

period, an ACO that was previously under a one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in the same agreement period under the one-sided model as it was at the time of termination.

(2) If the termination occurred more than half way through the agreement period, an ACO that was previously in its first agreement period under the one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in its second agreement period under the one-sided model. An ACO that was previously in its second agreement period under the one-sided model must reenter the program under a two-sided model.

(3) Regardless of the date of termination, an ACO that was previously under a two-sided model may only reapply for participation in a two-sided model.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32839, June 9, 2015; 83 FR 68065, Dec. 31, 2018]

**§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.**

(a) *General rules.* A renewing ACO or a re-entering ACO may apply to enter a new participation agreement with CMS for participation in the Shared Savings Program.

(1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, the ACO must submit a complete application in the form and manner and by the deadline specified 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 enter a new participation agreement under 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 its application with the Antitrust Agencies.

(4) The ACO must select a participation option in accordance with the requirements specified in § 425.600. Regardless of the date of termination or expiration of the participation agreement, a renewing ACO or re-entering ACO that was previously under a two-sided model may only reapply for participation in a two-sided model.

(b) *Review of application.* (1) CMS determines whether to approve a renewing ACO's or re-entering ACO's application based on an evaluation of all of the following factors:

(i) Whether the ACO satisfies the criteria for operating under the selected risk track.

(ii) The ACO's history of noncompliance with the requirements of the Shared Savings Program, including, but not limited to, the following factors:

(A) Whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

(B) For 2 performance years of the ACO's previous agreement period, regardless of whether the years are in consecutive order, whether the average per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark by an amount equal to or exceeding either of the following:

(1) The ACO's negative MSR, under a one-sided model.

(2) The ACO's MLR, under a two-sided model.

(C) Whether the ACO failed to repay shared losses in full within 90 days as required under subpart G of this part for any performance year of the ACO's previous agreement period in a two-sided model.

(D) For an ACO that has participated in a two-sided model authorized under section 1115A of the Act, whether the ACO failed to repay shared losses for any performance year as required under the terms of the ACO's participation agreement for such model.

(iii) Whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused any noncompliance identified in paragraph (b)(1)(ii) of this section to occur, and any other factors that may have caused the ACO to be terminated from the Shared Savings Program, and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(iv) Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program to enter a new participation agreement, including the ability to repay losses by establishing an adequate repayment mechanism under § 425.204(f), if applicable.

(v) The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.305(a)).

(2) Applications are approved or denied on the basis of the following information:

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

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

(iii) Other information available to CMS.

(3) CMS notifies the ACO when supplemental information is required for CMS to make such a determination and provides an opportunity for the ACO to submit the information.

(c) *Notice of determination.* (1) CMS notifies the ACO in writing of its determination to approve or deny the ACO's application.

(2) If CMS denies the application, the notice of determination—

(i) Specifies the reasons for the denial; and

(ii) Informs the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

[80 FR 32839, June 9, 2015, as amended at 83 FR 68065, Dec. 31, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022]

#### § 425.226 Annual participation elections.

(a) *General.* This section applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. Before the start of a performance year, an ACO may make elections related to its participation in the Shared Savings Program, as specified in this section, effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election in accordance with this section.

(1) *Selection of beneficiary assignment methodology.* An ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of this part. An ACO may select either of the following:

(i) Preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2).

(ii) Prospective assignment, as described in § 425.400(a)(3).

(2) *Selection of BASIC track level.* An ACO participating under the BASIC track in the glide path may select a higher level of risk and potential reward, as provided in this section.

(i) An ACO participating under the BASIC track's glide path may elect to transition to a higher level of risk and potential reward within the glide path than the level of risk and potential reward that the ACO would be automatically transitioned to in the applicable year as specified in § 425.605(d)(1). The automatic transition to higher levels of risk and potential reward within the BASIC track's glide path continues to apply to all subsequent years of the agreement period in the BASIC track.

(ii) An ACO transitioning to a higher level of risk and potential reward under paragraph (a)(2)(i) of this section must meet all requirements to participate under the selected level of performance-based risk, including both of the following:

(A) Establishing an adequate repayment mechanism as specified under § 425.204(f).

(B) Selecting a MSR/MLR from the options specified under § 425.605(b).

(b) *Election procedures.* (1) All annual elections must be made in a form and