Davis Wright Tremaine LLP

Final ACO Regulations: Legal Structure and Governance

Part two in a series of client advisories focusing on the new ACO regulations

11.08.11

By Robert L. (Bob) Schuchard

This is the second in our client advisory series on accountable care organizations ("ACOs"), focusing on ACO legal structure and governance. On Oct. 20, 2011, CMS released the Final ACO Rules ("Final Rules") implementing the voluntary Medicare Shared Savings Program for ACOs, pursuant to Section 3022 of the Patient Protection and Affordable Care Act ("ACA" or the "Act"). The ACA provides for the creation of an ACO comprised of physicians, hospitals, and other healthcare suppliers, willing to enter into a three-year shared savings program agreement with CMS and be accountable for the care of at least 5,000 Medicare beneficiaries. In the area of legal structure and governance, the basic requirements from the Proposed Rules did not change: (1) the form of entity must be recognized under state law; and (2) the ACO must have a tax identification number ("TIN"). CMS has, however, expanded the list of eligible ACO participants and provided additional guidance on governance.

Form of Entity

The Final Rules continue the very broad requirement that the ACO be an entity that is "authorized to conduct its business under applicable state law" and "be capable of: (1) receiving and distributing shared savings; (2) repaying shared losses or other monies determined to be owed to CMS; (3) establishing, reporting, and ensuring provider compliance with program requirements; and (4) performing the other ACO functions identified in the statute." These later four capabilities are operational in nature, and comprise the "statutory functions of an ACO." Thus, partnerships, corporations, unincorporated associations, and limited liability companies will all continue to be eligible structures for ACOs. Significantly, CMS did not approve contractual joint venture arrangements (because there is no separate legal entity), but it did expand the list of eligible entities to include those formed under federal or tribal law. The Final Rules, like the Proposed Rules, do not require that the ACO be enrolled in the Medicare program and do not require the formation of a new entity if an existing entity meets the eligibility and governance requirements.

Tax Identification Number

An ACO must have a TIN, as Medicare shared savings payments will be made to an ACO and tracked according to its TIN.

Eligible Participants

In an important development to expand the possible sources of primary care that was foreshadowed in the Proposed Rules, Federally Qualified Health Centers ("FQHCs") and Rural Health Clinics ("RHCs") were added to the list of entities eligible to both form and participate in an ACO. CMS apparently overcame its concerns about the different billing and payment methodologies utilized by FQHCs and RHCs and recognized that, in certain geographic areas, FQHCs and RHCs may be the only sources of primary care providers. The participants authorized by the Act, include (provided they can meet all other eligibility requirements):

- ACO professionals in group practice arrangements;
- ACO professionals including physicians or practitioners (including physician assistants, nurse practitioners, and clinical nurse specialists);
- Networks of individual practices of ACO professionals;
- Partnerships or joint ventures between hospitals and ACO professionals;
- Hospitals employing ACO professionals;
- Certain critical access hospitals;
- RHCs;

- FQHCs; and

- Such other providers of services and suppliers as the Secretary determines appropriate.

Although urged to do so by a number of commenters, CMS did not change its requirement that each ACO participant and provider/supplier "demonstrate a meaningful commitment . . . to the ACO's mission to ensure its likely success." This commitment may be evidenced by (1) financial investments, such as capital contributions; (2) human investment, such as serving on the governing board or committees or participating in other aspects of the ACO's operations; or (3) a willingness to be accountable for meeting the ACO's performance standards.

Governance

The Final Rules require that the ACO have a governing body, like a board of directors or board of managers, that has authority over the ACO's operations. CMS received a number of comments in the governance area and responded in many helpful ways.

First, CMS allowed for potential ACO participants to demonstrate alternative means of complying with certain Final Rules' requirements—most notably the requirement of 75% ACO participant control of the board and the one Medicare beneficiary on the board rule (discussed below)—where it can be shown that the ACO will involve participants in "innovative ways" and provide meaningful participation in the ACO governance to beneficiaries served by the ACO.

Second, CMS eliminated the requirements that (1) each ACO participant be a member of the governing board; and (2) there be proportionate representation of the participants on the governing board, in favor of a requirement that the ACO "provide for meaningful participation in the composition and control of the ACO's governing board" to ACO participants. Read literally, the Proposed Rules required each ACO participant that was a sole practitioner to be a board member. CMS recognized that ACOs needed greater flexibility. It seems likely, however, that sole practitioners as a class will have a representative on the board.

Third, the preamble clarified in part what CMS meant by governance and stated that the ACO's governing board "shall provide oversight and strategic direction, holding management accountable for meeting the goals of the ACO, which include the three part aim." CMS also elaborated that this oversight encompassed "not only care delivery, but also process to promote evidence-based medicine, patient engagement, reporting on quality and cost, care coordination, distribution of shared savings, establishing clinical and administrative systems, among other functions." Further, CMS requires that ACOs must have a transparent governance process and board members who have fiduciary duties to the ACO. These requirements do not appear to be much different than typical state law requirements that the activities and affairs of the corporation be managed by or under the direction of the board, which sets policy, delegates and oversees the activities of management, and has fiduciary duties of care and loyalty. CMS is stressing, however, the board's oversight responsibility for the functions of the ACO.

Fourth, if an ACO wants waivers of the Physician Self-Referral Law (the Stark law), the Federal Anti-Kickback Statute, and certain civil monetary penalties law, the ACO governing body must make a bona fide determination that the arrangement for which waiver protection is sought is reasonably related to the purposes of the Shared Savings Program (and are not arrangements merely furthering the financial or business interests of ACO participants or ACO providers/suppliers), and that the governing body had duly authorized the arrangement.

Fifth, CMS continued a number of other governance requirements from the Proposed Rules into the Final Rules, including:

- 75% Board Representation. 75 percent of the governing board must be chosen by the ACO participants. CMS acknowledged that non-Medicare-enrolled entities, such as entrepreneurial management companies and health plans, may offer needed capital and infrastructure and, as a result, a minority of board positions may be comprised of non-providers. However, CMS wants ACOs to be "provider driven." It remains to be seen, however, whether non-Medicare-enrolled entities will want to invest a majority of the ACO's initial capital without receiving a majority of the board seats. As noted above, in its ACO application to CMC, an ACO can propose a structure that varies from this requirement but will need to demonstrate to CMS why this is appropriate.

- One Medicare Beneficiary on the Governing Board. One of the members of the governing board must be a Medicare beneficiary served by the ACO. This beneficiary may not have any conflict of interest (presumably beyond being a patient serviced by the network) and may not be a provider/supplier for the ACO. CMS considered

other options for beneficiary involvement in governance, such as a beneficiary board of advisors. In a change from the Proposed Rules, CMS left open the possibility that an ACO could "involve beneficiaries in ACO governance" in another manner. It seems most likely that this alternative would take the form of board committees or advisory boards with direct access to the ACO governing board. Alternatives, if pursued by applicant, would be included in an ACO's application and would be subject to CMS approval.

Management. Each ACO must have an executive accountable to and subject to selection and removal by the governing board. The executive's leadership team must have the ability to influence or direct clinical practice to improve outcomes. The ACO must also have a compliance officer who reports directly to the governing board. The compliance officer cannot be legal counsel to the ACO. The Final Rules continue to call for a medical director, who is an ACO physician, but this official can be part-time as long as he is physically present at one of the ACO's locations on a "regular basis," is board-certified and is licensed in one of the states in which the ACO operates. The Final Rules also allow for an ACO to "describe innovative leadership and management structures" that do not meet these requirements, so long as such structures are approved by CMS.The Final Rules do not require that these officers be employees of the ACO so it is predictable that many of these officers will be provided by ACO participants or others under management services or independent contractor agreements.

Conflict of Interest Policy. Each ACO's governing board must have a conflict of interest policy calling for disclosure of relevant financial interests and for a procedure to determine whether conflicts exist and an appropriate process to resolve conflicts.

Quality Assurance Committee Not Required. The Final Rules eliminated the requirement of the Proposed Rules of a physician-directed quality assurance and process improvement committee, acknowledging that physician direction is not required for quality improvement to be successful. However, the ACO must describe in its application its quality assurance and improvement program led by a qualified professional.

Compliance Function. The Final Rules continue the requirement that the ACO adopt a compliance plan to address how the ACO will comply with applicable legal requirements. The plan must include the following elements:

- A designated compliance officer;
- Mechanisms to identify and address compliance issues;
- A method for employees and contractors to report suspected problems;
- Compliance training of employees and contractors;
- Required reporting of criminal activity to law enforcement agencies; and
- Required updating of the compliance plan to reflect changes in law, including any new mandatory compliance plan requirements of the ACA.

None of the governance requirements is terribly burdensome. The governance and leadership structures of these ACOs should be familiar to the healthcare industry.

Please also see our first installment in this series:

"Antitrust Enforcement Agencies Issue Final Guidance on ACOs" (11.02.11)