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What the Proposed ACO Regulations Say About Legal Structures and Governance

The third advisory in our series on the newly proposed ACO regulations implementing Section 3022 of the PPACA

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This advisory focuses on the permissible legal structures and governance options available under the proposed regulations. Although many aspects of the regulations have been characterized as burdensome or overly intrusive, they give would-be participants great flexibility and latitude to structure and govern an accountable care organization.

To briefly recap, the Patient Protection and Affordable Care Act (PPACA) provides for the creation of an ACO comprised of physicians, hospitals, and other health care suppliers willing to enter into a three-year Shared Savings Program agreement with the Centers for Medicare & Medicaid Services and be accountable for the care of at least 5,000 Medicare beneficiaries. If certain quality performance standards are met, the ACO is eligible to receive shared savings bonus payments in addition to normal fee for services payments.

The proposed regulations include four structural requirements, each of which is discussed in detail in this advisory: (1) the form of entity must be recognized under state law; (2) the ACO must have a tax identification number; (3) the ACO must be comprised of eligible ACO participants; and (4) the ACO must have an established mechanism for shared governance.

Form of entity

The proposed rules merely advise that the ACO be "authorized to conduct its business under applicable state law" and "be capable of (1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring compliance with program requirements; and (4) performing the other ACO functions identified in the statute." These latter four capabilities are operational in nature, and will be addressed in a later advisory.

State law authorizes a number of forms of legal entities, from partnerships (both limited and general), to corporations (both nonprofit and for-profit), unincorporated associations, cooperatives, and limited liability companies. The proposed regulations do not limit the form of entity. For a variety of reasons, we anticipate that many ACOs will be formed by hospitals employing physicians (operating as nonprofit or for-profit corporations) and that most new ACOs formed by more than one owner will be formed as limited liability companies (LLCs). LLCs allow their owners, called members, to limit their liability to the amount of capital contributed. LLCs also allow for maximum flexibility in the allocation of tax profits/losses as well as distributions of cash. Often LLCs are less formally run, without the need for board meetings, corporate resolutions, minutes, and the like.

The choice of entity for the ACO will depend upon a number of factors including, but not limited to, the risk tolerance of the participants; the nature and extent of protection from liability desired, e.g., if one segment of the business needs to be protected from the potential losses or liabilities of another; the desired tax status of the ACO; how the participants will be taxed and/or claim benefits from losses generated; and the desired formality of ACO governance.

Regardless of how the ACO is structured, the charter documents (e.g., articles of incorporation and bylaws of corporations, articles of organization and operating agreements of limited liability companies, and partnership and joint venture agreements for partnerships) as well as the manner of distributing the

shared savings will need to be disclosed to CMS in the application process to participate in the Shared Savings Program.

Tax identification number

The requirement that an ACO secure a tax identification number (TIN) is also not a limitation. In general, any business that is taxed in any way needs to secure a TIN. For individuals, this is a Social Security number; for businesses it is a nine-digit employer identification number that is generally obtained online by submitting a simple IRS Form SS-4.

Eligible participants

Although the ACO need not be enrolled in the Medicare program, the ACO must be comprised of eligible participants who are Medicare-enrolled providers of services (or suppliers). "Comprised" is not defined with reference to ownership, so it remains to be seen whether participation requires ownership or mere participation as a provider and in governance. The proposed rules only require that the ACO participants have a meaningful financial investment in the ACO or a meaningful human investment in the ongoing operations of the ACO sufficient to motivate the participant to make the ACO succeed. PPACA listed the following eligible participants:

- ACO professionals in group practice arrangements. ACO professionals include physicians or practitioners (including physician assistants, nurse practitioners, and clinical nurse specialists);
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals;
- Critical access hospitals (CAHs) that bill under Method II (where CAH bills for both professional and facility);
- Such other providers of services and suppliers as CMS determines appropriate.

The proposed rule signals CMS' willingness to consider entities such as federally qualified health plans and rural health clinics. However, in the commentary, CMS expresses some concerns with the differing billing and payment methodologies and data reporting used by these types of providers. More optimistically the proposed regulations speak in terms of allowing "a wide variety of ACO configurations" as well as allowing “greater opportunities for transforming the health care delivery system and increasing access to high quality and lower cost care under the Shared Savings Program. How CMS makes these determinations remains to be seen.

Hospitals and existing integrated delivery systems with access to capital are likely to have a distinct advantage in forming an ACO because of the significant initial capitalization and infrastructure that will be required, particularly in the area of health information technology.

Governance

The proposed rules do not define governance, but call for a governing body with authority over administrative, fiduciary, and clinical operations. The proposed rules cite as examples boards of directors of corporations and boards of managers of LLCs. For these governing boards, the proposed rules require:

> ***75 percent representation by providers.*** Seventy-five percent of the governing board needs to be chosen by the ACO participants. The rules also require that these board representatives be from "within the organization." We will need to await further clarification as to which organizations need

representation and what is meant by “appropriate proportionate control over governing body decision making.” For instance, an ACO comprised of a network of individual practices should not require representation from each individual practice—more likely representatives of each type of provider will be required (e.g., a representative of the individual practitioners). In the commentary, CMS acknowledges that non-Medicare-enrolled entities such as entrepreneurial management companies and health plans may offer needed capital and infrastructure that groups of small providers lack—and thus could comprise the remaining 25 percent of the board. A significant question remains, however, as to whether non-Medicare-enrolled entities will want to invest a majority of the ACO’s initial capital without receiving a majority of the board positions.

One Medicare beneficiary on the governing board. CMS wanted patient involvement in the governance process, so one of the members of the governing board needs to be a beneficiary served by the ACO. This beneficiary is not to have any conflict of interest (presumably beyond being a patient serviced by the network) and may not be an ACO provider/supplier within the ACO network. CMS considered other options for beneficiary involvement in governance, such as a beneficiary board of advisors, but settled on requiring one beneficiary to serve on the governing board where final decisions are made.

Management. The ACO is to have an executive accountable to the governing board; this executive is to be subject to selection and removal by the governing board and have a leadership team with 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, and this officer may not be the legal counsel to the ACO. The proposed rules also call for a “full time senior level” medical director, who is physically present, board-certified, and licensed to practice medicine in the applicable state. The proposed rules do not require that these officers be employees of the ACO so it is predictable that many of these officers will be provided under contract by ACO participants or others.

Conflict of interest policy. Each ACO's governing board is to have a conflict of interest policy calling for disclosure of relevant financial interests and for a procedure to determine whether a conflict exists and an appropriate process to address conflicts when they do exist.

Quality assurance committee. The ACO is to have a physician-directed quality assurance and process improvement committee to establish and enforce performance standards for quality of care and services, cost effectiveness and process and outcome improvements.

Compliance function. The proposed rules call for the ACO to adopt a compliance plan to address how the ACO will comply with applicable legal requirements. The plan is to include the following elements: (1) a designated compliance officer; (2) mechanisms to identify and address compliance issues; (3) a method for employees and contractors to report suspected problems; (4) compliance training of employees and contractors; and (5) required reporting of criminal activity to law enforcement agencies. CMS acknowledges that most participants will have existing compliance programs and that it is appropriate to build upon or use existing programs. Similar to other Medicare certifications, an "authorized representative of the ACO" will need to certify to CMS as to the “accuracy, completeness and truthfulness” not only as to its Shared Savings Program Application and three-year agreement, but also upon each application for a Shared Savings Program payment.

With the exception of clarifications needed around the 75 percent ACO provider board requirement and the possible lack of correlation between capital contributed and board representation, none of the governance requirements are surprising or terribly burdensome. The governance and leadership structures of these ACOs should be familiar to those in the health care industry.

In our ongoing series, we will be issuing a number of separate advisories focusing on specific topics

raised by the new regulations and the affiliated guidance and requests for comments including:

- Fraud and abuse, and waivers
- Beneficiary attributions and safeguards
- Quality metrics
- Shared savings calculations
- State law restrictions
- When things go wrong or circumstances change

Please also see our past installments in this series:

" The New ACO Regs: They're Here (Well, Sort of ...)" (04. 05.11)

"Antitrust Enforcement Agencies Issue Proposed Guidance on ACOs" (04.06.11)

Stay tuned … and in the meantime, if you have any questions, please contact us.