

(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) Require ACO participants and ACO providers/suppliers to comply with and implement each process (and sub-element 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) 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 or § 425.510, as applicable.

(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) Have a written plan to:

(A) Implement an individualized care program that promotes improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition patients.

(B) Identify additional target populations that would benefit from individualized care plans. Individualized care plans must take into account the community resources available to the individual.

(C) Encourage and promote use of enabling technologies for improving care coordination for beneficiaries. Enabling technologies may include one or more of the following:

(1) Electronic health records and other health IT tools.

(2) Telehealth services, including remote patient monitoring.

(3) Electronic exchange of health information.

(4) Other electronic tools to engage beneficiaries in their care.

(D) Partner with long-term and post-acute care providers, both inside and

outside the ACO, to improve care coordination for its assigned beneficiaries.

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§ 425.114 Participation in other shared savings initiatives.

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

§ 425.116 Agreements with ACO participants and ACO providers/suppliers.

(a) *ACO participant agreements.* For performance year 2017 and subsequent performance years, the ACO must have an ACO participant agreement with each ACO participant that complies with the following criteria:

(1) The only parties to the agreement are the ACO and the ACO participant.

(2) The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively.

(3) The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other

applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO participant to update its enrollment information, including the addition and deletion of ACO professionals and ACO providers/suppliers billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements and to notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address non-compliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS.

(8) The agreement must be for a term of at least 1 performance year and must articulate potential consequences for early termination from the ACO.

(9) The agreement must require completion of a close-out process upon termination or expiration of the agreement that requires the ACO participant to furnish all data necessary to complete the annual assessment of the