

(3) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in this part.

(b) An ACO formed by two or more ACO participants, each of which is identified by a unique TIN, must be a legal entity separate from any of its ACO participants.

(c) An ACO formed by a single ACO participant may use its existing legal entity and governing body, provided it satisfies the other requirements in §§ 425.104 and 425.106.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32834, June 9, 2015]

§ 425.106 Shared governance.

(a) *General rule.* (1) An ACO must maintain an identifiable governing body with ultimate authority to execute the functions of an ACO as defined under this part, including but not limited to, the processes defined under § 425.112 to promote evidence-based medicine and patient engagement, to report on quality and cost measures, and to coordinate care.

(2) The governing body of the ACO must satisfy all of the following criteria:

(i) Be the same as the governing body of the legal entity that is the ACO.

(ii) Be separate and unique to the ACO and must not be the same as the governing body of any ACO participant, except as provided in § 425.104(c).

(iii) Satisfy all other requirements of this section.

(b) *Responsibilities of the governing body and its members.* (1) The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities as described in this part.

(2) The governing body must have a transparent governing process.

(3) The governing body members must have a fiduciary duty to the ACO, including the duty of loyalty, and must act consistent with that fiduciary duty.

(c) *Composition and control of the governing body.* (1) The ACO must—

(i) Establish a mechanism for shared governance among the ACO partici-

pants or combinations of ACO participants (as identified in § 425.102(a)) that formed the ACO; and

(ii) Provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

(2) The ACO governing body must include a Medicare beneficiary who—

(i) Is served by the ACO;

(ii) Is not an ACO provider/supplier;

(iii) Does not have a conflict of interest with the ACO; and

(iv) Does not have an immediate family member who has a conflict of interest with the ACO.

(3) At least 75 percent control of the ACO's governing body must be held by ACO participants.

(4) The governing body members may serve in a similar or complementary manner for an ACO participant.

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraphs (c)(2) and (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.

(d) *Conflict of interest.* The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—

(1) Require each member of the governing body to disclose relevant financial interests; and

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.

(3) The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015]

§ 425.108 Leadership and management.

(a) An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program

and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) The ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

(c) Clinical management and oversight must be managed by a senior-level medical director. The medical director must be all of the following:

(1) A board-certified physician.

(2) Licensed in a State in which the ACO operates.

(3) Physically present on a regular basis at any clinic, office or other location of the ACO, an ACO participant, or an ACO provider/supplier.

(d) Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.

(1) Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.

(2) A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by § 425.112 and is held accountable for meeting the ACO's performance standards for each required process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015]

§ 425.110 Number of ACO professionals and beneficiaries.

(a)(1) The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subpart E of this part. The ACO must have at least 5,000 assigned beneficiaries.

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218.

(1) While under a CAP, the ACO remains eligible for shared savings and liable for shared losses.

(2) If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

(3) In determining financial performance for an ACO with fewer than 5,000 assigned beneficiaries, the MSR/MLR is calculated as follows:

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) are set at a level consistent with the number of assigned beneficiaries.

(ii) For performance years starting before July 1, 2019, for ACOs with a fixed MSR/MLR, the MSR/MLR remains fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

(iii) For performance years starting on July 1, 2019 and in subsequent years, for ACOs that selected a fixed MSR/MLR at the start of the agreement period or prior to entering a two-sided model during their agreement period, the MSR/MLR is calculated as follows:

(A) The MSR/MLR is set at a level based on the number of beneficiaries assigned to the ACO.

(1) The MSR is the same as the MSR that would apply in a one-sided model under § 425.604(b) (for Track 2 ACOs) or