

§ 425.304 Other program requirements.

(a) *Beneficiary inducements.* (1) 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) Consistent with the provisions of paragraph (a)(1) of this section and subject to compliance with all other applicable laws and regulations, ACO, ACO participants and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and 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.

(b) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers will be 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.

(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.

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

(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 business 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.

(d) *Required reporting of NPIs and TINs.* (1) The ACO must maintain, update, and annually furnish to CMS at the beginning of each performance year and at other such times as specified by CMS the list of each ACO participant's TIN and ACO providers/supplier's NPI that is required to be submitted under § 425.204(c)(5)(i).

(2) The ACO must notify CMS within 30 days of any changes to the list of NPIs and TINs.

§ 425.306 Participation agreement and exclusivity of ACO participant TINs.

(a) For purposes of the Shared Savings Program, each ACO participant TIN is required to commit to a participation agreement with CMS.

(b) Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO for