

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

(ii) For agreement periods beginning before January 1, 2024, in cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO par-

ticipants in innovative ways in ACO governance.

(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; 88 FR 79544, Nov. 16, 2023]

#### § 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.