

attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

Third-party marketing organization (TPMO) means 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 an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.

[86 FR 6103, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022]

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations 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 MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior review of each MA organization on whose behalf the materials were created or will be used.

(b) *CMS review of marketing materials and election forms.* MA organizations 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; or

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

(i) The MA organization 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 MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(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.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC)).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

[86 FR 6104, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the