages development of ACOs and protects consumers. He stated that the FTC wants to explore the development of safe harbors for ACOs as well as an expedited review process for ACOs that fall outside the safe harbors. Chairman Leibowitz acknowledged the difficulty of establishing safe harbors and stated that input from providers would be important.

The first panel addressed the issue of clinical integration and joint pricing. The panel, which included FTC-moderated providers, payers and policy experts,³ considered whether the FTC should establish a safe harbor whereby an ACO that meets CMS' criteria for ACO participation in the Medicare program would be treated by the FTC as being clinically integrated. Presumably, the safe harbor would provide that absent unusual circumstances, the agencies would not challenge the arrangement, including joint pricing, and if reviewed, a rule of reason analysis would apply. Discussion also touched on tension between safe harbors and the flexibility needed to promote innovation in new care delivery models.

The main topics discussed in the second panel were market power and exclusivity. The panel discussed whether there should be antitrust safety zones for ACOs with a market share equal to or less than an FTC-determined market share percentage. The discussion centered on whether an ACO needs to reach a certain size to be efficient and on concern that safety zones with arbitrary market share percentages could be detrimental to the creation of ACOs. Payers expressed concern that ACOs could result in market power for providers and increased pricing.

The panel also discussed exclusivity. An exclusive ACO is one in which the providers belonging to that ACO are prohibited from joining another ACO. Under the FTC's previous guidance on clinical integration, non-exclusivity has been favored over exclusivity. Panelists discussed whether exclusivity would be necessary in some instances for an ACO to function as intended and to succeed. The general consensus among the panelists was in favor of exclusivity solely for primary care physicians.

HHS Panel Discussion

The purpose of the HHS Panel that occurred during the afternoon was to discuss the different ways in which the Secretary might exercise waiver authority or create new exceptions and safe harbors related to the Stark physician self-referral law, the federal Anti-Kickback Statute and the CMP law in order to encourage the creation and development of ACOs. Mr. Barsky and Ms. Robinson kicked off the session by asking whether the HHS Panel members would prefer a waiver or, alternatively, the creation of new safe harbors and exceptions. While the majority of the HHS Panel was in favor of a waiver, several panelists believed that, because some integrated delivery systems already exist and are functioning well, fraud and abuse laws are not a significant impediment necessitating a waiver in all circumstances. Those in favor of a waiver stated that, due to the expense of forming an ACO and the uncertainty of safe harbors and exceptions, a waiver was an absolute necessity.

³ The panelists included representatives from Brown & Toland, Fairview Health Services, Weill Cornell Medical College, St. Louis Area Business Health Coalition, TMC HealthCare, Equity Healthcare, HEREIU Welfare Fund, Epstein, Becker Green, the Center for Health Care Quality and Payment Reform, Advocate Physician Partners & Advocate Health Care, BC/BS Massachusetts, CIGNA, American Medical Association, Covenant Health Partners/Covenant Health Care and the American College of Cardiology.

The Panel members generally agreed that any waivers granted should apply not only to the shared savings component of the ACO program, but also to the creation process, structure, capitalization and operation. As an example, the decision as to which entities would be responsible for the initial staffing and information technology expenditures should not create fraud and abuse hurdles.

Further probing the waiver issue, Mr. Barsky and Ms. Robinson asked the HHS Panel to discuss the types of business arrangements and providers that a waiver might cover. Several HHS Panel members expressed a need for flexibility and inclusiveness in order for ACOs to thrive. Other HHS Panel members commented on the need for a "level playing field" to account for differences in ACOs operating in rural areas rather than urban areas, as well as the regulatory burden for smaller ACOs.

The remainder of the session was spent discussing how to focus on protection of patients and on improving quality of care, the types of monitoring programs the government should require, and whether CMS should impose some type of governance structure on ACOs. The Panelists agreed flexibility was important and encouraged the government not to impede innovation with requirements that would have a chilling effect on the ACO program.

The HHS Panel discussion was followed by an HHS listening session in which workshop attendees were invited to provide comments to HHS regarding the interaction between ACOs and the physician self-referral law, the Anti-Kickback Statute and the CMP laws. The proposed regulations are expected sometime this fall.

If you have questions regarding the information in this alert, please contact any of the attorneys in our Antitrust and Trade Practices or Healthcare Practice Groups listed below.

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