

the District of Columbia are ineligible for the program if they have outpatient prescription drug coverage under Medicaid or a section 1115 waiver demonstration, section 1860D–31(j)(1) of the Act grants the Secretary the discretion to find Medicare beneficiaries residing in the territories eligible for the program even if they receive outpatient prescription drug coverage under Medicaid or a section 1115 waiver demonstration. As provided in § 403.817(d) of our regulations, beneficiaries residing in the territories who have outpatient prescription drug coverage under these sources will be eligible for the program.

To ensure that eligible individuals residing in the territories have access to endorsed programs offering negotiated prices, we will select for special endorsement at least one applicant to provide discounts for covered drugs in the territories. In accordance with § 403.817(a) of our regulations, these applicants must agree to offer endorsed programs to residents of all the territories. Section 1860D–31(j)(1) of the Act allows us to waive the requirement for two endorsed sponsors per State in section 1860D–31(h)(2)(D) of the Act, if necessary to secure access to negotiated prices for beneficiaries in the territories. Therefore, we will elect to limit the number of special endorsed sponsors operating in each of the territories to at least one in order to assure that a sufficient number of beneficiaries will enroll in special endorsed sponsors' endorsed programs in the territories, thereby justifying from a business perspective their offering such programs. We believe these volume considerations will be a critical factor in whether an applicant seeks special endorsement in the territories.

We are concerned that in the absence of a competitive process for special endorsement in the territories, an insufficient number of applicants will seek to offer endorsed programs in the territories and we therefore will be unable to ensure that residents of the territories have access to negotiated prices.

Selection criteria for special endorsement in the territories will include understanding, as well as prior experience with, the unique challenges of providing a drug discount card in the territories, the extensiveness of an applicant's pharmacy network in the territories, the feasibility of the applicant's plan for offering an endorsed program in the territories, and timeliness of implementation of its plan. We will further discuss the selection criteria and the competitive process for special endorsement in the solicitation.

As permitted by section 1860D–31(j)(1) of the Act, we will waive certain sponsor requirements of the Medicare drug discount card program in the territories if doing so is necessary to: (1) Ensure that a sufficient number of applicants seek special endorsement in the territories; (2) enable the Medicare drug discount card program to start within six months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (3) accommodate the unique challenges faced by special endorsed sponsors in the territories.

As provided in § 403.817(c)(2) of our regulations, special endorsed endorsed sponsors in the territories will not be required to meet the pharmacy network access standard set forth in § 403.806(f) of our regulations and as explained in section II.C.3 of this document. In addition, special endorsed sponsors are not required to maintain a service area covering an entire territory if it proves impracticable to do so, as otherwise required in § 403.806(f)(2) of our regulations. The pharmacy access standard provides that the pharmacies included in an endorsed sponsor's network may not dispense drugs solely by mail-order and must be located within certain distances of most beneficiaries. We waive the distance requirement because in some territories there are few retail pharmacies, and relative to pharmacies in the 50 States and the District of Columbia, these pharmacies generally are less inclined to participate in pharmacy networks established by pharmacy benefit managers, discount drug cards, and similar programs. Special endorsed sponsors therefore may be unable to secure the participation of a sufficient number of pharmacies in the territories to meet our pharmacy access standard. For this reason, if after a good faith effort a special endorsed sponsor in the territories is unable to secure the participation of a retail pharmacy in a particular locale, they may offer a mail-order only pharmacy in that locale. Because it may be impracticable to provide drugs by mail to residents in more remote areas within a territory, we do not require special endorsed sponsors to provide residents of these particular areas with access to mail-order pharmacies, but the special endorsed sponsor must demonstrate that a good faith effort has been made to provide residents of these remote areas with discounts through retail pharmacies, and must explain the reason why mail order is impracticable. Provided endorsed sponsors make a good faith effort to secure the

participation in their networks of retail and mail-order pharmacies throughout a territory, we will deem the service area requirement set forth in § 403.806(f)(2) and the network access requirement set forth in § 403.806(f)(3) of our regulations to be met, as provided in § 403.817(c)(2) of our regulations.

In recognition of the special challenges involved in delivering mail-order drugs to residents of the territories, special endorsed sponsors will need to educate their card enrollees in the territories about any considerations they need to take into account to assure that they receive safe and timely access to their prescription drugs, such as the need to order their drugs in advance of their need for such drugs. We recognize that in some cases special packaging needs (for example, refrigeration) for particular covered discount card drugs may make it impracticable to ship specific medications to the territories. Card enrollees should be made aware of these limitations.

As provided in § 403.817(c)(1)(ii) of our regulations, special endorsed sponsors in the territories will not be required to comply with § 403.806(d)(8) of our regulations requiring that retail pharmacies inform card enrollees of any differential between the price of the drug to the card enrollee under their endorsed program and the price to the card enrollee of the lowest priced generic covered discount card drug that is therapeutically equivalent and bioequivalent under the program. In recognition that few discount drug cards currently have contractual relationships with retail pharmacies in the territories, we are waiving this requirement to reduce the administrative complexity of special endorsed sponsors' contracts with participating retail pharmacies in the territories, which we believe we will enhance applicants' willingness to apply for special endorsement in the territories. However, mail-order drugs sent to residents in the territories should include this price differential information in the same manner such information is provided to card enrollees in the 50 States and District of Columbia who obtain mail-order drugs under the program.

Because the arrangements between special sponsors and pharmacies in the territories represent new types of arrangements for most special endorsed sponsors, as with special endorsed sponsors agreeing to include long-term care and for I/T/U pharmacies in their networks, we only require that special endorsed sponsors in the territories make a good faith effort to finalize these arrangements as soon as practicable; we