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 at the time of its initial application, participation agreement renewal process, and when adding 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]

§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 participant list and the ACO provider/supplier list.

(b) *Changes to the ACO participant list*—(1) *Additions.* (i) An ACO must submit to CMS a request to add an entity and its Medicare enrolled TIN to its ACO participant list. This request must be submitted at such time and in the form and manner specified by CMS.

(ii) If CMS approves the request, the entity and its Medicare enrolled TIN is added to the ACO participant list effective January 1 of the following performance year.

(iii) CMS may deny the request on the basis that the entity is not eligible to be an ACO participant or on the basis of the results of the screening performed under §425.305(a).

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after the termination of an ACO participant agreement. Such notice must be submitted in the form and manner specified by CMS and must include the termination date of the ACO participant agreement.

(ii) The entity is deleted from the ACO participant list as of the termination date of the ACO participant agreement.

(3) *Adjustments.* (i) CMS annually adjusts an ACO's assignment, historical benchmark, the quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the list of ACO participants that is submitted to CMS before the start of a performance year in accordance with paragraph (a) of this section.

(ii) Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments.

(c) *Changes to the ACO provider/supplier list*—(1) *Additions.* (i) An ACO must notify CMS within 30 days after an individual or entity becomes a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the ACO timely submits notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the ACO fails to submit timely notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date of the notice.

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after an individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) The deletion of an ACO provider/supplier from the ACO provider/supplier list is effective on the date the individual or entity ceased to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant.

(d) *Update of Medicare enrollment information.* The ACO must ensure that all changes to enrollment information for ACO participants and ACO providers/suppliers, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516.

[80 FR 32836, June 9, 2015, as amended at 83 FR 68063, Dec. 31, 2018]

Subpart C—Application Procedures and Participation Agreement

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the participation agreement will be one of the following:

(i) April 1, 2012 (term of the participation agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the participation agreement is 3 years and 6 months).

(2) *For 2013 and through 2016.*

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and 2018.*

(i) The start date is January 1 of that year; and