

the standardized format specified by CMS is not subject to marketing review and approval under § 425.310.

(d) *Public reporting by CMS.* CMS may publicly report ACO-specific information, including but not limited to the ACO public reporting Web page address and the information required to be publicly reported under paragraph (b) of this section.

[80 FR 32840, June 9, 2015, as amended at 83 FR 68068, Dec. 31, 2018; 87 FR 70232, Nov. 18, 2022]

§ 425.310 Marketing requirements.

(a) *Requirements.* Marketing materials and activities must:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304 regarding beneficiary incentives.

(4) Not be materially inaccurate or misleading.

(b) *Monitoring.* (1) CMS may request the submission of marketing materials and activities at any time. If CMS determines that the marketing materials and activities do not comply with the requirements of paragraph (a) of this section, CMS will issue written notice of disapproval to the ACO.

(2) The ACO shall discontinue, and require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue, use of any marketing materials or activities disapproved by CMS.

(c) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

[87 FR 70233, Nov. 18, 2022]

§ 425.312 Beneficiary notifications.

(a) *Notifications to fee-for-service beneficiaries.* (1) An ACO shall ensure that Medicare fee-for-service beneficiaries are notified about all of the following in the manner set forth in paragraph (a)(2) of this section:

(i) That each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program.

(ii) The beneficiary's opportunity to decline claims data sharing under § 425.708.

(iii) Beginning July 1, 2019, the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated for purposes of voluntary alignment (as described in § 425.402(e)).

(2) Notification of the information specified in paragraph (a)(1) of this section must be carried out through the following methods:

(i) By an ACO participant posting signs in all of its facilities.

(ii) By an ACO participant making standardized written notices available upon request in all settings in which beneficiaries receive primary care services.

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each fee-for-service beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all fee-for-service beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

(iv) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished during the performance year for which the beneficiary is prospectively assigned to the ACO.

(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