

(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.

§ 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 who is a physician and one of its ACO providers/suppliers, who is physically present on a regular basis at any clinic, office, or other location participating in the ACO, and who is a board-certified physician and licensed in a State in which the ACO operates.

(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.

(e) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting paragraphs (b) through (c) of this section.

§ 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 specified in paragraph (a)(1) of this section if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period, using the assignment methodology in subpart E of this part, is 5,000 or more.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a CAP.

(1) While under the CAP, the ACO remains eligible for shared savings and losses during that performance year and its MSR will be set at a level consistent with the number of assigned beneficiaries.

(2) If the ACO's assigned population is not returned to at least 5,000 or more by the end of next performance year, the ACO's agreement will be terminated and the ACO will not be eligible

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to share in savings for that performance year.

§ 425.112 Required processes and patient-centeredness criteria.

(a) *General.* (1) An ACO must—

(i) Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;

(ii) Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and

(iii) Have defined processes to fulfill these requirements.

(2) An ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes included in paragraphs (b)(1) through (4) of this section.

(3) For each process specified in paragraphs (b)(1) through (4) of this section, the ACO must—

(i) Explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and

(ii) Explain how it will employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

(b) *Required processes.* The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:

(1) Promote evidence-based medicine. These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.

(2) Promote patient engagement. These processes must address the following areas:

(i) Compliance with patient experience of care survey requirements in § 425.500.

(ii) Compliance with beneficiary representative requirements in § 425.106.

(iii) A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(A) In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.

(B) An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.

(iv) Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(v) Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;

(vi) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(3) Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.

(4) Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must—

(i) Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and

(ii) As part of its application, the ACO must:

(A) Submit a description of its individualized care program, along with a sample individual care plan, and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients.