

outside the ACO, to improve care coordination for its assigned beneficiaries.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015; 82 FR 53368, Nov. 15, 2017; 85 FR 85038, Dec. 28, 2020]

**§ 425.114 Participation in other shared savings initiatives.**

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

**§ 425.116 Agreements with ACO participants and ACO providers/suppliers.**

(a) *ACO participant agreements.* For performance year 2017 and subsequent performance years, the ACO must have an ACO participant agreement with each ACO participant that complies with the following criteria:

(1) The only parties to the agreement are the ACO and the ACO participant.

(2) The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively.

(3) The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other

applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO participant to update its enrollment information, including the addition and deletion of ACO professionals and ACO providers/suppliers billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements and to notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address non-compliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS.

(8) The agreement must be for a term of at least 1 performance year and must articulate potential consequences for early termination from the ACO.

(9) The agreement must require completion of a close-out process upon termination or expiration of the agreement that requires the ACO participant to furnish all data necessary to complete the annual assessment of the

ACO's quality of care and addresses other relevant matters.

(b) *Agreements with ACO providers/suppliers.* ACOs have the option of contracting directly with its ACO providers/suppliers regarding items and services furnished to beneficiaries aligned to the ACO. For performance year 2017 and subsequent performance years, an ACO's agreement with an ACO provider/supplier regarding such items and services must satisfy the following criteria:

(1) The only parties to the agreement are the ACO and the ACO provider/supplier.

(2) The agreement must be signed by the ACO provider/supplier and by an individual who is authorized to bind the ACO.

(3) The agreement must expressly require the ACO provider/supplier to agree to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO provider's/supplier's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO provider/supplier to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO provider/supplier to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO provider/supplier to—

(i) Update its enrollment information on a timely basis in accordance with Medicare program requirements; and

(ii) Notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action including the following against the ACO provider/supplier to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS:

(i) Imposition of a corrective action plan.

(ii) Denial of incentive payments.

(iii) Termination of the ACO participant agreement.

(c) *Submission of agreements.* The ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner set forth in § 425.204(c)(6) or as otherwise specified by CMS.

[80 FR 32835, June 9, 2015; as amended at 86 FR 65683, Nov. 19, 2021]

**§ 425.118 Required reporting of ACO participants and ACO providers/suppliers.**

(a) *List requirements.* (1) The ACO must maintain, update, and submit to CMS an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its NPI or other identifier) in accordance with this section.

(2) Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list and an ACO provider/supplier list. The ACO may request consideration of claims billed under merged and acquired Medicare-enrolled TINs in accordance with the process set forth at § 425.204(g).

(3) The ACO must certify the submitted lists in accordance with § 425.302(a)(2).

(4) All Medicare enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program before the ACO submits the ACO