

## Final Rule On Accountable Care Organizations Released

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On October 20, 2011, the Centers for Medicare & Medicaid Services (CMS) announced its final rule implementing the Medicare Shared Savings Program (Final Rule), more commonly known as the accountable care organization (ACO) program, set to take effect January 1, 2012. The Medicare Shared Savings Program was established by Congress in 2010 as part of the Patient Protection and Affordable Care Act and aims to create a new delivery and payment model to better coordinate care for individuals, provide more efficient care for populations, and ultimately lower growth in health care spending. The program allows participating providers who align to achieve these goals to receive a portion of any Medicare savings generated by their collaborative efforts.

CMS' proposed rule, issued in March, 2011, met significant criticism among stakeholders as overly complex, and presenting too much risk without enough reward. Our Alert on the proposed rule can be viewed [here](#). In response to the over 1,300 public comments received on the proposed rule, CMS made several changes to the Medicare Shared Savings Program in the Final Rule to incentivize participation and provide more flexibility to participating providers. We have highlighted several of the more noteworthy changes here. The full text of the Final Rule can be found by clicking [here](#).

### Organization and Structure

The Final Rule attempts to establish a more flexible framework for the operation and governance of an ACO. CMS retained the requirement that each ACO be a legal entity, but extended the group of eligible providers and suppliers that may form their own ACOs to include critical access hospitals using Method II billing, Rural Health Centers and Federally Qualified Health Centers, in addition to the eligible ACO participants previously designated in the proposed rule (e.g., group practices and hospitals with employed physicians). The Final Rule sets forth requirements for ACO organization, leadership and management as in the proposed rule. The Final Rule, however, also provides that ACOs that do not meet such regulatory requirements but nonetheless have an innovative management and leadership structure may still be able to participate in the Shared Savings Program, subject to CMS' approval.

In response to several comments calling for more flexibility, the Final Rule abandons CMS' initial proposal that board representation be proportional to ownership by ACO participants. CMS did maintain the requirement that ACO participants have at least 75% control of the ACO's governing body and acknowledged the underlying implication that management companies, health plans and other non-Medicare enrolled entities may participate in ACOs but are limited to an aggregate of no more than 25% voting control of the ACO governing body.

**Assignment of Beneficiaries**

The Final Rule retains the requirement that an ACO have at least 5,000 beneficiaries assigned to it but modifies CMS' proposed method for retrospective assignment of beneficiaries, which received considerable criticism when released in the proposed rule. According to the Final Rule, CMS will assign ACO beneficiaries prospectively, based on a determination of each beneficiary's prior utilization of primary care services. The assignment will be subject to quarterly adjustment and final reconciliation at year end. This modification is intended to give ACO participants, providers and suppliers a better idea of the population for which they are responsible for coordinating care.

The Final Rule clarifies that each Medicare-enrolled tax identification number (TIN) that bills for primary care services may only participate in a single ACO. This limitation seeks to avoid duplication of benefits or rewards a provider may receive for achieving savings with respect to the cost of care provided to a beneficiary. Practically speaking, this means that each primary care provider upon whom assignment of beneficiaries is based can only be part of a single ACO, unless they bill under multiple TINs.

**Fewer Quality Measures**

The Final Rule significantly reduces the number of proposed measures to assess quality from 65 measures to 33 measures. Participating ACOs will be paid for reporting quality measures during the first three years of their agreement and will also be paid for performance during the second and third years. Previously, CMS had proposed paying only for demonstrated performance on quality measures after an ACO's first year. Additionally, the Final Rule drops as a condition of participation the requirement that 50% of primary care physicians in the ACO be defined as meaningful users of electronic health records by the start of the ACO's second performance year. Meaningful use of electronic health records by primary care providers is still relevant, however, as a more heavily weighted quality measure. In the future, quality measures can be expected to evolve as CMS plans to modify these in future reporting cycles to reflect changes in standards of care.

**Continued Participation for Underperforming ACOs**

CMS chose not to adopt its proposed regulation to bar ACOs with net losses during their first agreement period from continued participation in the Shared Savings Program. Provided such ACOs meet all other participation requirements, ACOs that experience losses during their first agreement period may reapply to continue participation in the Shared Savings Program, but will have to explain, and be accountable for, such losses going forward.

**Risk-Sharing**

Consistent with the proposed rule, the Final Rule provides ACOs with a choice of two tracks upon enrollment in the Shared Savings Program. CMS has, however, significantly modified Track 1. CMS had initially proposed that ACOs enrolled in Track 1 would automatically transition to a "two-sided" risk model (sharing in losses and savings) in the third year of the initial agreement. The Final Rule provides that under Track 1, CMS will determine savings and allow the ACO to share in those savings, but will not require the ACO to share in any losses for the entire duration of the ACO's initial three-year agreement (i.e., a "savings-only" option). CMS retained the option for more experienced ACOs to immediately participate in a "two-sided" risk model in Track 2. Under Track 2, an ACO would be eligible for higher sharing rates but also must undertake greater risk by agreeing to share in any

losses generated by the ACO. As in the Final Rule, all ACOs must eventually transition to the two-sided risk model for all agreement periods after the initial period, if the ACO chooses to continue in the Shared Savings Program.

### **Timing of the Application Process**

CMS will begin to accept applications on a rolling basis for the Shared Savings Program on January 1, 2012 with initial agreement periods for enrolled ACOs set to begin on either April 1, 2012 or July 1, 2012. In the Final Rule, CMS extended the length of the initial performance year to eighteen or twenty-one months, depending upon the initial agreement's start date in an effort to allow ACOs more time to ramp up and begin realizing savings. ACOs that report on quality measures for 2012 are eligible to receive interim payments and will also need to report 2013 quality measures to receive shared savings for the first performance year.

### **Advance Payment Model**

In an effort to make ACO formation possible for certain providers that may lack access to capital, such as physician-based ACOs, CMS announced the establishment of an Advance Payment Model. Under this Model, CMS plans to provide up to 50 ACOs with upfront payment and a monthly payment depending on the size of the ACO to defray infrastructure costs associated with establishing an ACO. CMS would, however, recoup this amount from any savings the ACO produces. Only two types of organizations are eligible to participate in the Advance Payment Model: (i) ACOs that do not include any inpatient facilities and have less than \$50 million in total annual revenue, and (ii) ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and have less than \$80 million in total annual revenue. ACOs that are co-owned with a health plan are ineligible for the Advance Payment Model.

Applicants to the Advance Payment Model must submit both the application for the Medicare Shared Savings Program and the application for the Advance Payment Model. Interested organizations must be accepted for participation in the Shared Savings Program for an initial enrollment period beginning either April 1, 2012 or July 1, 2012 to be considered for the Advance Payment Model.

### **Other Government Agencies Weigh In**

To help foster ACO participation in the Shared Savings Program, CMS and the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG) jointly issued an Interim Final Rule establishing certain waivers with respect to the Stark Law, the Anti-kickback Statute and the civil monetary penalties law (CMP) applicable to gainsharing for participating ACOs. In response to public comments, this Interim Final Rule adds three new waivers not included in the April 2011 joint notice of CMS and the OIG previously released simultaneously with the proposed ACO regulations: (i) an "ACO pre-participation" waiver of the Stark Law, Anti-kickback and gainsharing CMP in anticipation of participating in the Shared Savings Program, (ii) an "ACO participation" waiver of the Stark Law, Anti-kickback Statute and gainsharing CMP that applies to ACO-related arrangements during the term of the ACO's participation in the Shared Savings Program and for a specified time thereafter, and (iii) a "patient incentive" waiver of the CMP law prohibiting inducements to beneficiaries and the Anti-kickback Statute for medically related incentives offered by ACOs to beneficiaries to encourage preventative care and compliance with treatment regimes. These three new waivers are in addition to previously announced waivers—the shared savings distributions waiver that applies to distributions

and uses of shared savings payments earned under the Shared Savings Program, and the “compliance with Stark Law” waiver for ACO arrangements that implicate the Stark Law and meet an existing exception.

These waivers are self-implementing—meaning that other than meeting the applicable waiver conditions, no special action or application process is required for parties to be covered by a waiver. The Interim Final Rule is subject to a 60-day comment period. Access the Interim Final Rule by clicking [here](#).

In connection with CMS’ announcement of the Medicare Shared Savings Program, antitrust regulators at the Department of Justice and Federal Trade Commission released a final antitrust enforcement policy statement on ACOs, which modifies these regulators’ prior proposal with respect to ACOs. Please click [here](#) for the text of that statement. Most notably, mandatory antitrust review of certain ACOs will no longer be required as a condition of entry into the Shared Savings Program. This final policy statement generally applies to all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Shared Savings Program—not just those formed after March 23, 2010, the date of enactment of the Patient Protection and Affordable Care Act. Nevertheless, antitrust planning is essential—concerns may arise for ACOs that include a dominant share of local hospitals or physicians in major specialties. At the same time, however, providers should be aware of those parts of the statement that do not raise real concerns. The statement includes a number of provisions which go well beyond what can be supported by the antitrust case law. In our view, those provisions are quite unlikely to be bases for enforcement action. Click [here](#) to view a copy of our “ACO Antitrust Do’s and Don’ts” with respect to the final policy statement.

The IRS also issued a fact sheet on tax-exempt organizations and ACOs, which can be found by clicking [here](#). The fact sheet, which is in a question and answer format, confirms that **IRS Notice 2011-20**, issued in April 2011, continues to reflect IRS expectations regarding the Shared Savings Program and ACOs even though the Final Rule varies significantly from the proposed rule.

The fact sheet reaffirms the IRS’ position that tax-exempt charitable organizations, like 501(c)(3) hospitals, may participate in the Shared Savings Program through an ACO without adversely affecting their tax exempt status as long as they continue to meet existing tax-exemption rules. The IRS also confirmed that the participation of an exempt organization in the Shared Savings Program through an ACO comprised of several participants will not be deemed to result in inurement or impermissible private benefit to private party ACO participants if the ACO has been structured in accordance with five factors set forth in IRS Notice 2011-20. The fact sheet also acknowledges that ACOs with exempt participants may be involved in other activities, unrelated to the Shared Savings Program. The IRS will apply existing federal income tax rules for tax-exempt organizations to activities of the ACO that are not related to the Shared Savings Program.

If you have any questions about the Final Rule, or for assistance in applying to become an ACO, contact any of the health care attorneys listed on the front page of this Alert.