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Alerts

Accountable Care Organization Overview

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Health Care Alert

The Centers for Medicare & Medicaid Services (CMS) recently issued proposed regulations for accountable care organizations (ACO). These regulations provide significant guidance but also raise significant questions for those contemplating the establishment of an ACO.

This is the first of a series of *Hinshaw Health Law Alerts* on the subject of ACOs. Future alerts will discuss the application process, data sharing requirements and shared saving programs. This alert includes a discussion of eligibility requirements, as well as other requirements, including those involving quality reporting.

Background

The Patient Protection and Affordable Care Act (PPACA) added provisions to the Social Security Act to establish shared savings programs that promote accountability for a patient population, coordination of services delivered under Medicare Part A and Part B, and investment in infrastructure and redesign of care processes for high-quality and efficient delivery of service. The PPACA established the types of providers of service and suppliers of service who, through a shared governance system, are eligible to participate as accountable care organizations. They include:

- ACO professionals in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals;
- Critical access hospitals that bill Medicare for both facility and professional services;
- Federally qualified health centers and rural health centers that may not form ACOs themselves but that may participate in ACOs formed by others; and
- Such other groups of providers of services and suppliers as the Secretary of HHS determines appropriate.

Requirements for Participation

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The basic requirements for eligible groups to form ACOs to participate in the program are as follows:

1. The ACO must be willing to become accountable for the quality, cost and overall care for service beneficiaries assigned to it.
2. The ACO must enter into an agreement with the Secretary of HHS to participate in the program for not less than a three-year period.
3. The ACO must have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participant providers of services and suppliers.
4. The ACO should include primary care professionals in such sufficient numbers to provide services to beneficiaries assigned to it. At a minimum, the ACO must have at least 5,000 beneficiaries assigned to it in order to be eligible to participate in a shared savings program.
5. The ACO shall provide the Secretary of HHS with such information regarding ACO professionals as the Secretary determines necessary to support the assignment of Medicare service beneficiaries.
6. The ACO shall have in place leadership/management structures that include clinical and administrative systems.
7. The ACO shall define processes to promote evidence-based medicine and patient engagement. It shall report on quality and cost measures and coordinate care such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.
8. The ACO must be able to demonstrate to the Secretary of HHS that it meets patient-centered-related criteria such as the use of patient and caregiver assessments for the use of individualized care plans.

An ACO may be structured as a corporation, partnership, limited liability company, foundation, or other entity permitted by state law. In order to implement the statutory requirements that ACOs have a shared governance mechanism and a formal legal structure, each ACO must (1) be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable state law, and (2) have its own taxpayer identification number. This does not mean that existing organizations have to reorganize to establish a separate legal entity. It was indicated that a hospital employing ACO professionals may be eligible to participate in a shared savings program as an ACO with its current legal structure and would not necessarily have to be part of a separate legal entity.

ACOs must establish and maintain a governing body with adequate authority to execute the ACO's statutory functions. The governance mechanism should allow for appropriate control for ACO participants giving the participants a voice in the ACO's decision making process. As the legal entity structure may involve corporations, limited liability companies or other legal entities, the governing body may be a board of directors, a board of managers, or any other governing body that provides a mechanism for shared governance and decision making for all ACO participants, as long as it has the authority to execute the ACO's statutory functions. The governance body must include proportional representation of ACO participants or their designated representatives (who must make up at least 75 percent of the governing body), and at least one Medicare beneficiary representative served by the ACO.

The leadership and management structure must include administrative and clinical systems. The ACO's operations can be managed by an executive officer, manager or general partner, whose appointment and removal is under the control of the organization's governing body. Clinical management and oversight should be provided by a senior-level medical director who is a board-certified physician and licensed in the state in which the ACO operates.

The ACO will be required to have physician-directed quality assurance and process improvement programs in place and oversee an ongoing quality assurance and improvement program. It will also be required to develop and implement evidence-based medical practices or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals and better health for populations.

Measures of Assessment

In its regulations, CMS has proposed measures to assess: (1) the quality of care furnished by an ACO; (2) requirements for data submission by ACOs; (3) quality performance standards; (4) incorporation of reporting requirements; and (5) requirements for public reporting by ACOs. The PPACA requires the Secretary of HHS to determine the appropriate

measures to assess the quality of care furnished by the ACO. Such measures would include clinical processes and outcomes; patient and, wherever practical, caregiver experiences of care; and utilization such as rates of hospital admissions for ambulatory-sensitive conditions.

CMS has proposed 65 measures, which are grouped into five areas, for use in the calculation of the ACO quality performance standards. These standards involve patient caregiver experience, care coordination, patient safety, preventative health, and at-risk populations/frail elderly health. Proposed are table format measures for use in establishing quality performance standards that ACOs must meet for shared savings. For the first year of the shared savings program, CMS proposes that an ACO will meet quality performance standards and earn either 60 percent or 50 percent of the shareable savings if the ACO completely and accurately reports data on all program measures. For subsequent years, the percentage of potential shareable savings will vary based on the ACO's performance on the measures as compared to established benchmarks that will be developed in the future rulemaking.

Other Considerations

As the structures of ACOs involve the sharing of information, cost savings and, in some cases, incentives for more efficient care, many existing laws are impacted. These include concerns with regard to (1) the Civil Monetary Penalties Act, Federal Anti-Kickback Statute and Ethics in Patient Referral Law; and (2) tax-exempt status. The Internal Revenue Service (IRS) has indicated that it will solicit public comments as to whether existing guidance relating to the Internal Revenue Code is sufficient for those tax-exempt organizations planning to participate in shared savings programs through ACOs. If not, the IRS wants to know what additional guidance is needed. CMS plans to work with the IRS to ensure a coordinated and intra-agency effort for implementation of the program.

With regard to antitrust concerns, it should be noted that there is an antitrust policy statement setting forth an antitrust safety zone for certain ACOs. The statement provides that antitrust agencies, absent extraordinary circumstances, will not challenge an ACO that otherwise meets CMS criteria to participate in shared savings programs. This safety zone applies so long as the ACO participants providing the same service have a combined share of 30 percent or less of each common service in each ACO's primary service area wherever two or more ACO participants provide that service to patients from the primary service area. Also, for providers in rural areas, the antitrust policy statement contains a rural exception that specifies that under certain circumstances the ACO may qualify for protection under the safety zone even if the combined primary service area share for common services would exceed 30 percent.

The antitrust policy statement further indicates that an ACO outside the safety zone may proceed without scrutiny by antitrust agencies if its combined primary service area share for each common service, wherever two or more ACO participants provide that service to patients from the primary service area, is less than or equal to 15 percent. In light of the policy statement, the regulations proposed by CMS would require that an ACO with a primary service area share above 50 percent for any common service that two or more ACO participants provide from the service area must submit to CMS as part of its shared savings program application a letter from the reviewing antitrust agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

For more information, please contact Roy M. Bossen, Michael A. Dowell or your regular Hinshaw attorney.

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