

and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—

- (i) Are targeted to current enrollees;
- (ii) Are customized or limited to a subset of enrollees or apply to a specific situation;
- (iii) Do not include information about the plan's benefit structure; and
- (iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010]

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.*

(1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when appli-

cable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19826, Apr. 15, 2010]

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or

§ 423.2266

42 CFR Ch. IV (10–1–13 Edition)

otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, Part D plan sponsors must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

[73 FR 54222, Sept. 18, 2008, as amended at 76 FR 21577, Apr. 15, 2011]

§ 423.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

§ 423.2268 Standards for Part D marketing.

In conducting marketing activities, a Part D plan may not—

(a) Provide cash or other remuneration as an inducement for enrollment or otherwise.

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or

Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

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

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment (48 hours in advance, when practicable).

(h) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(i) Distribute marketing materials for which, before expiration of the 45-day period, the PDP Sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the PDP Sponsor, its marketing representatives, or CMS.

(j) Use providers, provider groups, or pharmacies to distribute printed information for beneficiaries to use when comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidelines.

(k) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices, pharmacies or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

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