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Emerging ACO models raise legal and regulatory issues for providers regarding risk-bearing, care delivery and organizational arrangements

In the second year of implementation of the Affordable Care Act (enacted in March 2010), many hospitals, medical groups, and other providers continue to progress towards the goal of delivering care via the Accountable Care Organization (ACO) model.[1] On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) issued the proposed rule for implementing the Medicare Shared Savings Program (MSSP) to establish ACOs. At the same time, the Federal Trade Commission (FTC), the Office of Inspector General (OIG), the Department of Justice (DOJ), and the Internal Revenue Service (IRS) released notices addressing self-referral, anti-kickback, tax, and antitrust issues, underscoring the legal and regulatory challenges that may arise for ACOs.[2]

In addition to driving to meet Medicare's requirements to qualify as ACO's, many providers are starting to establish commercial ACO-like arrangements with private payers. One challenge posed by both the MSSP and private arrangements is the question of the extent to which ACO's must abide not only by federal regulations, but by state restrictions as well. For example, the proposed rule issued by CMS does not preempt California state law, which is in some ways stricter than federal requirements (*e.g.* with respect to the confidentiality of shared data, security and privacy). [3]Areas of California law that require particular consideration include the Knox-Keene Act, which regulates risk-bearing provider organizations, and the corporate practice of medicine doctrine, which limits the scope of activity of entities not owned and controlled by providers.[4] Even at the federal level, there remain serious legal questions, such as federal antitrust enforcement, participation in ACO's by tax exempt organizations, self-referral regulations, Stark and the Anti-Kickback Statute, and laws relating to gainsharing.

Providers operating under an ACO model will need to navigate the aforementioned issues and other risks in determining their organizational structure, financial arrangements, and coordination of care. Unless (and until) the federal government and states establish "safe harbor" provisions to address the many legal concerns, ensuring ACO compliance will be an especially challenging task. It is advisable for providers to take the time to understand the intricacies of these issues — and to involve counsel — in their decisionmaking.

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1 http://www.nejm.org/doi/pdf/10.1056/NEJMp1100950
2 http://www.cms.gov/sharedsavingsprogram/30_Statutes_Regulations_Guidance.asp#TopOfPage
3 http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/A/PDF%20ACOProgrammaticLegalConsiderations.pdf
4 http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/A/PDF%20ACOProgrammaticLegalConsiderations.pdf