

*Urban* means a five-digit zip code in which the population density is greater than 3000 persons per square mile.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52022, Sept. 1, 2005]

**§ 403.804 General rules for solicitation, application and Medicare endorsement period.**

(a) *Application.* (1) Except as provided in paragraph (a)(2) of this section, an applicant must submit an application to CMS by the deadline announced in the solicitation to be eligible for Medicare endorsement of its prescription drug discount card program. The applicant must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(2) A new Medicare managed care organization may simultaneously apply to offer a new Part C plan or plans and an exclusive card program after the deadline announced in the solicitation. New Medicare managed care organizations seeking endorsement of their prescription drug discount card programs must submit an application to CMS at the time that they submit their Part C applications. New Medicare managed care organizations will be eligible for endorsement provided CMS approves their Part C application, the new Medicare managed care organizations demonstrate to CMS that they meet the criteria under paragraph (b) of this section, and the new Medicare managed care organizations demonstrate that they will meet the requirements of paragraph (e)(2) of this section.

(b) *Eligibility to receive endorsement.* Except as specified in §§ 403.814, 403.816 and 403.817, an applicant will be eligible for endorsement if its application demonstrates to CMS's satisfaction that the applicant meets the requirements of § 403.806(a) and § 403.806(b)(1) and that it would operate its endorsed program in a manner consistent with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m). An applicant that submits a complete application that meets all of the requirements of this subpart will be eligible to enter into a contract with CMS to operate a Medicare-endorsed prescription drug discount card program. Following the receipt of its Medicare endorsement, an

endorsed sponsor must comply with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m) through the end of the transition period.

(c) *Ability to subcontract with other organizations and entities.* (1) An applicant for endorsement may demonstrate that it meets the requirements of this subpart by combining with subcontractors.

(2) Any subcontracts must be in final form satisfactory to CMS, signed by all applicable parties, and filed with CMS before an endorsed sponsor will be permitted to engage in any enrollment or information and outreach.

(3) Once endorsed, an endorsed sponsor must ensure that its subcontractors comply with all applicable requirements of this subpart.

(d) *Period of endorsement.* An applicant eligible to receive endorsement will be required to sign a contract with CMS agreeing to operate its approved Medicare-endorsed prescription drug discount card program(s) until the end of the transition period.

(e)(1) Except as provided in paragraph (e)(2) of this section, we expect an endorsed sponsor to be ready by June 8, 2004, to initiate enrollment and fully operate its endorsed program in compliance with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m).

(2) A new Medicare managed care organization must be ready to initiate enrollment and fully operate its exclusive card program in compliance with the requirements of §§ 403.806(b)(2) and (b)(3) through § 403.806(m) upon approval of its Part C application and application for Medicare endorsement of its prescription drug discount card program.

**§ 403.806 Sponsor requirements for eligibility for endorsement.**

Except as specified in §§ 403.814, 403.816, and 403.817, an endorsed sponsor must meet the following requirements:

(a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.

(2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean—

(i) Adjudicating and processing claims for drugs at the point of sale;

(ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and

(iii) Administering and tracking individuals' subsidies or benefits in real time.

(3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

(b) *Financial stability and business integrity.* (1) An applicant must demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.

(2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.

(3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.

(c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, in-

cluding the Federal anti-kickback statute (section 1128B(b) of the Act).

(d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and formulary requirements:

(1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.

(2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

(3) Offer a negotiated price on a generic drug in at least 55 percent of the lowest level categories in each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS.

(4) In setting negotiated prices under this section, an endorsed sponsor may vary its prices and the drugs included on the formulary by pharmacy contract and enrollee characteristics, such as transitional assistance eligibility status.

(5) Synchronize changes in the list of, and negotiated prices for, covered discount card drugs included in the endorsed sponsor's formulary with formulary and negotiated prices published on a price comparison Web site, as described in paragraph (i)(4)(v) of this section.

(6) Obtain rebates, discounts, or other price concessions from manufacturers on covered discount card drugs and pass a share of such concessions to enrollees through negotiated prices.

(7) Guarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale.

(8) Guarantee that a network pharmacy, at the point of sale, inform a discount card enrollee of any differential

between the price of a prescribed drug (if it is a covered discount card drug) and the price of the lowest priced generic covered discount card drug that is therapeutically equivalent and bio-equivalent and available at such pharmacy. Mail order pharmacies are to provide this information at the time of delivery of the drug.

(9) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), ensure that any increase in the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy.

(e) *Transitional assistance administration.* An endorsed sponsor must administer transitional assistance funds, including any roll-over funds as described in § 403.808(f), for transitional assistance enrollees, through the following procedures:

(1) Establish accounting procedures to manage the transitional assistance funds for each transitional assistance enrollee.

(2) Ensure that transitional assistance funds are applicable to, and only to, all covered discount card drugs available at the endorsed sponsors' network and mail order pharmacies, regardless of formulary.

(3) Ensure that, at network and mail order pharmacies, transitional assistance funds are applied at the lower of negotiated price (if any) and the pharmacy's usual and customary price.

(4) Ensure that network pharmacies make available to the transitional assistance enrollee, electronically or by telephone, at the point-of-sale of covered discount card drugs, the amount of transitional assistance remaining available to the transitional assistance enrollee. Mail order pharmacies are to make this information available by telephone.

(5) Maintain a toll-free telephone number that discount card enrollees

may use to determine their transitional assistance balances.

(6) Enforce coinsurance requirements described in § 403.808(e) and ensure that the portion of the price paid through coinsurance is not deducted from the total transitional assistance funds available to the discount card enrollee.

(f) *Service area and pharmacy access.* An endorsed sponsor must meet the following requirements for its service area and its pharmacy network:

(1) The service area must cover one or more States.

(2) The endorsed sponsor's discount card program must be available to all eligible individuals residing in each State in the endorsed sponsor's service area and may not be offered to individuals residing outside of the United States.

(3) The endorsed sponsor must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the endorsed sponsor's service area the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the endorsed program, live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the endorsed program, live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the endorsed program, live within 15 miles of a network pharmacy.

(4) The endorsed sponsor's pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (f)(3) of this section are met.

(g) *Information and outreach and customer service.* (1) An endorsed 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 except as provided in paragraph (g)(5)(vi) of this section.

(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, the materials are 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.

(vi) All materials related to products and services that are Part D plans must comply with the requirements specified in § 423.50 of this chapter.

(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.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

#### § 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:

(1) \$600 in calendar year 2004; and

(2) \$600 in calendar year 2005.

(b) *Individuals determined eligible for transitional assistance in 2005.* Subject to paragraph (d) of this section, an individual who, in calendar year 2005, is determined eligible for transitional assistance under § 403.810(b) is entitled to one of the following amounts for calendar year 2005:

(1) If the complete application for the individual's transitional assistance eligibility is received on or after January 1, 2005 and before April 1, 2005, \$600.

(2) If the complete application for the individual's transitional assistance eligibility is received on or after April 1, 2005 and before July 1, 2005, \$450.

(3) If the complete application for the individual's transitional assistance eligibility is received on or after July 1, 2005 and before October 1, 2005, \$300.

(4) If the complete application for the individual's transitional assistance eligibility is received on or after October 1, 2005 and on or before December 31, 2005, \$150.