

drugs obtained by transitional assistance enrollees who are American Indians and Alaska Natives and who receive prescription drugs through I/T/U pharmacies as allowed under paragraph (d)(2) of this section;

(2) Offer contractual arrangements to any I/T/U pharmacy that is in the special endorsed sponsor's service area and seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who are also American Indians/Alaska Natives;

(3) Include special terms and conditions in its contracts with network I/T/U pharmacies to facilitate access to and the administration of transitional assistance for transitional assistance enrollees who are American Indians/Alaska Natives, including, but not limited to the following:

(i) Permitting an I/T/U pharmacy to limit its services to only those transitional assistance enrollees who are American Indians/Alaska Natives, and

(ii) Allowing an I/T/U pharmacy to select which drugs to stock, which may be a more limited set than other retail pharmacies.

(4) Except as noted in paragraph (e) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(e) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance through I/T/U pharmacies:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for I/T/U pharmacies if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of I/T/U pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for I/T/U pharmacies must request such waivers or modifications in writing in a manner required by the Secretary.

**§ 403.817 Special rules concerning the territories.**

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for all of the territories.

(2) Of qualified applicants, the Secretary will select at least one of the best-qualified applicants to receive a special endorsement for the territories.

(3) Applicants for special endorsement for the territories must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(b) *Requirements—*(1) *Negotiated prices.* A special endorsed sponsor for residents of the territories must provide access to negotiated prices in the territories.

(2) *Transitional assistance.* Any transitional assistance in the territories must be in accordance with paragraph (e) of this section.

(3) *Requirements, exception.* Except as specified in paragraph (c) of this section, a special endorsed sponsor for the territories must meet the requirements of §§ 403.804 and 403.806.

(c) *Waiver of requirements and alternative requirements.* (1) Section 403.806(d)(8) (requiring information about price differentials) shall not apply to pharmacies located in the territories and which are in the special endorsed sponsor's pharmacy network.

(2) Sections 403.806(f)(2) and (f)(3) will be deemed met if the special endorsed sponsor makes a good faith effort to secure the participation of retail and mail order pharmacies throughout a territory.

(3)(i) As the Secretary determines appropriate on a case-by-case basis, any

additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for the territories if—

(A) Such waiver is necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D-31 of the Act, or accommodate the unique needs of pharmacies in the territories; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for the territories must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *Other exceptions.* A special endorsed sponsor for the territories may enroll in its endorsed discount card program Medicaid enrollees with coverage for outpatient prescription drugs, as described in § 403.810(a)(2).

(e) *Transitional assistance provided by Territories.* (1) Transitional assistance in the territories may be administered only according to a plan submitted by a territory and approved by CMS.

(2) Territories choosing to provide transitional assistance must submit a plan to CMS within 90 days of the publication of this regulation. The plan must—

(i) Describe how funds allocated to the territory are to be used to cover the cost of covered discount card drugs obtained by individuals who reside in the territory, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and

(ii) Describe how the territory will ensure that amounts received under the allotment are to be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance, as described in paragraph (e)(2)(i) of this section, and

(iii) Provide such written assurance for the requirements in paragraph (e)(2)(ii) of this section.

(3) CMS will review and approve plans submitted and make allotments to territories with approved plans.

(4) CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

#### **§ 403.820 Sanctions, penalties, and termination.**

(a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:

(i) Suspension of enrollment of Medicare beneficiaries.

(ii) Suspension of information and outreach activities to Medicare beneficiaries.

(2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

(3) *Sanctionable violations.* The violations for which intermediate sanctions may be imposed are as follows:

(i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);

(ii) Substantial failure to comply with CMS Information and Outreach Guidelines;

(iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;

(iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that 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 changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);

(v) Charging drug card enrollees additional fees beyond a \$30 enrollment fee;