

## § 425.300

## 42 CFR Ch. IV (10–1–24 Edition)

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) For performance years starting on January 1, 2019 through 2024, 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; 88 FR 79544, Nov. 16, 2023]

**§ 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 sec-

tion, 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 in the case of an ACO approved to operate a beneficiary incentive program beginning on July 1, 2019, or 12 months in the case of an ACO approved to operate a beneficiary incentive program beginning on January 1 of a performance year.

(B) For each consecutive year that an ACO wishes to operate its beneficiary incentive program after the CMS-approved initial period, it must certify all of the following by a deadline specified by CMS:

(1) Its intent to continue to operate the beneficiary incentive program for the entirety of the relevant performance year.

(2) That the beneficiary incentive program meets all applicable requirements.

(ii) *Beneficiary eligibility.* A fee-for-service beneficiary is eligible to receive an incentive payment under a

beneficiary incentive program if the beneficiary is assigned to the ACO through either of the following:

(A) Preliminary prospective assignment, as described in § 425.400(a)(2).

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

(iii) *Qualifying service.* For purposes of this section, a qualifying service is a primary care service (as defined in § 425.20) with respect to which coinsurance applies under Part B, if the service is furnished through an ACO by one of the following:

(A) An ACO professional who has a primary care specialty designation included in the definition of primary care physician under § 425.20.

(B) An ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist.

(C) A FQHC or RHC.

(iv) *Incentive payments.* (A) An ACO that establishes a beneficiary incentive program must furnish an incentive payment for each qualifying service furnished to a beneficiary described in paragraph (c)(3)(ii) of this section in accordance with this section.

(B) Each incentive payment made by an ACO under a beneficiary incentive program must satisfy all of the following conditions:

(1) The incentive payment is in the form of a check, debit card, or a traceable cash equivalent.

(2) The value of the incentive payment does not exceed \$20, as adjusted annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, rounded to the nearest whole dollar amount.

(3) The incentive payment is provided by the ACO to the beneficiary no later than 30 days after a qualifying service is furnished.

(C) An ACO must furnish incentive payments in the same amount to each eligible Medicare fee-for-service beneficiary without regard to enrollment of such beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan.

(4) *Program integrity requirements—(i) Record retention.* An ACO that establishes a beneficiary incentive program must maintain records related to the beneficiary incentive program that include the following:

(A) Identification of each beneficiary that received an incentive payment, including beneficiary name and HICN or Medicare beneficiary identifier.

(B) The type and amount of each incentive payment made to each beneficiary.

(C) The date each beneficiary received a qualifying service, the corresponding HCPCS code for the qualifying service, and identification of the ACO provider/supplier that furnished the qualifying service.

(D) The date the ACO provided each incentive payment to each beneficiary.

(ii) *Source of funding.* (A) An ACO must not use funds from any entity or organization outside of the ACO to establish or operate a beneficiary incentive program.

(B) An ACO must not directly, through insurance, or otherwise, bill or otherwise shift the cost of establishing or operating a beneficiary incentive program to a Federal health care program.

(iii) *Beneficiary notifications.* An ACO or its ACO participants shall notify assigned beneficiaries of the availability of the beneficiary incentive program in accordance with § 425.312(b).

(iv) *Marketing prohibition.* Except for the beneficiary notifications required under this section, the beneficiary incentive program is not the subject of marketing materials and activities, including but not limited to, an advertisement or solicitation to a beneficiary or any potential patient whose care is paid for in whole or in part by a Federal health care program (as defined at 42 U.S.C. 1320a–7b(f)).

(5) *Effect on program calculations.* CMS disregards incentive payments made by an ACO under paragraph (c) of this section in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses.

(6) *Income exemptions.* Incentive payments made under a beneficiary incentive program are not considered income or resources or otherwise taken