



Alerts

Accountable Care Organization Application Requirements

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Health Law Alert

This Hinshaw *Health Law Alert* describing the application process for entities wishing to participate in Shared Savings Programs is the second in a series of advisories regarding accountable care organizations (ACOs).

The Centers for Medicare & Medicaid Services (CMS) has proposed regulations detailing several application requirements for those entities wishing to participate in Shared Savings Programs. They would require an ACO to submit, with its application, materials that describe the ACO's leadership and management structure, including the clinical and administrative systems designed to support the Shared Savings Program's three main goals: (1) better care for individuals; (2) better care for ACOs' assigned patients; and (3) decrease in the cost of expenditures.

ACO Application Period

ACOs would have an annual application period during which they could apply and would be evaluated for appropriate eligibility requirements to participate in a Shared Savings Program. CMS would review the applicants and approve applications for those organizations that are eligible prior to the end of each calendar year. If approved, the ACO agreement would be effective for a three-year period, with a 60-day notice termination provision and provisions for financial penalties if the ACO failed to continually meet program requirements.

ACO Application Documents

The ACO application process would require submission of documents that address the subject matter areas listed below:

- **Rights and Obligations.** Documents that describe the ACO participant's rights and obligations in the ACO, the shared savings that will encourage ACO participants to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines;
- **Quality Assurance and Clinical Integration.** Documents that describe the scope and scale of the quality assurance and clinical integration program, including all relevant systems and processes;
- **Organizational and Management Structure.** Material that documents the organizational and management structure, including an organizational chart, a list of committees and their structures, and job descriptions for senior

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administrative and clinical leaders;

- **Medical Director/CMS Liaison.** Documents confirming that a board-certified physician serves as the ACO medical director and is licensed in the ACO's state, and that a principal CMS liaison is identified in the ACO's leadership structure;
- **Governing Body.** Documents demonstrating that the governing body includes persons who represent the ACO participants and that the ACO participants hold at least 75 percent control of the governing body;
- **Shared Savings Program.** Documents that describe the applicant's plans to: promote evidence-based medicine and patient engagement; report on internal and quality cost measures; and coordinate care, which may be through telehealth and other technologies. The ACO application must also include a description of the criteria that the ACO plans to employ for distributing shared savings among ACO participants;
- **Patient-Centered Criteria.** Documents that describe how the ACO applicant will meet patient-centered criteria requirements; and
- **Health Needs Evaluation.** Documents that describe the ACO's procedures for evaluating the health needs of its Medicare population, including consideration of diversity and a plan to address the needs of those persons.

Upon request, the ACO would be required to provide documents effectuating its formation and operation, including, for example, charters, bylaws, and articles of incorporation, and a description of the remedial process that will apply when ACO participants and suppliers fail to comply with the internal procedures and performance standards. Such processes would have to include corrective action plans and the circumstances under which expulsion may occur.

General ACO Applicant Requirements

ACO applicants would be required to engage in a detailed analysis of their market shares and, if those shares exceeded a 50-percent threshold, the ACO applicant would have to obtain approval from the federal antitrust enforcement agencies before CMS would approve its application for participation in the Shared Savings Program.

ACOs would be required to have systems in place to identify high-risk individuals and processes to develop individual care plans for targeted patient populations. The plans would have to:

1. be tailored to the beneficiary's health and psychosocial needs;
2. account for beneficiary preferences and values; and
3. identify community and other resources to support the beneficiary in following the plan.

ACO Applicant Certifications

The ACO application process would require that ACO officers or directors certify that the applicant meets certain requirements, including but not limited to:

- **Legal Entity.** That the ACO is recognized as a legal entity under state law and authorized by the state to conduct its business. An ACO with operations in multiple states would have to certify that it is recognized as a legal entity in the state in which it was established and that it is authorized to conduct business in each state in which it operates;
- **Accountability.** That to the best of his or her knowledge, information and belief that the ACO participants are willing to become accountable for, and to report to CMS on, the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO;
- **Compliance With ACO Agreement.** That to the best of his or her knowledge, information, and belief the ACO participants agree to the requirements set forth in the three-year agreement between the ACO and CMS; and
- **Accuracy of Information Submitted to CMS.** The ACO must certify the accuracy, completeness and truthfulness of information contained in its Shared Savings Program application, three-year agreement, and submissions of quality data and other information.

ACO Applicant Fraud and Abuse Protections

Lastly, there would have to be criteria to establish mechanisms to protect the Shared Saving Programs from fraud and abuse and to ensure that such programs do not become a vehicle for, or increase the potential for, fraud and abuse in



other parts of the Medicare program. Thus, CMS has proposed that ACOs must have a compliance plan that addresses how the ACO will comply with the applicable legal requirements. The plan must include a designated compliance officer, who is not legal counsel to the ACO and who reports directly to the ACO's governing body. The plan should also include mechanisms for identifying and addressing compliance problems related to the ACO's operation and performance; methods for employees or contractors to report suspected concerns related to the ACO; compliance training for employees and contractors; and requirements for reporting suspected violations to appropriate law enforcement agencies.

Conclusion

The ACO application process is formidable and will require the guidance of competent health care legal counsel. Upcoming issues of the Hinshaw *Health Law Alert* will discuss data-sharing requirements and Shared Savings Programs, as well as proposed waiver provisions.

For more information, please contact [Michael A. Dowell](#), [Roy M. Bossen](#) or your regular [Hinshaw attorney](#).

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