

# AGENCIES RELEASE PROPOSED RULES ON ACOs – 7 KEY COMPONENTS TO CONSIDER

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## Agencies Release Proposed Rules on ACOs – 7 Key Components to Consider

On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) released a 429-page display copy of a [proposed rule](#) titled “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations” (the Regulations). The Medicare Shared Savings Program (MSSP) was created by Section 3022 of the Patient Protection and Affordable Care Act (the Act). Under the MSSP – to take effect no later than Jan. 1, 2012 – ACOs meeting certain requirements established by the Secretary of Health and Human Services will be eligible to receive additional payments from Medicare where certain performance guidelines are met and cost-savings targets are achieved. The amount of the additional payment will be a percentage of the difference between the estimated per capita Medicare expenditures for patients assigned to the ACO and the cost-savings per capita Medicare expenditures threshold.

Up until now, CMS had issued scant guidance on any specifics about participation in the MSSP aside from a brief Preliminary Questions & Answers document posted on its website. The Regulations set forth a comprehensive set of requirements for the formation and operation of ACOs under the MSSP. It is important to keep in mind, however, that these are only proposed regulations and the final regulations could be revised or clarified by CMS in response to comments it receives from stakeholders during the 60-day comment period.

In addition to the Regulations, other notices that address related legal issues affecting ACOs were also released on March 31, 2011:

1. CMS and the OIG issued a [notice](#) titled “Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center” that provides waivers for application of Stark, Federal Anti-Kickback, and gainsharing and civil monetary penalty laws for certain arrangements by ACOs.
2. FTC and DOJ issued a [notice](#) titled “Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program” that discusses how antitrust laws will be applied and enforced for ACOs.
3. The IRS issued [Notice 2011-20](#), requesting comments regarding the need for guidance on participation of tax-exempt organizations in the MSSP through ACOs.

This unprecedented cross-agency collaboration provides significant guidance for the development of ACOs for purposes of participating in the MSSP. In an effort to assist our clients in digesting these voluminous materials, the McGuireWoods’ ACO Task Force has briefly summarized the key provisions of the proposed rules and notices

issued yesterday. In subsequent articles over the coming weeks, the ACO Task Force will provide more in-depth discussion of the legal issues affecting ACOs.

## **ACO LEGAL STRUCTURE AND GOVERNANCE**

ACOs can include a variety of different types of groups of providers and suppliers including:

- Physician group practices
- Networks of individual practices of physicians and hospitals
- Partnerships or joint ventures between hospitals and physicians
- Hospitals employing physicians

The Regulations make it clear that an ACO's legal structure must provide both the basis for its shared governance, as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and providers/suppliers. The ACO's legal entity may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by state law. The key items for consideration relating to legal structure and governance are:

- each ACO must be a legal entity formed and authorized to conduct business under applicable state(s) law(s) and must have a taxpayer identification number (TIN);
- the ACO itself need not be enrolled in the Medicare program, in contrast to this requirement for each ACO participant;
- existing legal entities appropriately recognized under state law need not form a separate new entity for the purpose of participating in the MSSP;
- an ACO must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO;
- the ACO participants must have at least 75% control of the ACO's governing body and each of the ACO participants must have a representative on the governing body; and
- primary care physicians may only participate in one ACO.

## **SHARED SAVINGS CALCULATION**

After some deliberation, CMS chose a hybrid approach for ACOs to participate in shared savings. ACOs may choose one of two tracks when they first join the program.

- Under Track 1, the shared savings amount is reconciled annually for the first two years of the initial three-year agreement using a “one-sided” shared

savings approach. In the first two years, the ACO will only share in shared savings. In the third year of the agreement, the ACO will also be at risk to share in any losses. After the first three-year agreement is completed, an ACO wishing to continue participation in the shared savings program must participate in Track 2.

- Under Track 2, ACOs that are ready to share in losses and want an opportunity for a greater reward, may elect to immediately enter into the “two-sided” model, sharing in savings, as well as losses in all three years.
- For Track 1, the Maximum Savings Rate is 52.5% with a varied Minimum Savings Rate. For Track 2, the Maximum Savings Rate is 65% with a flat 2% Minimum Savings Rate and a Maximum loss which ramps up to 10% in year 3.
- For each new agreement period (three years) under either track, CMS will set a benchmark for that period, to determine savings or loss. In determining the benchmark, CMS considered two options. Under Option 1, CMS looks at beneficiaries who would have been assigned to the ACO in each of the three years prior to the start of the ACO’s agreement using the ACO participant’s TINs. Under Option 2, CMS looks at the beneficiaries who are actually assigned to the ACO during each performance year. CMS chose Option 1. Under Option 1, CMS will use the claim records of the ACO participants to determine a list of beneficiaries who receive a plurality of their primary care services from primary care physicians participating in the ACO in each of the prior three most recent available years. Then CMS will estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics using per capita FFS expenditures for beneficiaries that would have been assigned to the ACO in each of those three prior years. This benchmark will then be updated annually during the agreement period based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS Program.

## **TIMING ISSUES**

The Regulations contain several timing considerations:

- The deadline for comments on the Regulations is expected to be June 6, 2011 (depending upon the date of publication in the Federal Register).
- ACO applications must be submitted pursuant to an agency deadline. The agency will review the applications and approve eligible applications by calendar-year end.
- The requisite 3-year agreement period for the ACO will begin on January 1 following the year of approval, and the yearly

performance periods will also begin on January 1 of each year of the agreement period.

- The Regulations also contain some guidance on deadlines for appealing adverse determinations.

## **WAIVER OF STARK, ANTI-KICKBACK AND GAINSHARING CMP LAWS**

Arrangements between ACOs, participants, and providers/suppliers, may implicate Stark, the federal Anti-Kickback Statute, and gainsharing and civil monetary penalty (CMP) laws. To address these issues, CMS and the OIG issued a [separate notice](#) proposing waivers of application of Stark, the federal Anti-Kickback Statute, and gainsharing and CMP laws to ACOs. The waivers apply to ACOs participating in the MSSP in the following circumstances:

- For Stark and Anti-Kickback, a waiver would apply only to distributions of shared savings (not any other financial relationships) received by an ACO from the MSSP to or among ACO participants and providers/suppliers, or others outside the ACO for activities necessary and directly related to the ACO's participation in the MSSP.
- For gainsharing and CMP, where distributions of shared savings received by an ACO from the MSSP are made from a hospital to a physician in the ACO, a waiver would apply so long as the payments are not made to knowingly induce the physician to reduce or limit medically necessary items or services.
- Where a financial relationship other than distribution of shared savings is between or among the ACO, participants, and providers/suppliers directly related to participation in the MSSP (not outside the ACO) and where Stark is implicated, an available exception must be met. Where one is met, a waiver of Anti-Kickback and gainsharing CMP also applies, so the ACO is immunized under these laws by virtue of meeting a Stark exception.

## **ANTITRUST ENFORCEMENT**

A major concern among ACOs is the potential for antitrust challenges of proposed collaborations in the commercial market and under the Regulations, compliance with antitrust law is a requirement for ongoing participation in the MSSP. The FTC and the DOJ (the Antitrust Agencies) have issued a [proposed antitrust enforcement policy](#) that includes the following provisions:

- For the duration of participation in the MSSP, the Antitrust Agencies will provide more favorable "rule of reason" treatment for ACOs that meet CMS's proposed eligibility requirements, balancing collaborative efficiencies against potential anticompetitive effects.

- New safety zone: an ACO providing less than 30% of a service in its Primary Service Area will not be challenged by the Antitrust Agencies. There are additional exceptions for rural ACOs and ACOs providing services not offered by other ACOs.
- Proposed ACOs with greater than 50% share in their Primary Service Areas will be subject to mandatory antitrust review before approval as an ACO. The Antitrust Agencies are committed to providing 90-day expedited review.
- The Antitrust Agencies provide guidelines for avoiding antitrust challenges for ACOs that fall between the Safety Zone and mandatory review.

## HIPAA AND OTHER IMPLICATIONS FOR INFORMATION TECHNOLOGY

The Regulations highlight the role that healthcare information technology plays in successful creation and sustainment of ACOs. Primarily, ACOs will require providers to build a technology infrastructure that supports clinical coordination, collaboration and continuity of care. Some key highlights of the information technology capabilities that ACOs will need to include are detailed below:

- **Coordination of Care** - In order to be eligible to participate in the MSSP, the ACO must be able to define processes to coordinate care. Examples of such processes include: predictive modeling, remote monitoring, telehealth, and electronic health information exchanges.
- **Evidenced Based Medicine** - ACOs will need the infrastructure, including information technology infrastructure, to enable the collection and evaluation of data and provide feedback and information to influence care to the ACO providers/suppliers across the entire organization. Shared clinical decision support systems is an example of such infrastructure.
- **Physician Quality Reporting Systems** - Group Practice Reporting Option (GPRO), an electronic reporting tool currently used by the government in the physician quality reporting system, will be updated to interface with electronic health records (EHR) for ACO reporting use.
- **Meaningful EHR Users** - At least 50% of an ACO's primary care physicians must be "meaningful EHR users" by the start of the second MSSP performance year in order to continue participation in the MSSP.

Additionally, the Regulations have implications for health information privacy. Specifically, the rule proposes to allow organizations within an ACO to share individually identifiable patient information for operational purposes.

## ACOs AND TAX EXEMPT STATUS

In IRS Notice 2011-20, the IRS cited existing precedent for tax exemption under section 501(c)(3) and flagged two issues of concern to all existing exempt organizations: private inurement and unrelated business income. The Notice also discussed the charitable purpose of “lessening the burdens of government,” that typically serves as the basis for many hospitals’ tax-exemptions. The IRS also said that the activities of limited liability companies treated as a partnership for income tax purposes are considered to be activities of a tax-exempt organization that is an owner of the LLC when evaluating whether the tax-exempt entity is operated exclusively for 501(c)(3) purposes. Another key issue is whether the activities generating payment are related to the performance of its charitable purposes.

What does this all mean for structuring ACOs? Simply that the IRS is looking through the health activities of the ACO and attributing the partnership’s commercial arrangements that are unrelated to Medicare to the tax exempt entity if such arrangements violate tax exempt purposes. Also, the IRS is looking at whether the ACO meets the control requirements of Revenue Ruling 98-15. I.e., does the tax exempt entity have a sufficient level of control over the ACOs activities to cause it to serve the organization’s charitable purposes. The IRS has asked the healthcare industry for comments on whether there is sufficient published guidance and what additional guidance may be needed. These comments are to be submitted on or before May 31, 2011.

## OTHER ISSUES

In addition to the topics discussed above, the Regulations address certain matters that are worth mentioning:

- **Demonstration Programs** - CMS acknowledges that four existing demonstration programs, such as the Innovation Center, may reveal ways to improve the ACO model and generate a need to make regulatory changes. ACOs will be subject to future regulatory changes, except for changes related to (1) eligibility requirements concerning the structure and governance of ACOs, (2) calculating the sharing rate, or (3) the assignment of Medicare beneficiaries to an ACO.
- **Other ACO Owners/Participants** - The Regulations provide that in addition to the providers and suppliers explicitly named in the Act, CAHs billing under method II will be able to form an ACO and FQHCs and RHCs will be able to become ACO participants. CMS invites the public to submit comments on whether other provider types and suppliers should own or participate in an ACO.
- **ACO Marketing Material Approval** - The Regulations propose that all ACO marketing materials, communications, and activities related to the ACO and its participation in the MSSP, such as mailings, telephone calls or community

events, that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers, must receive prior approval from CMS.

- **Administrative and Judicial Review** - CMS restates the statutory limitations on judicial and administrative review related to the MSSP in the Regulations. Judicial and administrative review is not available to an ACO under several provisions, including:
  - CMS assessment of quality of care furnished by an ACO and the establishment of performance standards.
  - Assignment of Medicare beneficiaries to an ACO.
  - The determination of whether an ACO is eligible for shared savings and the amount of shared savings.
  - The percent and any limit on the total amount of shared savings.
  - The termination of an ACO for failure to meet ACO quality performance standards.

In subsequent articles over the coming weeks, we will provide more in-depth discussion of each of these areas discussed above.