

sponsor must provide through the Internet and some other tangible medium (such as a mailing) to Medicare beneficiaries information and outreach materials describing its endorsed drug card program, including the following information—

- (i) The enrollment fee;
- (ii) Negotiated prices offered for covered discount card drugs;
- (iii) If offered, discounts on over-the-counter drugs;
- (iv) Any other products or services offered under the endorsement; and
- (v) Any other information that CMS determines is necessary for a full description of the endorsed discount drug card program.

(2) An endorsed sponsor must include on a Web site the following:

- (i) Information regarding when the Web site was last updated; and
- (ii) A disclaimer that the information on the Web site may not be current.

(3) An endorsed sponsor must use the following forms which incorporate standard elements provided by CMS:

- (i) An enrollment form (except as may be modified for an exclusive card sponsor as discussed in § 403.814(b)(5)(iii); and
- (ii) An eligibility determination notice.

(4) An endorsed sponsor must provide to each enrollee a card that complies with National Council for Prescription Drug Programs standards.

(5) An endorsed sponsor must meet the following requirements for the review and approval of information and outreach materials:

- (i) Comply with the Information and Outreach Guidelines published by CMS; and
- (ii) Except as provided in paragraph (g)(5)(iii) of this section, not distribute any information and outreach materials until or unless they are approved by CMS.

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, then the materials will be deemed approved under paragraph (g)(5)(ii) of this section.

(iv) Information and outreach materials may discuss only products or services inside the scope of endorsement, as described in paragraph (h) of this section.

(v) Information and outreach materials include the same kinds of materials described in 42 CFR 422.80(b), as well as the enrollment form, eligibility determination form, and membership card described in paragraphs (g)(3) and (g)(4) of this section, Web site content, and information regarding discounts for over-the-counter drugs.

(6) An endorsed sponsor must maintain a toll-free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practices. The endorsed sponsor must inform enrollees that the toll-free telephone number provides information on the amount of remaining transitional assistance, in accordance with paragraph (e)(5) of this section.

(7) An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use.

(h) *Products and services inside and outside the scope of the endorsement.*

(1) An endorsed sponsor may provide, under the endorsement, only those products and services inside the scope of the endorsement, including conducting enrollment. An endorsed sponsor must ensure that discount card enrollees are not charged any additional fee (other than the enrollment fee allowed under § 403.811(c)) for products or services inside the scope of the endorsement.

(2) Products and services inside the scope of the endorsement are limited to—

(i) Products or services offered for no additional fee, other than the enrollment fee allowed under § 403.811(c), that are directly related to a covered discount card drug; or

(ii) A discounted price for an over-the-counter drug.

(i) *Reporting.* (1) An endorsed sponsor must report to CMS on a periodic basis information on the major features of the endorsed sponsor's programs that correspond to the qualifications for endorsement, including, but not limited to, information concerning—

(i) Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;

(ii) Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;

(iii) Dispensing fees;

(iv) Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;

(v) Participant utilization and spending statements;

(vi) Utilization and spending for selected drugs;

(vii) Performance on customer service metrics such as call center performance;

(viii) Grievance logs; and

(ix) Endorsed sponsor's compliance with the pharmacy network access standards.

(2) An endorsed sponsor must provide notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

(3) An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(4) Through a price comparison Web site, an endorsed sponsor must report the following information:

- (i) Customer service hours;
- (ii) Customer service contact information;

(iii) Endorsed program Web site address;

(iv) Annual enrollment fee; and

(v) Negotiated prices (including any applicable dispensing fee), for every covered discount card drug included in the discount card program's offering.

(5) CMS may require endorsed sponsors to submit, in standard terminology, descriptions of other discount card related services they provide, such as pharmacist services.

(j) *Grievance process.* An endorsed sponsor must establish and maintain a grievance process. This process must be designed to track and appropriately address in a timely manner enrollees' complaints about any aspect of their endorsed program for which the endorsed sponsor is responsible.

(k) *Eligibility, enrollment, and disenrollment.* (1) An endorsed sponsor must make preliminary eligibility determinations in accordance with § 403.810 and conduct enrollment and disenrollment in accordance with § 403.811.

(l) *Authorized representative.* An endorsed sponsor must treat an individual's authorized representative as the individual, if under applicable law, the authorized representative has the legal authority to act on behalf of the individual with respect to the action at issue.

(m) *Other.* An endorsed sponsor must meet the requirements of §§ 403.812, 403.813, and 403.822 of this subpart.

§ 403.808 Use of transitional assistance funds.

(a) *Individuals determined eligible for transitional assistance in 2004.* Subject to paragraph (d) of this section, an individual who, in calendar year 2004, is determined eligible for transitional assistance under § 403.810(b) is entitled to the following: