

will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

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

### Subpart V—Part D Marketing Requirements

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

#### § 423.2260 Definitions concerning marketing materials.

As used in this subpart—

*Marketing materials.* Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

- (1) Promote the Part D plan.
- (2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.
- (3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.
- (4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.
- (5) May include, but are not limited to—
  - (i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.
  - (ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
  - (iii) Presentation materials such as slides and charts.
  - (iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).
  - (v) Membership communication materials such as membership rules, subscriber agreements, member handbooks

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