

ACO Update: Federal Agencies Release Coordinated ACO Shared Savings Program Legal Issues

March 31, 2011

Today, several agencies simultaneously announced guidance for Accountable Care Organizations (ACOs). Today's announcements include: (1) the proposed rule for the Medicare Shared Savings Program from the Centers for Medicare & Medicaid Services (CMS), (2) a notice and request for comments released jointly by CMS and the Department of Health and Human Service's Office of Inspector General (OIG) regarding the fraud and abuse waiver authorities, (3) joint guidance from the Department of Justice (DOJ) and Federal Trade Commission (FTC) on related antitrust issues and (4) a notice and solicitation of comments from the Internal Revenue Service (IRS) related to tax-exempt organizations. The Shared Savings Program will begin operating on January 1, 2012.

CMS released its much anticipated new proposed rule, which can be found at www.cms.gov/sharedsavingsprogram. This 400-plus page proposed rule provides incentives to health care providers and is designed to bridge the gap in the current "fragmented" health care system to bring high quality, low cost care to patients. In addition, CMS and OIG issued a joint notice related to waivers of the federal physician self-referral law, the anti-kickback statute, and the civil monetary penalty law related to the Medicare Shared Savings Program. The CMS and OIG joint notice and related comment period are available online at www.oig.gov/inspection.aspx?AspxAutoDetectCookieSupport=1. Both sets of rules will be published in the Federal Register on April 7, 2011 and the agencies will accept comments until June 6, 2011.

As expected, the Federal Trade Commission and the Department of Justice also jointly issued a "Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (Antitrust Policy Statement) today describing the enforcement stance of both agencies. This Antitrust Policy Statement can be found at: www.ftc.gov/opp/aco/. The Internal Revenue Service (IRS) issued a notice requesting comments regarding participation by tax-exempt organizations in ACOs in the shared savings program. The link to the IRS notice is available at www.irs.gov/pub/irs-drop/n-11-20.pdf.

Below is an outline of the key provisions under these proposed rules and guidance. The [Ober|Kaler ACO Team](#) will provide a comprehensive review of the ACO framework in the

coming days. Also, watch for the latest updates related to the Medicare Shared Savings Program at www.ober.com.

Application and Agreement

Providers must either form or join an ACO and then complete an application, which CMS must approve before the ACO is accepted into the shared savings program under a three-year agreement

Governance and Corporate Structure

The ACO must establish shared governance to meet the requirement of true care integration including representation of service providers, suppliers and Medicare beneficiaries. The IRS provided notice and solicitation of comments for tax-exempt entities, including hospitals, contemplating the corporate structures listed in the proposed CMS regulations.

Quality Monitoring and Reporting

Under the proposed rule, ACOs will be required to monitor and report claims and review financial and quality data, as well be required to submit quarterly and annual reports, perform site visits and conduct patient surveys, including in these five areas:

- patient/caregiver care experiences
- care coordination
- patient safety
- preventive health
- at-risk population/frail elderly health

Shared Savings

Providers in an ACO will receive reimbursement under the original Medicare payment systems and will receive shared savings based on benchmarks developed by CMS. ACOs must opt into one of two risk-sharing models, which will determine the percentage of savings that ACOs are eligible to receive:

- *one-sided risk model* – savings only are shared for the first two years and then in the third year savings and losses are shared (50% of the savings are shared)
- *two-sided risk model* – savings and losses are shared for all three years (60% of the savings are shared)

Fraud and Abuse

Under a separate notice and request for comment, CMS and OIG jointly proposed waivers to the Stark self-referral regulations, the anti-kickback statute and the civil monetary penalty provision

addressing hospital payments to physicians to reduce or limit services. The waivers address only the distribution of shared savings. CMS and OIG stated that they will endeavor to make the waivers under the three laws as uniform as possible. CMS and OIG have also requested comments on areas where waivers were not granted, such as arrangements relating to the establishment of an ACO.

Antitrust

The proposed Policy Statement provides for an antitrust "safety zone" and criteria for analyzing ACOs that fall within and outside of the safety zone, based on the ACOs primary service area share, and expedited antitrust review of ACOs that request it or are subject to mandatory review.

- The Policy Statement applies to collaborations among otherwise independent hospitals and physicians who seek to become ACOs in the Medicare Shared Savings Program, but *not* to mergers.
- The DOJ and FTC will use the proposed CMS eligibility criteria for governance structure and clinical integration under the Shared Savings Program to determine whether ACOs will be analyzed under the Policy Statement's standard.
- The DOJ and FTC committed to a 90-day expedited review of both ACOs subject to mandatory review and those voluntarily seeking prospective guidance.

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