

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application to determine whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program, and approves or denies applications accordingly. Applications are approved or denied on the basis of the following:

(i) Information contained in and submitted with the application by an application deadline specified by CMS.

(ii) Supplemental information that was submitted in response to a CMS request and by a deadline specified by CMS.

(iii) Other information available to CMS.

(2) CMS notifies an ACO applicant when supplemental information is required for CMS to make a determination on the ACO's application and provides an opportunity for the ACO to submit the information.

(3) CMS may deny an application if an ACO applicant fails to submit requested information by the deadlines established by CMS.

(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.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32838, June 9, 2015]

§ 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).

(6) The information blocking provision of the 21st Century Cures Act (42 U.S.C. 300jj–52).

(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.

[76 FR 67973, Nov. 2, 2011, as amended at 89 FR 54717, July 1, 2024]

§ 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 limited to, those specified in the participation agreement with CMS.