

Client Alert

Healthcare Practice Group

April 1, 2010

Developments Regarding Accountable Care Organizations: Proposed Rules and Agency Notices Issued March 31, 2010

On March 31, 2010 the following proposed rules and agency notices were issued regarding the formation and operation of Accountable Care Organizations under Section 3022 of the Affordable Care Act:

For more information, contact:

Glen Reed

+1 404 572 3393
gareed@kslaw.com

Patrick Morrissey

+1 202 626 3740
pmorrissey@kslaw.com

Kim Roeder

+1 404 572 4675
kroeder@kslaw.com

Nancy LeGros

+1 713 751 3249
nlegros@kslaw.com

Joe Lynch

+1 202 626 8998
jlynch@kslaw.com

Robert Keenan

+1 404 572 3591
rkeen@kslaw.com

Tom Hawk

+1 404 572 4704
thawk@kslaw.com

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- ACO Proposed Rule - The Centers for Medicare and Medicaid Services (CMS) issued its ACO proposed rule (the “ACO Rule”) describing how ACOs must be organized and operated to qualify for sharing in any cost savings they achieve. Click [here](#) for the ACO Rule. For CMS’s Summary of the ACO Rule, click [here](#).
- Notice Regarding Proposed Waivers of Stark/Anti-Kickback/CMP Laws for ACOs - CMS and the Office of the Inspector General in the U.S. Department of Health and Human Services (the “OIG”) jointly issued a notice seeking public comment on proposed waivers for certain ACO payments under the federal Stark, Anti-kickback and Civil Monetary Penalties laws. The notice also solicits public comments on additional waivers that may be needed for a variety of transactions not addressed in these published proposals. Click [here](#) for the proposed waivers rule.
- FTC/DOJ Antitrust Laws Notice - The Federal Trade Commission (FTC) and the U.S. Department of Justice Antitrust Division (DOJ) issued a joint notice (the “Antitrust Agencies’ Notice”) with comment period establishing a proposed antitrust “safety zone” for ACOs that meet specified requirements. For ACOs that cannot qualify for the proposed safety zone, the Antitrust Agencies’ Notice also describes the proposed process and factors on which FTC and DOJ would rely in determining whether such an ACO would be viewed as comply with or violating federal antitrust law requirements. Click [here](#) for the Antitrust Agencies’ Notice.
- IRS Notice - The Internal Revenue Service issued a notice soliciting comments regarding whether guidance is needed concerning the tax law requirements or tax implications for tax-exempt organizations participating in an ACO. Click [here](#) for the IRS Notice.

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The substance of these proposed rules and notices, and the fact that these proposed rules and notices were issued on the same day, indicate that the federal agencies mentioned above have made a concerted effort to propose a regulatory and enforcement landscape for ACOs that encourages and facilitates the formation and operation of many different types of ACOs by a broad range of providers. However, based on our preliminary review of these proposed rules and notices, we believe significant clarifications and modifications will be required to make it feasible for most providers to consider investing the substantial time and resources necessary to form and operate an ACO that can comply with the many requirements and restrictions in these proposed rules and notices.

Over the coming weeks our Healthcare Reform Task Force will be providing additional information regarding the substance and implications of these proposed rules and notices, and information concerning areas in which we believe further clarification or modification is necessary regarding the ACO regulatory and enforcement landscape these proposed rules and notices would create. In addition, on Friday, April 15 we will be presenting one of our Roundtables in Atlanta and via webinar on these proposed rules and notices. Our announcement for that Roundtable will be circulated next week.

For additional information on our Healthcare Reform Task Force, please visit www.kslaw.com/practices/Healthcare-Reform or view our electronic publication [here](#).

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.