

§ 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) *Disclosure of prior participation.* (1) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare Shared Savings Program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO.

(2) The ACO must specify whether the related ACO 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 agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must submit to CMS the following supporting materials to demonstrate that the ACO satisfies the eligibility requirements set forth in subpart B of this part:

(i) Documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, including 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 evidenced-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 including administrative and clinical leaders specifically noted in § 425.108.

(iv) Evidence that the governing body is an identifiable body, that the governing body is comprised of representatives of the ACO's participants, and that the ACO participants have at least 75 percent control of the ACO's governing body.

(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 ACO's agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

- (i) Charters.
- (ii) By-laws.
- (iii) Articles of incorporation.
- (iv) Partnership agreement.
- (v) Joint venture agreement.
- (vi) Management or asset purchase agreements.
- (vii) Financial statements and records.
- (viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the—

(i) Governing body requirements in § 425.106, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO

governance or provide meaningful representation in ACO governance by Medicare beneficiaries or both; or

(ii) Leadership and management requirements in § 425.108, the ACO must describe how its alternative leadership and management structure will be capable of accomplishing the ACO's mission.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among multiple, independent ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and their Medicare-enrolled TINs.

(A) For each ACO participant, the ACO must submit a list of the ACO providers/suppliers and their provider identifier (for example, NPI) and indicate whether the ACO provider/supplier is a primary care physician as defined in § 425.20.

(B) The list specified in paragraph (c)(5)(i)(A) of this section must be updated in accordance with § 425.302(d).

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) If the ACO includes an FQHC or RHC as an ACO participant, it must also do the following:

(A) Indicate the TINs, organizational NPIs, and other identifying information for its participant FQHCs or RHCs or both, as well as NPIs and other identifying information for the physicians that directly provide primary care services in the participant FQHCs or RHCs or both.

(B) Submit any other specific identifying information for its participant FQHCs or RHCs or both as required by CMS in the application process.

(iv) The ACO must certify the accuracy of this information.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe the following:

(1) How it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its ACO participants and ACO providers/suppliers.

(2) How the proposed plan will achieve the specific goals of the Shared Savings Program.

(3) How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(e) *Selection of track and option for interim payment calculation.*

(1) As part of its application, an ACO must specify whether it is applying to participate in Track 1 or Track 2 (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay losses for which it may be liable, and any other monies determined to be owed upon first performance year reconciliation.

(i) As part of its application, an ACO that is applying to participate under the two-sided model of the Shared Savings Program or requesting an interim payment calculation under the one-sided model must submit for CMS approval documentation that it is capable of repaying losses or other monies determined to be owed upon first year reconciliation.

(ii) The documentation specified in paragraph (f)(1)(i) of this section must include details supporting the adequacy of the mechanism for repaying losses, or other monies determined to be owed upon first year reconciliation,

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equal to at least 1 percent of the ACO's total per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark.

(2) An ACO may demonstrate its ability to repay losses, or other monies determined to be owed upon first year reconciliation, by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing another appropriate repayment mechanism that will ensure its ability to repay the Medicare program.

(3) An ACO participating under the two-sided model must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application on the basis of the information contained in and submitted with the application.

(2) CMS notifies applicant ACOs when the application is incomplete and provide an opportunity to submit information to complete the application. Applications remaining incomplete by the application due date will be denied.

(b) *Notice of determination.* (1) CMS notifies in writing each applicant ACO of its determination to approve or deny the ACO's application to participate in the Shared Savings Program.

(2) If CMS denies the application, the notice will indicate that the ACO is not qualified to participate in the Shared Savings Program, specify the reasons why the ACO is not so qualified, and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

§ 425.208 Provisions of participation agreement.

(a) *General rules.* (1) Upon being notified by CMS of its approval to participate in the Shared Savings Program,

an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement.

(2) Under the participation agreement the ACO must agree to comply with the provisions of this part in order to participate in the Shared Savings Program.

(b) *Compliance with laws.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree, or to comply with all applicable laws including, but not limited to, the following:

(1) Federal criminal law.

(2) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(3) The anti-kickback statute (42 U.S.C. 1320a-7b(b)).

(4) The civil monetary penalties law (42 U.S.C. 1320a-7a).

(5) The physician self-referral law (42 U.S.C. 1395nn).

(c) *Certifications.* (1) The ACO must agree, as a condition of participating in the program and receiving any shared savings payment, that an individual with the authority to legally bind the ACO will certify the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, including, but not limited to, the application form, participation agreement, and any quality data or other information on which CMS bases its calculation of shared savings payments and shared losses.

(2) Certifications must meet the requirements at § 425.302.

§ 425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.

(a) The ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance.

(b) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of this part, including, but not