

revenue center codes designated under § 425.400(c).

Quality measures means the measures defined by the Secretary, under section 1899 of the Act, to assess the quality of care furnished by an ACO, such as measures of clinical processes and outcomes, patient and, where practicable, caregiver experience of care and utilization.

Re-entering ACO means an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions:

(1) Is the same legal entity as an ACO, as defined in this section, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—

(i) An ACO whose participation agreement expired without having been renewed; or

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220.

(2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

Renewing ACO means an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either—

(1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or

(2) An ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program.

Reporting period, for purposes of subpart F of this part, means the calendar year from January 1 to December 31.

Rural health clinic (RHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

Shared losses means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures,

above the applicable benchmark, it must repay to CMS. An ACO's eligibility for shared losses will be determined for each performance year. For an ACO requesting interim payment, shared losses may result from the interim payment calculation.

Shared savings means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, below the applicable benchmark, it is eligible to receive payment for from CMS. An ACO's eligibility for shared savings will be determined for each performance year. For an ACO requesting interim payment, shared savings may result from the interim payment system calculation.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109-1.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G of this part.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32833, June 9, 2015; 80 FR 71385, Nov. 16, 2015; 81 FR 38013, June 10, 2016; 82 FR 53368, Nov. 15, 2017; 83 FR 60092, Nov. 23, 2018; 83 FR 68062, Dec. 31, 2018; 87 FR 70232, Nov. 18, 2022; 88 FR 79543, Nov. 16, 2023]

Subpart B—Shared Savings Program Eligibility Requirements

§ 425.100 General.

(a) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that meets the criteria specified in this part. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) An ACO is eligible to receive payments for shared savings under subpart G of this part if all of the following conditions are met:

(1) The ACO meets or exceeds the applicable minimum savings rate established under §§ 425.604, 425.605 (except as provided under § 425.605(h)), 425.606, 425.609, or 425.610.

§ 425.102

(2) The ACO meets the minimum quality performance standards established under § 425.500 (for performance years or a performance period beginning on or before January 1, 2020), or under the quality performance standard established under § 425.512 (for performance years beginning on or after January 1, 2021).

(3) The ACO otherwise maintains its eligibility to participate in the Shared Savings Program under this part.

(c) ACOs that operate under a two-sided model and meet or exceed a minimum loss rate established under § 425.605, § 425.606, § 425.609 or § 425.610 must share losses with the Medicare program under subpart G of the part.

(d) An ACO is eligible to receive advance investment payments if it meets the criteria under § 425.630(b).

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32834, June 9, 2015; 83 FR 60092, Nov. 23, 2018; 83 FR 68083, Dec. 31, 2018; 85 FR 85038, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022]

§ 425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) CAHs that bill under Method II (as described in § 413.70(b)(3) of this chapter).

(6) RHCs.

(7) FQHCs.

(8) Teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible to participate through an ACO formed by one or more

42 CFR Ch. IV (10–1–24 Edition)

of the ACO participants identified in paragraph (a) of this section.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 71386, Nov. 16, 2015]

§ 425.104 Legal entity.

(a) An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for purposes of the following:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses or other monies determined to be owed to CMS.

(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.