

Subpart F—Quality Performance Standards and Reporting

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SOURCE: 76 FR 67973, Nov. 2, 2011, unless otherwise noted.

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). For performance year 2025 and subsequent performance years, a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary—

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled 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).

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, or to identify assignable beneficiaries, or both.

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 Medicare because of disability; or

(8) Is diagnosed with a mental health or substance abuse disorder.

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

(1) A Medicare fee-for-service beneficiary (as defined at § 425.20) who –

(i) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(ii) Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(2) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

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.

Expanded window for assignment means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

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, 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. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during 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 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, 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. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any 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