

§ 425.300

42 CFR Ch. IV (10–1–23 Edition)

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 manner and according to the time-frame established by CMS.

(2) ACO executive who has the authority to legally bind the ACO must certify the elections described in this section.

[83 FR 68066, Dec. 31, 2018]

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.* (1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500 or § 425.510, as applicable, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements;

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or

services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS; and

(iii) That the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

(iv) That the ACO has moved all advance investment payments received during that performance year into a designated advance investment payments account established under § 425.630(e) and the advance investment payments have been dispersed only for allowable uses.

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 83 FR 60092, Nov. 23, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022]

§ 425.304 Beneficiary incentives.

(a) *General.* (1) Except as set forth in this section, or as otherwise permitted by law, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Nothing in this section shall be construed as prohibiting an ACO from using shared savings received under this part to cover the cost of an in-kind item or service or incentive payment provided to a beneficiary under paragraph (b) or (c) of this section.

(b) *In-kind incentives.* ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to Medicare fee-for-service beneficiaries if all of the following conditions are satisfied:

(1) There is a reasonable connection between the items and services and the medical care of the beneficiary.

(2) The items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(3) The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

(c) *Monetary incentives*—(1) *General.* For performance years beginning on July 1, 2019 and for subsequent performance years, an ACO that is participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track may, in accordance with this section, establish a beneficiary incentive program to provide monetary incentive payments to Medicare fee-for-service beneficiaries who receive a qualifying service.

(2) *Application procedures.* (i) To establish or reestablish a beneficiary incentive program, an ACO must submit a complete application in the form and manner and by a deadline specified by CMS.

(ii) CMS evaluates an ACO's application to determine whether the ACO satisfies the requirements of this section, and approves or denies the application.

(iii) If an ACO wishes to make a material change to its CMS-approved beneficiary incentive program, the ACO must submit a description of the material change to CMS in a form and manner and by a deadline specified by CMS. CMS will promptly evaluate the proposed material change and approve or reject it.

(3) *Beneficiary incentive program requirements.* An ACO must begin to operate its approved beneficiary incentive program beginning on July 1, 2019 or January 1 of the relevant performance year.

(i) *Duration.* (A) Subject to the termination provision at paragraph (c)(7) of this section, an ACO must operate its approved beneficiary incentive program for an initial period of 18 months