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Accountable Care Organizations Series: How Are ACOs Compliant?

The passage of the Patient Protection and Affordable Care Act (ACA) introduced many changes within the healthcare industry, including Section 3022, the Medicare Shared Savings Program (MSSP), and the introduction of accountable care organizations (ACOs).[1] At the same time that the ACA touted the triple aim of lower healthcare costs, better access and higher quality, emerging reimbursement and organizational arrangements forced governing agencies to rethink regulatory structures.[2] ACOs push the regulatory boundaries as physicians work to coordinate care across specialties and practices. In the sixth and final part of the Accountable Care Organizations Series, this article considers regulatory compliance to address the question: *How Are ACOs Compliant?*

Stark and Anti-kickback

Stark and anti-kickback laws both prohibit the transfer of money between healthcare entities as a means of soliciting referrals. Stark Law focuses on institutions and individuals offering Medicare services that have a financial relationship with each other and assesses civil penalties for violations. The anti-kickback statue is a criminal law that applies to all healthcare entities.[3] Although each law allows a set of exceptions and safe-harbors, none directly addresses the myriad of arrangements ACOs may require.[4] To ensure ACO are in compliance, the ACA provides the Secretary of Health and Human Services (HHS) the authority to waive compliance with each law "*as may be necessary to*" conduct any payment model for ACOs.[5]

In April 2011, HHS released proposed waivers under this ACA provision. For arrangements implicating Stark Law, HHS proposed to waive compliance for CMS shared savings distributions to anyone inside an ACO, as well as, physicians outside an ACO who receive compensation for activities directly relating to the ACO's participation in the shared savings program. Similar waivers were proposed for compliance under the anti-kickback statute. Under the proposed rule, only those ACOs participating in the Federal Medicare Shared Savings Program would be eligible for these Stark and anti-kickback waivers. [6]

Civil Monetary Penalty

The current fee-for-service reimbursement system incentivizes physicians to increase patient volume. Both federal and commercial ACOs will likely decrease the volume of patients seen and instead focus on the quality of care provided. This may result in compliance issues with the civil monetary penalty (CMP), which prohibits payments by hospitals to physicians to reduce or limit care to Medicare or Medicaid patients.[7] An additional concern surrounding ACOs and the CMP relates to the possibility that ACOs may redirect higher-cost patients away in order to meet quality goals necessary to receive shared savings.[8] The ACA allows HHS to offer waivers to the CMP.[9]

CMS has proposed to allow waivers for shared savings payments as long as physicians are not incentivized to reduce or limit *medically necessary care* and the entities in question are ACO providers or suppliers under the Federal program. To remain compliant within the proposed waivers, ACOs should employ structures aimed at improving efficiency and controlling cost rather than including incentives to underprovide care.[10]

Antitrust

Antitrust laws attempt to encourage market competition by preventing monopolies and anti-competitive behavior, such as price-fixing.[11] Since ACOs require collaboration between multiple entities, potential legal mergers may lead to monopolistic behavior and antitrust violations. In addition, negotiated fees or contracts with providers and suppliers outside of an ACO may be interpreted as price fixing.[12] To address these matters, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have published a proposed policy for ACOs regarding antitrust violations.

ACOs involving mergers will be evaluated under the FTC's *Horizontal Merger Guidelines*, and collaborations must comply under the proposed rule to avoid an antitrust violation. The rule distinguishes three levels of risk for antitrust violation based on an ACO's market share (i.e., all contiguous zip codes from which 75 percent of patients originate). ACOs that comprise 50 percent of a market for any service are designated as having a high level of risk and are subject to mandatory review.[13] High risk ACOs must obtain approval from either the FTC of DOJ before being allowed to participate in the Federal ACO program. ACOs with moderate level of risk are urged to seek FTC or DOJ approval, but neither moderate (between 30 – 50 percent

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market share) nor low risk (less than 30 percent market share) cases are required to seek approval for participation.[14] As the FTC was reluctant to include private ACOs in the proposed rule (which currently only applies to Federal ACOs), commercial ACOs may find that vertical integration where ACO providers share substantial financial risk are less likely to arouse suspicion of antitrust violations.[15]

CONCLUSION

Regulatory agencies and prospective ACOs may have to be flexible as they tackle compliance issues for these emerging healthcare organizations. While Federal laws have started to address and accommodate potential ACO hurdles, there has been less discussion on how states may address ACO violation of state anti-kickback laws or regulations against the corporate practice of medicine. Additionally, there has been limited discussion related to commercials ACO compliance, as all proposed waiver programs only apply to Federal ACOs. Although there are still many uncertainties on the horizon, this series hopes to have highlighted important issues regarding the Who, What, When, Where, Why and How of ACOs.

1 "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center; Proposed Rule and Notice," Fed. Reg. Vol. 76 No. 67 (April 7, 2011).

2 "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center; Proposed Rule and Notice," Fed. Reg. Vol. 76 No. 67 (April 7, 2011).

3 "Stark Law" 42 U.S.C. §1395nn (2010); "Anti-Kickback Statute" 42 U.S.C.§ 1320a–7b(b)(1)-(2) (2011).

4 "5 Key Regulatory Concerns for ACOs" By Lindsey Dunn, Becker's Hospital Review (September 14, 2010).

5 "Patient Protection and Affordable Care Act" Public Law 111-148, Section 3022, 124 STAT 395 (March 23, 2010).

6 "CMS Finally Proposes to Waive Certain Fraud and Abuse Laws for ACOs" By Gary J. McRay and Nicole E. Stratton, Foster Swift, April 8, 2011, http://www.fosterswift.com/news-publications-CMS-Waive-Certain-Fraud-Abuse-Laws.html (Accessed 10/6/2011).

7 "Civil Monetary Penalty Law" 42 U.S.C. §1320a-7a(b) (2011)

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

9 "Patient Protection and Affordable Care Act" Public Law 111-148, Section 3022, 124 STAT 395 (March 23, 2010).

10 "5 Key Regulatory Concerns for ACOs" By Lindsey Dunn, Becker's Hospital Review (September 14, 2010).

11 "The Sherman Antitrust Act" 15 U.S.C. §1-7 (2004).

12 "Accountable Care Organizations: Promise of Better Outcomes at Restrained Costs; Can They Meet Their Challenges?" By C. Frederick Geilfuss and Renate M. Gray, BNA's Health Law Reporter, Vol. 19, no. 956 (July 8, 2010).

13 "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Saving Program" 76 FR 75 (April 19, 2011), p. 21895.

14 "The FTC and DOJ Release Accountable Care Organization Antitrust Policy Statement" By Jan P. Levine and Robin P. Summer, Health Care Antitrust Law Alert, Pepper Hamilton, LLP, April 5, 2011.

15 "Barak Richman: ACOs Should Not Involve Collaboration of Rivals" By Sandra Yin, Fierce Healthcare, February 11, 2011, www.fiercehealthcare.com/node/53407/print (Accessed 2/16/11).

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