

## Federal Government Releases Proposed Rule for Accountable Care Organizations:

Interested Providers Need to Prepare Now for Detailed and Potentially Onerous Application, Operation and Reporting Requirements



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On March 31, 2011, the Centers for Medicare and Medicaid Services (“CMS”) unveiled the long-awaited proposed rule that would elaborate on the provisions of the Patient Protection and Affordable Care Act (the “Affordable Care Act”) regarding accountable care organizations (“ACOs”). Under these provisions (found in Section 3022 of the Affordable Care Act), beginning January 1, 2012 providers of services and supplies may be eligible for additional Medicare payments based on meeting certain specified quality and savings requirements.

CMS states that ACOs are intended to be part of a program “that promotes accountability for a patient population and coordinates items and services under [Medicare] parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.” The aim of the program, referred to by CMS as the “three-part aim,” is: (i) better care for individuals, (ii) better health for populations, and (iii) lower growth in expenditures. The quality standards for ACOs would focus on five key areas:

- Patient/caregiver care experiences
- Care coordination
- Patient safety
- Preventive health
- At-risk population/frail elderly health

### What is an ACO?

Under the proposed rule, an ACO refers to a group of providers and suppliers of services (e.g. hospitals, physicians and others involved in patient care) that will work

together to coordinate care for the Medicare fee-for-service beneficiaries they serve. The proposed rule states that CMS believes that the goal of an ACO is to deliver seamless, high-quality care for Medicare beneficiaries, instead of the so-called “fragmented care” that historically has been part of fee-for-service health care.

### When Will CMS’ New ACO Program Begin?

Section 3022 of the Affordable Care Act added a new section to the Social Security Act that requires the Secretary of Health and Human Services (the “Secretary”) to establish a Shared Savings Program by January 1, 2011. The Shared Savings Program is intended to encourage providers to create ACOs by rewarding an ACO that lowers growth in health care costs while meeting performance standards set by CMS. The ACO is to be held accountable for improving health and experience of care for individuals.

### Who is Eligible?

The Affordable Care Act specifies that an ACO may, but is not required to, include the following providers:

- ACO professionals (physicians and hospitals meeting the statutory definition) in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals; or
- Hospitals employing ACO professionals

The proposed rule also grants power to the Secretary to add other care providers to the list of those permitted to participate in an ACO.

### How Does an ACO Participate In The Shared Savings Program?

In order to participate in the Shared Savings Program, all ACOs will be required to enter into a three-year agreement with CMS that will include annual performance periods that begin on January 1 of each respective year during the ACO’s agreement period. The agreement will include a requirement that the ACO provide care for a minimum of five thousand (5,000) Medicare beneficiaries. If the ACO falls short of the 5,000 Medicare beneficiary requirement, it will be placed on a corrective action plan and may be terminated from the Shared Savings Program. As mentioned above, the first such three-year agreement period will begin on January 1, 2012. All subsequent three-year periods will start on January 1 following approval of an application.

### How Will An ACO Be Structured?

An ACO must be established as a legal entity for the purpose of, among other things, receiving and distributing shared savings, repaying shared losses and establishing reporting to CMS. CMS has provided a great deal of latitude when it comes to the basic structure, provided the ACO is capable of:

- Receiving and distributing shared savings;
- Repaying shared losses;
- Establishing, reporting and ensuring ACO participation and ACO provider/supplier compliance with the Shared Savings Program, including quality performance standards; and
- Performing other ACO functions identified in the law.

## How Will ACO Reimbursement Be Structured?

An ACO participating in the Shared Savings Program will continue to receive payment under the original fee-for-service model through which Medicare providers have received payment in the past. Under the Shared Savings Program, a participating ACO also may be eligible for payment for shared Medicare savings if the ACO:

(i) meets the applicable quality performance standards established by the Office of Inspector General (OIG), and (ii) achieves certain levels of savings as compared to a benchmark of expected average per-capita Medicare expenses.

CMS considered several payment model options, and offered these options for comment. Of all of its proposed payment model options, CMS recommended an approach that is a hybrid of the other payment methods described in the proposed rule. CMS believes that this payment model would allow participation by less experienced ACOs, while allowing them an opportunity to gain “hands-on” population management experience. At the same time, this option would allow more experienced ACOs to participate in a payment model that permits greater reward for greater responsibility.

Under this model, CMS proposes that ACO applicants choose between: (i) the “One-Sided Model” (“Track 1”) and (ii) the “Two-Sided Model” (“Track 2”).

Under Track 1, ACOs would enter the Shared Savings Program under the One-Sided Model and be required to transition to the Two-Sided Model for the third year of the initial three-year agreement period. The One-Sided Model allows the ACO to share in up to fifty percent (50%) of its cost savings without being responsible for sharing in any of the ACO’s losses (i.e. costs surpassing the ACO’s benchmark as determined by CMS) in its first two years. Thereafter, the ACO would be required to participate under the Two-Sided Model.

In the Two-Sided Model, the ACO shares in the both its savings and its losses for all three years and in all subsequent years, and is eligible for up to sixty percent (60%) of its cost savings. All ACOs that participate in the Two-Sided Model will be subject to a twenty-five percent (25%) withholding of shared savings to offset any future losses under the Two-Sided Model. If an ACO

successfully completes its three-year agreement, CMS will fully refund any portion of shared savings withheld during the course of the three-year agreement that is not needed to offset losses.

To prepare for risk and potential payment for losses, ACOs must establish a self-executing method for repaying losses annually. An ACO may repay funds by obtaining reinsurance, placing funds in escrow, obtaining a surety bond, establishing a line of credit (evidenced by a letter of credit that Medicare can draw from) or establishing other repayment mechanisms that will appropriately position the ACO should it need to reimburse CMS for any ACO losses. ACOs must be able to demonstrate that they could repay losses equal to at least one percent (1%) of per capita expenditures for its assigned beneficiaries from the most recent year available.

## How Will CMS Share Its Cost Savings With ACOs?

Under the proposed rule, merely achieving cost savings is not sufficient for an ACO to participate and share in its savings. The ACO also must report quality measures and satisfy quality standards to earn shared savings.

- **Quality Measures** – CMS proposes sixty-five (65) measures for ACOs to report for the first performance period of the Shared Savings Period. The proposed quality measures include a mix of process, outcome and patient experience measures. Some of the process measures address the use of information systems, including meaningful use requirements for electronic health records (EHRs). CMS will propose measures for future reporting periods in subsequent rulemakings.
- **Shared Savings for the First Year of the Shared Savings Program** – CMS proposes that ACOs that fully and accurately report on the quality measures will earn their full share of the savings (50% under Track 1 or 60% under Track 2) for the first year of the Shared Savings Program.
- **Shared Savings for Subsequent Years** – After the first year, ACOs must continue to fully and accurately report quality measures. However, an ACO’s portion of cost savings, if any, would depend on its actual performance. An ACO would earn up to a maximum of 50% or 60% of shared savings,

depending on its quality level. An ACO achieving higher quality would achieve a correspondingly higher percentage of shared savings.

## How Will Patients Be Assigned to an ACO?

CMS proposes to retrospectively assign beneficiaries to an ACO while at the same time provide ACOs with beneficiary data regarding the beneficiaries assigned to the ACO during the benchmark period (e.g. the three-year period prior to the ACO’s performance year). This means that at the end of each year of an ACO’s agreement, beneficiaries would be assigned to an ACO based upon the ACO’s primary care physicians’ provision of primary care services to beneficiaries during the prior year. CMS proposes that beneficiaries be assigned to the ACO that provided the beneficiary with the highest complexity and intensity of primary care services in that prior year. CMS said that it believes that the combination of retrospective and prospective assignment encourages ACOs to focus on improving care for all beneficiaries, rather than simply those that are assigned to the ACO for shared savings purposes.

## How Will An ACO Report Its Data?

CMS proposes a number of methods for collecting and reporting the data, including claims submission, survey instruments and a data collection tool. The data collection tool would allow ACOs to submit clinical information from EHRs. CMS anticipates that certified EHR technology also will be a reporting mechanism in future years. CMS cautioned that failure to accurately report could result in sanctions, including termination from the Shared Savings Program.

## How Will Payments Be Distributed Among Various ACO Providers?

ACO distribution methodologies are not specified in the law. CMS explained that it does not have the authority to specify how payments will be distributed between ACO providers. However, an ACO must inform CMS about its distribution plan, and, at its discretion, inform the public. CMS indicated in the proposed rule that the ACO’s distribution methodology should include safeguards to prevent improper financial incentives.

## How Will the ACO Be Governed?

Regardless of the form of legal entity, the proposed rule requires each ACO to

establish a governing body that provides a mechanism for representation and control in its shared decision-making for all ACO participants. The governing body must represent ACO providers, suppliers and Medicare beneficiaries. At least seventy-five percent (75%) of the governing body must consist of ACO providers who are enrolled in Medicare. Each ACO provider must select an appropriate representative from within its organization to represent it in the governing body.

ACO participants and ACO providers must have a meaningful commitment to the ACO's clinical integration, which may consist of a financial investment or meaningful human investment in the ongoing operations of the ACO, such that potential loss or recoupment is likely to motivate the participant. The ACO also will be responsible for routine self-assessment, monitoring and reporting of the care it delivers.

#### **How Will ACOs be Led and Managed?**

All ACOs must have a leadership and management structure that includes clinical and administrative systems that satisfy the following:

- The ACO's operations should be managed by an executive, officer, manager or general partner whose appointment and removal are under control of the ACO's governing body;
- Clinical management and oversight should be managed by a senior-level medical director;
- ACO participants and ACO providers should have a meaningful financial investment in the ACO's clinical integration program to ensure its likely success;
- The ACO should have a physician-directed quality assurance and process improvement committee that oversees an ongoing quality assurance and improvement program;
- The ACO should develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care with the goals of better care at a lower growth in expenditures;
- The ACO should have an infrastructure that enables the ACO to collect and evaluate data and provide feedback to the ACO providers across the entire organization (this information technology component is discussed in greater detail below).

All ACO participants and providers must agree to abide by the ACO's guidelines. The guidelines must include that remedial actions are a possibility for non-compliance, and ACOs must have written policies and procedures for ACO expulsion of participants and/or providers.

#### **How Will The Cost Baseline Be Established?**

Only Medicare Part A (hospital reimbursement) and Part B (physician reimbursement) costs will be included in the baseline calculation. Part D (prescription drug reimbursement) will not be included. No adjustment will be made for indirect medical education and Disproportionate Share Hospital payments to hospitals.

#### **How Will Beneficiaries Be Informed?**

CMS places a high value on transparency and the right of Medicare beneficiaries to have a free choice of providers and adequate information to make choices. ACOs will be required to post signs indicating provider participation in an ACO and offer standard written information about ACOs to Medicare fee-for-service beneficiaries. The ACO also will be required to offer beneficiaries a form that will allow them to opt out of data sharing.

#### **Will An ACO Be Required to Implement Health Information Technology?**

The proposed rule requires ACOs to have an infrastructure that enables the ACO to collect and evaluate data and provide feedback to ACO participants and providers across the entire ACO. This requirement most likely would be achieved through the use of an EHR system that is certified for CMS' meaningful use program.

In conjunction with the federal government's plan to integrate EHRs into health care, by the ACO's second year, at least fifty percent (50%) of an ACO's primary care physicians must be meaningful users of EHR technology. Failure to fulfill this obligation will lead to an ACO's termination from the Shared Savings Program.

#### **Will ACOs Be Subject to Marketing Guidelines?**

In the proposed rule, CMS expressed a strong desire to prevent ACOs from misleading beneficiaries about services available from an ACO or about the providers from whom beneficiaries will receive services. As a result, all ACO

marketing materials, communications and activities related to promotion of the ACO must be approved by CMS to ensure that they are not confusing or misleading. This provision appears to be extremely broad and applies to all general audience materials such as brochures, advertisements, letter to beneficiaries, web pages and other marketing items produced on behalf of the ACO. CMS did, however, identify a small number of items that will not be subject to the approval process.

#### **Will The ACO Need A Separate Compliance Plan?**

All ACOs must have a compliance plan that addresses how the ACO will comply with applicable legal requirements. Specifically, an ACO must demonstrate that it has a compliance plan that includes at least the following:

- A designated compliance official who is not legal counsel to the ACO and who reports directly to the ACO's governing body;
- Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
- A method for employees or contractors of the ACO or ACO providers to report suspected problems;
- A compliance training program for all ACO employees and contractors; and
- A requirement to report suspected violations of law to an appropriate law enforcement agency.

CMS also is requiring that the ACO and its participants and downstream contractors and subcontractors certify the accuracy, completeness and truthfulness of any information or data used by CMS in determining the ACO's eligibility for, and amount of, shared savings payments or the amount owed to CMS by the ACO. CMS also is requiring that these parties provide the government with access to such data for audit purposes. Because of the significance of the data collection and reporting in relation to payments made to ACOs by CMS, increased audit activity likely is on the horizon.

As with all regulations of this kind, there will be a sixty-day public comment period where the public, including physicians and Medicare beneficiaries, are urged to submit comments to CMS as it develops its final rule.

## What Do ACOs Mean for Physicians and Other Providers?

At this stage of the changes occurring in health care, it would be easy to underestimate the future significance of ACOs. A similar minimization of Medicare's future impact occurred when Medicare first became a reality.

The objective of ACOs is simple: encourage physicians and hospitals to work together to provide health care on an affordable basis to patients in need. ACOs that make the parts all work together will receive bonus compensation from CMS for their effort.

The year 2012 is the year of implementation. The ultimate effect will be consolidation among health care providers.

This year, 2011, is the year of pre-organization and organization activity. Early organizational steps have begun all around the country, not only for Medicare patients (the subject of the law) but also for insured patients.

To solidify their market position, several hospitals are advocating the early joinder of physicians into hospital-physician

ACO joint ventures. Other hospitals have accelerated their pace of physician practice acquisitions.

In the meantime, primary care physicians and other physicians have begun to form multispecialty physician organizations (similar to IPAs) servicing the 5,000 patient requirement to place themselves in the best organizational and negotiating position for the future. These groups also can function as "buyers' co-ops" for members, purchasing supplies and services at reduced cost.

Laws are being introduced to remove conflicting anti-trust, anti-kickback and Stark law impediments, and the Anti-Trust Division of the Justice Department has agreed to expedite organizational reviews. ACO consulting firms are forming, even in absence of clear regulatory direction.

The environment is ripe for the "herd instinct" to prevail. Rushing to join a group – any group – without carefully working through the details and the business considerations can lead to disaster.

We strongly believe that it is important to plan ahead and explore the opportunities.

But planning and exploration should be approached methodically and carefully. Any consolidation of providers requires a thoughtful consideration of business and professional philosophy and an evaluation of the ethics, skills and resources of the consolidation partners. Among the skills and resources necessary to make an ACO successful are:

- Good cross-provider communication systems and skills
- Practice standards and objectives
- Practice systems to reduce waste and duplication
- Provider performance tracking system
- Payment distribution to allocate and distribute "rewards" among provider members
- A solid information technology system
- An internal governance system that monitors, measures, and directs the ACO operation

The success of the ACO will require non-traditional systems, thinking out of the box, and a commitment to a team effort. 2011 will be an interesting and challenging year for health providers.

Please contact us at your convenience and we can arrange a time to discuss how the new laws may affect your practice or business.

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