

(ii) The Council will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the Council finds good cause under the standard established in §§ 405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the Council considers the enrollee's reasons for disagreeing with the decision of the ALJ or attorney adjudicator. If the Council concludes that there is no reason to change the decision of the ALJ or attorney adjudicator, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ or attorney adjudicator is warranted. In this instance, the decision of the ALJ or attorney adjudicator is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the Council may assume jurisdiction at any time. If the Council assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or attorney adjudicator or remanding the case to an ALJ or attorney adjudicator for further proceedings, including a new decision. The new decision of the Council is the final decision of the Secretary after remand.

(c) *Council assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ or attorney adjudicator, the Council may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the Council about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the Council will either issue a final deci-

sion of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ or attorney adjudicator for further proceedings, including a new decision.

(d) *Exceptions are not filed and the Council does not otherwise assume jurisdiction.* If no exceptions are filed and the Council does not assume jurisdiction over the case within 60 calendar days after the date of the ALJ's or attorney adjudicator's written decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

Subpart V—Part D Communication Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise noted.

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the Part D sponsor (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any

downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a Part D plan or plans.

(B) Influence a beneficiary's decision making process when making a Part D plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the Part D sponsor's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

Third-party marketing organization (TPMO) are organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of a Part D plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 423.4, but may also be entities that are not FDRs but provide services to a Part D sponsor or a Part D sponsor's FDR.

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements.* Part D sponsors must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor or, where materials have been developed by a Third Party Marketing Organization for multiple Part D sponsors or plans, by a Third Party Marketing Organization with prior review of each Part D sponsor on whose behalf the materials were created or will be used.

(b) *CMS review of marketing materials and election forms.* Part D sponsors may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS.

(3) The material has been accepted under File and Use, as follows:

(i) The Part D sponsor may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

[86 FR 6121, Jan. 19, 2021, as amended at 87 FR 27901, May 9, 2022]