



## GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE

### **CMS Releases Highly-Anticipated Accountable Care Organization Final Rule**

Embracing a series of measures designed to incentivize greater participation, the Centers for Medicare & Medicaid Services (“CMS” or the “Agency”) on October 20, 2011, released its final rule regarding Accountable Care Organizations (“ACOs”) under the Medicare Shared Savings Program (the “Final Rule”). This Final Rule contains a number of important changes from the proposed rule published by the Agency in the Federal Register on April 7, 2011 (the “Proposed Rule”), and is part of a multi-agency effort to implement the ACO provisions of the Patient Protection and Affordable Care Act.

Additionally, on the same day, CMS and the Office of the Inspector General (“OIG”) jointly issued an Interim Final Rule which establishes waivers of certain fraud and abuse laws for ACOs. CMS and OIG are accepting comments on the Interim Final Rule for 60 days after it is published in the Federal Register on November 2, 2011.

In this update, we discuss below a number of significant items under the Final Rule and outline the waivers issued in the Interim Final Rule.

#### **I. ACO Eligibility and Governance**

In a shift from the Proposed Rule, the Final Rule allows for both federally qualified health centers and rural health clinics to be eligible to form an ACO independently or to participate in an ACO formed by another eligible entity. Certain critical access hospitals are also eligible to participate. In order to participate in the Shared Savings Program, each ACO must maintain a governing body with the authority to execute the functions of the ACO, including (i) promoting the use of evidence-based medicine, (ii) promoting beneficiary engagement, (iii) reporting internally on quality and cost metrics, and (iv) coordinating patient care. Seventy-five percent of the control of the governing body must be held by ACO participants themselves.

#### **II. Start Date Options and Other Operational Issues**

CMS will accept applications from prospective ACOs for the statutorily required 3-year minimum period shortly after January 1, 2012. ACOs will be permitted to add and subtract ACO participants and ACO providers/suppliers over the course of the agreement period.

### III. Provision of Aggregate and Beneficiary Identifiable Data

To participate in the Shared Savings Program, ACOs are required to account for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to them. The Final Rule implements the proposal to provide to ACOs aggregated, de-identified metrics and utilization data based on the data used to calculate an ACO's benchmark. The Proposed Rule did not contemplate sharing identifying information about those individuals whose data forms the basis of aggregate reports. The Final Rule, however, allows for sharing, on a quarterly basis, of the name, date of birth, sex, and Health Insurance Claim number of such individuals.

### IV. Assignment of Medicare Fee-for-Service Beneficiaries

Under the Act, only individuals enrolled in the original Medicare fee-for-service program under Medicare Parts A and B may be assigned to an ACO. The Agency clarified that beneficiaries will still retain their freedom to choose other health care providers regardless of their ACO assignment. CMS will adopt a two-step beneficiary assignment process based on a beneficiary's utilization of services, rather than through an enrollment or voluntary selection process.

### V. Quality and Other Reporting Requirements

In a significant shift from the Proposed Rule, the Final Rule reduces the number of quality measures from 65 to 33. These measures are grouped into the 4 domains discussed above (*i.e.*, patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk populations). In contrast to the Proposed Rule, the Final Rule also includes a longer phase-in of quality measures. Under the Final Rule, ACOs will be paid for accurate reporting in the first year and paid based on a combination of reporting and performance during the second and third years.

While the Proposed Rule would have required ACOs to achieve the quality performance standard on 100% of measures, under the Final Rule, ACOs will be required to achieve the quality performance standard on only 70% of the measures in each domain. If this is not achieved, the ACO will be placed on a corrective action plan and re-evaluated the next year. Additionally, if in any year an ACO scores zero for an entire domain measure, it will be ineligible for shared savings.

### VI. Shared Savings and Losses

In a significant shift from the Proposed Rule, which required ACOs in the one-sided track to share losses in the third year of the agreement, the Final Rule allows ACOs to participate in the one-sided track for the entire length of their first agreement period. The Final Rule also allows more experienced providers to assume the risk of losses in exchange for greater potential rewards: ACOs may share up to 50% of the savings under the one-sided model and up to 60% of the savings under the two-sided model, depending on their quality and performance.

In response to comments that the Proposed Rule would not encourage providers to participate in ACOs, the Final Rule provides for:

- Shared savings on a "first dollar" basis for all ACOs in both tracks once savings meet or exceed the minimum savings rate, whereas under the Proposed Rule, shared savings in the one-sided track began only after providers showed savings of at least 2% once they exceeded the minimum savings rate.
- Increased payment performance limit for both models, since the payment limit for the one-sided model increased to 10% (from the proposed 7.5%) of the ACO's updated benchmark and the payment limit for the two-sided model increased to 15% (from the proposed 10%) of an ACO's updated benchmark.

- Decreased shared loss rate for Track 2, since a Track 2 ACO's shared loss rate will be capped at 60% (the same as the maximum shared savings rate) rather than 100%.

## VII. Additional Program Requirements and Beneficiary Protections

- In a shift from the Proposed Rule, the Final Rule permits ACOs to use marketing materials five days after filing them with CMS, if the ACO certifies that the materials comply with the applicable marketing requirements.
- Because ACOs are considered group practices, CMS intends to report ACO quality performance measures on Physician Compare, an online directory of physicians who are enrolled in Medicare, along with other PQRS group practices.
- The Final Rule includes several program integrity requirements designed to prevent fraud and abuse, including: (i) implementation of a compliance plan (including a requirement that the ACO report probable violations to a law enforcement agency); (ii) annual certifications regarding accuracy of data submitted and compliance with laws and program requirements; (iii) implementation of a conflicts of interest policy for ACO governing bodies; and (iv) a prohibition on certain referrals and beneficiary inducements.

## VIII. Coordination With Other Agencies

CMS also worked with other agencies across the Federal government to create additional guidance documents regarding ACOs, including:

- An Internal Revenue Service Notice and other applicable guidance;
- A joint Federal Trade Commission and Department of Justice Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Shared Savings Program; and
- The joint Interim Final Rule with OIG, which establishes waivers of the Federal Anti-Kickback Statute ("AKS"), the Physician Self-Referral law ("Stark"), and the Civil Monetary Penalties ("CMPs") for Gainsharing and Beneficiary Inducements.

The Interim Final Rule finalizes five self-implementing waivers (meaning no application is necessary) that will apply uniformly to each ACO, ACO participant, and ACO provider/supplier. These five waivers are:

1. ACO Pre-Participation Waiver: Waives AKS, Stark, and the Gainsharing CMP for start-up arrangements that intend to apply and become an ACO within one year, with limited exceptions.
2. ACO Participation Waiver: Waives AKS, Stark, and the Gainsharing CMP for "reasonably related" ACO activities during the term of the ACO participation agreement, and in some circumstances, six months thereafter.
3. Shared Savings Distribution Waiver: Waives AKS, Stark, and the Gainsharing CMP for distributions and uses of shared savings payments earned under the Program.
4. Compliance with the Stark Law Waiver: Waives AKS and the Gainsharing CMP when the arrangement meets a Stark exception.
5. Patient Incentive Waiver: Waives AKS and the Beneficiary Inducement CMP for ACO, ACO participants, and ACO providers/suppliers when supplying both beneficiaries and non-beneficiaries with free or below fair-market value in-kind items or services related to preventive care (*i.e.*, drug/treatment/follow-up care adherence, chronic disease management, etc.).

Each of the waivers contains multiple conditions that must be met in order to be protected by the waiver, but an arrangement only needs to meet one of the waivers to be protected. The Interim Final Rule states that drug and device manufacturers, distributors, durable medical equipment suppliers and home health suppliers cannot be parties to an arrangement covered by the ACO pre-participation waiver. CMS is specifically seeking comments on this policy.

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