

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, including 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 bioequivalent 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