

about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and materials or activities that do not constitute “marketing” under 45 CFR 164.501 and 164.508(a)(3)(i).

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under both parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

Newly assigned beneficiary means a beneficiary that is assigned to the ACO in the current performance year who was neither assigned to nor received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under subpart G of this part.

Participation agreement means the written agreement required under § 425.208(a) between the ACO and CMS that, along with the regulations in this part, govern the ACO’s participation in the Shared Savings Program.

Performance-based risk Medicare ACO initiative means, for purposes of this part, an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period, including the following options and initiatives:

(1) Participation options within the Shared Savings Program as follows:

(i) For performance years beginning prior to January 1, 2023, BASIC track (Levels A through E).

(ii) For performance years beginning January 1, 2023 and in subsequent years, BASIC track (Levels C through E).

(iii) ENHANCED track.

(iv) Track 2.

(2) The Innovation Center ACO models under which an ACO accepts risk for shared losses as follows:

(i) Pioneer ACO Model.

(ii) Next Generation ACO Model.

(iii) Comprehensive ESRD Care Model two-sided risk tracks.

(iv) Track 1+ Model.

(3) Other initiatives involving two-sided risk as may be specified by CMS.

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement.

Physician means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Physician Quality Reporting System (PQRS) means the quality reporting system established under section 1848(k) of the Act.

Primary care physician means:

(1) For performance years 2012 through 2015, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, or geriatric medicine;

(2) For performance years 2016 through 2018, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine; and

(3) For performance year 2019 and subsequent years, a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine.

Primary care services means the set of services identified by the HCPCS and

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.