

(v) Following the provision of the standardized written notice to a beneficiary, as specified in paragraphs (a)(2)(iii) and (iv) of this section, the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary.

(A) The follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided.

(B) The ACO must retain a record of all beneficiaries receiving the follow-up communication, and the form and manner in which the communication was made available to the beneficiary. The ACO must make these records available to CMS upon request.

(b) *Beneficiary incentive program notifications.* (1) Beginning July 1, 2019, an ACO that operates a beneficiary incentive program under § 425.304(c) shall ensure that the ACO or its ACO participants notify assigned beneficiaries of the availability of the beneficiary incentive program, including a description of the qualifying services for which an assigned beneficiary is eligible to receive an incentive payment (as described in § 425.304(c)).

(2) Notification of the information specified in paragraph (b)(1) of this section must be carried out by an ACO or ACO participant during each relevant performance year by providing each assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

(c) The beneficiary notifications under this section meet the definition of marketing materials and activities under § 425.20 and therefore must meet all applicable marketing requirements described in § 425.310.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 83 FR 68068, Dec. 31, 2018; 86 FR 65684, Nov. 19, 2021; 87 FR 70233, Nov. 18, 2022]

§ 425.314 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to

ACO activities to agree, that the CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities that pertain to all of the following:

(1) The ACO's compliance with Shared Savings Program.

(2) The quality of services performed and determination of amount due to or from CMS under the participation agreement.

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(4) The ACO's operation of a beneficiary incentive program.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree to the following:

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, information related to operation of a beneficiary incentive program, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and

notifies the ACO at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(c) *Responsibility of the ACO.* Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its participation agreement with CMS, including the requirements set forth in this section.

(d) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 81 FR 38013, June 10, 2016; 83 FR 68068, Dec. 31, 2018]

§ 425.315 Reopening determinations of ACO shared savings or shared losses to correct financial reconciliation calculations.

(a) *Reopenings.* (1) If CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the initial determination or a final agency determination under subpart I of this part and issue a revised initial determination:

(i) At any time in the case of fraud or similar fault as defined in § 405.902; or

(ii) Not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year under § 425.604(f), § 425.605(e),

§ 425.606(h), § 425.609(e) or § 425.610(h), for good cause.

(2) Good cause may be established when—

(i) There is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or

(ii) The evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

(3) A change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under this section.

(4) CMS has sole discretion to determine whether good cause exists for reopening a payment determination under this section.

(b) [Reserved]

[81 FR 38013, June 10, 2016, as amended at 83 FR 60092, Nov. 23, 2018; 83 FR 68068, Dec. 31, 2018]

§ 425.316 Monitoring of ACOs.

(a) *General rule.* (1) In order to ensure that the ACO continues to satisfy the eligibility and program requirements under this part, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregate annual and quarterly reports.

(ii) Analysis of beneficiary and provider complaints.

(iii) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, on-site compliance reviews).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* (1) CMS may use one or more of the methods described in

paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500 or § 425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO pro-

viders/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either