

## Subpart A—General Provisions

### § 425.10 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. The regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare, except as permitted under section 1899(f) of the Act.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Application procedures and provisions of the participation agreement.

(3) Program requirements and beneficiary protections.

(4) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(5) Quality performance standards, reporting requirements, and data sharing.

(6) Payment criteria and methodologies (one-sided model and two-sided models).

(7) Compliance monitoring and sanctions for noncompliance.

(8) Reconsideration review process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32833, June 9, 2015]

### § 425.20 Definitions.

As used in this part, unless otherwise indicated—

*Accountable care organization* (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants(s) that is(are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).

*ACO participant* means an entity identified by a Medicare-enrolled bill-

ing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118.

*ACO participant agreement* means the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

*ACO professional* means an individual who is Medicare-enrolled and bills for items and services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

*ACO provider/supplier* means an individual or entity that meets all of the following:

(1) Is a—

(i) Provider (as defined at § 400.202 of this chapter); or

(ii) Supplier (as defined at § 400.202 of this chapter).

(2) Is enrolled in Medicare.

(3) Bills for items and services furnished to Medicare fee-for-service beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations.

(4) Is included on the list of ACO providers/suppliers that is required under § 425.118.

*ACO's regional service area* means all counties where one or more beneficiaries assigned to the ACO reside.

*Agreement period* means the term of the participation agreement.

*Antitrust Agency* means the Department of Justice or Federal Trade Commission.

*Assignable beneficiary* means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

*Assignment* means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from ACO professionals so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark or performance year.

*Assignment window* means the 12-month period used to assign beneficiaries to an ACO.

*At-risk beneficiary* means, but is not limited to, a beneficiary who—

- (1) Has a high risk score on the CMS-HCC risk adjustment model;
- (2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;
- (3) Is dually eligible for Medicare and Medicaid;
- (4) Has a high utilization pattern;
- (5) Has one or more chronic conditions.
- (6) Has had a recent diagnosis that is expected to result in increased cost.
- (7) Is entitled to Medicaid because of disability; or
- (8) Is diagnosed with a mental health or substance abuse disorder.

*BY* stands for benchmark year.

*Certified Electronic Health Record Technology (CEHRT)* has the same meaning given this term under § 414.1305 of this chapter.

*Continuously assigned beneficiary* means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

*Covered professional services* has the same meaning given these terms under section 1848(k)(3)(A) of the Act.

*Critical access hospital (CAH)* has the same meaning given this term under § 400.202 of this chapter.

*Eligible clinician* has the same meaning given this term under § 414.1305 of this chapter.

*Eligible professional* has the meanings given this term under section 1848(k)(3)(B) of the Act.

*Experienced with performance-based risk Medicare ACO initiatives* means an ACO that CMS determines meets the criteria in either paragraph (1) or (2) of this definition.

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years.

*Federally qualified health center (FQHC)* has the same meaning given to this term under § 405.2401(b) of this chapter.

*High revenue ACO* means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

*Hospital* means a hospital as defined in section 1886(d)(1)(B) of the Act.

*Inexperienced with performance-based risk Medicare ACO initiatives* means an ACO that CMS determines meets all of the following:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not

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deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years.

*Low revenue ACO* means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

*Marketing materials and activities* include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information 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 center (RHC)* has the same meaning given to this term under § 405.2401(b).

*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

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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]

### 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.

(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

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§ 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 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.