

#### § 425.314

#### 42 CFR Ch. IV (10–1–23 Edition)

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 obvi-

ous 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.