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performing functions or services related to ACO activities.

§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 atrisk 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 $\S425.216(a)(1)$ 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. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at §425.216 and §425.218, CMS will take the following actions:

(1) The ACO may be given a warning for the first time it fails to meet the minimum attainment level in one or more domains as determined under §425.502 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.

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

(3)(i) If an ACO fails to report one or more quality measures or fails to report completely and accurately on all

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measures in a domain, CMS will request that the ACO submit—

(A) The required measure data;

(B) Correct the data;

(C) Provide a written explanation for why it did not report the data completely and accurately; or

(D) A combination of the submission requirements in paragraphs (c)(3)(i)(A) through (c)(3)(i)(C) of this section.

(ii) If ACO still fails to report, fails to report by the requested deadline, or does not provide a reasonable explanation for not reporting, the ACO will be terminated immediately.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting of the quality performance measures, or fails to make timely corrections following notice to resubmit, may be terminated.

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

Subpart E—Assignment of Beneficiaries

§425.400 General.

(a)(1)(i) A Medicare fee-for-service beneficiary is assigned to an ACO when the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in $\S425.402$.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2)(i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 months of data.

(iii) Final assignment is determined after the end of each performance year, based on data from the performance year.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS codes, G codes, or revenue center codes as indicated in the definition of primary care services under § 425.20.

§ 425.402 Basic assignment methodology.

(a) CMS employs the following stepwise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a physician who is an ACO provider/supplier of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO providers/suppliers in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed