

(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effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election in accordance with this section.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