

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

into account for purposes of either of the following:

(i) Determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or under any State or local program financed in whole or in part with Federal funds.

(ii) Any Federal or State laws relating to taxation.

(7) *Termination.* CMS may require an ACO to terminate its beneficiary incentive program at any time for either of the following:

(i) Failure to comply with the requirements of this section.

(ii) Any of the grounds for ACO termination set forth in § 425.218(b).

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#### § 425.305 Other program safeguards.

(a) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Program integrity history issues include, but are not limited to, a history of Medicare program exclusions or other sanctions, noncompliance with the requirements of the Shared Savings Program, or violations of laws specified at § 425.208(b).

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(b) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from doing the following:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program busi-

ness that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

[83 FR 68067, Dec. 31, 2018, as amended at 89 FR 54717, July 1, 2024]

#### § 425.306 Participant agreement and exclusivity of ACO participants.

(a) Each ACO participant must commit to the term of the participation agreement and sign an ACO participant agreement that complies with the requirements of this part.

(b)(1) Except as specified in paragraph (b)(2) of this section, ACO participants are not required to be exclusive to one Shared Savings Program ACO.

(2) Each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of this part must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims runout for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment under subpart E of this part, then:

(i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment