

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 § 423.2267(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.

(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 §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor'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 6122, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023]

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current contract year or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification

card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, “Super Medicare Drug Plan (PDP)”. Part D sponsors are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment except for factually accurate descriptions of the PDP sponsor’s policies adopted in accordance with § 423.44(b)(1) and (d)(1) of this chapter.

(xiii) Use the term “free” to describe a \$0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(xviii) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term “Medicare-approved” to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor’s product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor’s product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1-800-MEDICARE or Medicare TTY appears, the Part D sponsor must prominently include, at least once, the hours and days of operation for 1-800-MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID)*. (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, "S" for PDPs, or "Y" for MCE, a means of identification available for Plans/Part D sponsors that have multiple PDP contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word "MULTI-PLAN" instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI-PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase "C" for communication materials or an uppercase "M" for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

- (i) Membership ID card.
- (ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.
- (iii) OMB-approved forms/documents, except those materials specified in § 423.2267.
- (iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).
- (v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

[86 FR 6122, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023]

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined

in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that "Other pharmacies are available in the network."

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, a Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year;