

ACOs and the Stark Law-How to Co-exist

The Patient Protection and Affordable Care Act (ACA) in 2010 brought sweeping changes to healthcare delivery, including initiatives regarding the development of Accountable Care Organizations (ACOs). As discussed in the August 2010 issue of *Health Capital Topics*, ACOs are healthcare organizations in which a set of providers are held accountable for the cost and quality of care delivered to a specific local population.¹ Because of an ACO's integrated structure, whereby physicians and hospitals collaborate to deliver a continuum of care to patients, questions have arisen related to the legal permissibility of these arrangements in light of Stark Law prohibitions against self-referral for designated health services (DHS) to entities in which they have a financial interest. ACO reimbursement structures including gainsharing payments and bundled payment programs do not currently fit within any type of Stark safe harbor or waiver provisions.

Section 3022 of the ACA gives the Secretary of HHS the authority to waive compliance with the Stark law "as may be necessary to" conduct any payment model for ACOs that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare shared savings program and bundled payment pilot program.³ However, questions remain as to whether waivers should be broad in scope, in order to encourage innovation, or whether waivers should be narrowly construed to avoid attempts at overreaching by providers.⁴ The American Health Insurance Plans (AHIP) has advocated that codified waivers are unnecessary because the ACA gives the Secretary of HHS discretion to issue waivers on a case-by-case basis. Furthermore, AHIP maintains and that any waivers issued should be narrowly construed and contingent upon an ACO meeting a certain set of criteria to be defined by HHS.⁵ However, provider groups such

as the American Medical Association (AMA) and American Hospital Association (AHA) have urged HHS to issue formal broad waivers that encompass all ACO structures to ensure a level playing field between insurers and providers.^{6,7}

At an ACO workshop held by the Federal Trade Commission (FTC), Centers for Medicare & Medicaid Services (CMS), and the Office of Inspector General (OIG) on October 5, 2010, panels discussed criteria that should be inherent in any waivers or safe harbors, including: (1) they should be broad enough to encourage competition and innovation among ACOs; (2) they should be applied uniformly; (3) the process used to develop waivers should be fair; (4) they should apply at the initial formation of an ACO to protect the development of ACOs going forward.⁸ CMS is expected to issue further guidance regarding the creation and development of Stark waivers for ACOs during the first part of 2011.

¹ "Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?" By Kelly Devers and Robert Berenson, Urban Institute, (October 2009) p. 1.

² "Physician-Hospital Clinical Integration: Navigating the Complexities," Webinar Presented by Stratford, October 10, 2010.

³ Transcript from: "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback and Civil Monetary Penalty Laws," Department of Health and Human Services, October 5, 2010, p. 3

⁴ AHIP Response to CMS's Request for Information Regarding ACOs By Carmella Bocchino, AHIP (December 3, 2010), p. 10.

⁵ "AHA Letter Responding to CMS's Request for Information Regarding ACOs" By Linda E. Fishman, American Hospital Association (December 3, 2010).

⁶ "AMA Letter Responding to CMS's Request for Information Regarding ACOs" By Michael D. Maves, American Medical Association (December 2, 2010).

⁷ "Workshop Examines Effects of Waiver Authority on Development of ACOs," McDermott Will & Emery Newsletter, October 11, 2010, http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/27c34c48-82c5-4f46-8acf-77a1cea77d31.cfm, (Accessed October 14, 2010).



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