

**§ 423.46**

of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

**§ 423.46 Late enrollment penalty.**

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

**§ 423.48 Information about Part D.**

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

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**§ 423.50 Approval of marketing materials and enrollment forms.**

(a) *CMS review of marketing materials.*

(1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), 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 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 paragraph (c) of this section; and

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

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

(b) *Definition of 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.

(c) *Examples of marketing materials.* Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

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

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) 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—

(i) 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.

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

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

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

(3) 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.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval.* If CMS has not disapproved the distribution of a marketing material or form 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.

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) 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 the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services 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.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

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(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

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

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

**§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.**

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D-22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under