

§ 425.202

agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(3) For an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c) or § 425.510, as applicable, and as applicable according to §§ 425.608 and 425.609.

(e) *Optional fourth year.* (1) To qualify for a fourth performance year as described in paragraph (b)(3)(ii) of this section, the ACO must meet all of the following conditions:

(i) The ACO's first agreement period in the Shared Savings Program under Track 1 began in 2014 or 2015.

(ii) Is currently participating in its first agreement period under Track 1.

(iii) Has requested renewal of its participation agreement in accordance with § 425.224.

(iv) Has selected a two-sided model (as described under § 425.606 or § 425.610 of this part) in its renewal request.

(v) Has requested an extension of its current agreement period and a 1-year deferral of the start of its second agreement period in a form and manner specified by CMS.

(vi) CMS approves the ACO's renewal, extension, and deferral requests.

(2) An ACO that is approved for renewal, extension, and deferral that terminates its participation agreement before the start of the first perform-

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ance year of the second agreement period is—

(i) Considered to have terminated its participation agreement for the second agreement period under § 425.220; and

(ii) Not eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 81 FR 38013, June 10, 2016; 83 FR 60092, Nov. 23, 2018; 83 FR 68063, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85038, Dec. 28, 2020]

§ 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* For determining eligibility for agreement periods beginning before July 1, 2019: (1) PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(2) A Pioneer ACO may use a condensed application form to apply for participation in the Shared Savings Program if it satisfies all of the following criteria:

(i) The applicant is the same legal entity as the Pioneer ACO.

(ii) The applicant's ACO participant list does not contain any ACO participant TINs that did not appear on the "Confirmed Annual TIN/NPI List" (as

defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model.

(iii) The applicant is not applying to participate in the one-sided model.

(c) *Application review.* CMS reviews applications in accordance with § 425.206.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 83 FR 68063, Dec. 31, 2018]

§ 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Prior participation.* Upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Medicare Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b).

(2) The ACO must specify whether the related participation agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must certify that the ACO satisfies the requirements set forth in this part. Upon request, the ACO must submit the following supporting materials to demonstrate that it satisfies the requirements set forth in this part:

(i) Documents (for example, ACO participant agreements, agreements with ACO providers/suppliers, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers/suppliers' rights and obligations in and representation by the ACO, and how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines.

(ii) A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.

(iii) Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders specifically noted in § 425.108 and § 425.112(a)(2).

(iv) Evidence that the governing body—

(A) Is an identifiable body;

(B) Represents a mechanism for shared governance for ACO participants;

(C) Is composed of representatives of its ACO participants; and

(D) Is at least 75 percent controlled by its ACO participants.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the participation agreement with CMS becomes effective.