

its contracts with pharmacies participating in its network such terms and conditions as necessary to ensure that the endorsed sponsor meets all requirements for endorsement. This includes the requirement that subcontractors comply with all applicable Federal and State laws (including the anti-kickback law). Each application for endorsement must include one sample copy of every customized contract or letter of agreement used across the entire network. That is, we are asking to see every version of the contracts/letters of agreement across the network.

If the applicant is unable to provide with its application final versions or templates of letters of agreement or contracts that represent the exact terms and conditions under the program with each of its subcontractors and pharmacies satisfactory to CMS, the applicant may submit revised documentation following receipt of the Medicare endorsement. We expect the applicant, however, to provide such documentation no later than 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and we reserve the right to revoke endorsement if the materials are submitted later. In addition, an applicant may not commence outreach and enrollment activities prior to our receipt of such documentation and our determination that such documentation meets our requirements. The 6-month deadline and prohibition on outreach and enrollment activities may be waived for endorsed sponsors receiving special endorsement for the purpose of fulfilling obligations related to special endorsement provided such sponsors make a good faith effort to meet these documentation requirements as soon as possible, as provided in § 403.816 and § 403.817.

2. Service Area

As provided in section 1860D–31(h)(3) of the Act, if an endorsed program enrolls beneficiaries residing in any part of a State, the program must permit any discount card eligible beneficiary residing in any portion of the State to also enroll in its endorsed program. We interpret this to mean, and provide in § 403.806(f)(1) of our regulations, that a State is the smallest service area permitted under the Medicare drug discount card program. Accordingly, an endorsed program may not limit enrollment to only a portion of a State, with the exception of exclusive card programs, which, as discussed in section II.G. of this document, may limit their service area to the service area of

the Medicare managed care plan(s) whose members may enroll in the exclusive card program (which may include part of a State). Further, an endorsed program's service area could be regional, meaning it operates in more than one State (contiguous or not). In addition, we define "national" endorsed programs as endorsed programs operating in each of the 50 States and the District of Columbia; an endorsed program that does not operate in each of the 50 States and the District of Columbia may not describe itself as a "national" endorsed program. Finally, an endorsed program may not operate outside of the 50 States and the District of Columbia, with the exception of sponsors receiving special endorsement permitting them to operate in the territories, as discussed in section II.J of this document.

3. Pharmacy Network Access

As provided in section 1860D–31(e)(1)(B) of the Act, an endorsed discount card sponsor must ensure that its card enrollees have convenient access to covered discount card drugs at negotiated prices by securing the participation in its network of a sufficient number of pharmacies that dispense drugs (other than solely by mail order) directly to card enrollees. Specifically, consistent with the statement of work of solicitation #MDA906–03–R–0002 of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003, we are requiring in § 403.806(f)(3) of our regulations that, at all times during the program, beginning upon the date an endorsed sponsor initiates its outreach and enrollment activities—

- In urban areas served by the endorsed program, at least 90 percent of Medicare beneficiaries, on average, live within 2 miles of a pharmacy participating in the endorsed program's network;

- In suburban areas served by the endorsed program, at least 90 percent of Medicare beneficiaries, on average, live within 5 miles of a pharmacy participating in the endorsed program's network; and

- In rural areas served by the endorsed program, at least 70 percent of Medicare beneficiaries live, on average, within 15 miles of a pharmacy participating in the endorsed program's network.

For the purposes of meeting these access standards, as also defined in the statement of work of solicitation #MDA906–03–R–0002 of the Department of Defense—

- Urban is defined as a five-digit ZIP Code in which the population density is greater than 3,000 persons per square mile;

- Suburban is defined as a five-digit ZIP Code in which the population density is between 1,000 and 3,000 persons per square mile; and

- Rural is defined as a five-digit ZIP Code in which the population density is less than 1,000 persons per square mile.

The endorsed sponsor must meet or exceed these access standards at the endorsed program level, that is, across the entire geographic region serviced by the endorsed program. Only pharmacies that are under contract and are not mail order can be included in the count.

As we will explain further in the solicitation, applicants must demonstrate their capacity to satisfy the pharmacy network access standard using mapping software, provided by us, which will compute beneficiaries' access to the pharmacies participating in the applicant's network using one hundred percent of beneficiary counts (that is, the entire beneficiary population) by zip code. These data and the population density information will be provided by CMS on request. Tables generated by the mapping software must be included with the application and must include the urban, suburban, and rural areas in each of the States covered under the applicant's drug discount card program.

As discussed in greater detail in II.J. of this document, endorsed programs receiving special endorsement to operate in the territories may exclude the territories from the calculation as to whether the endorsed sponsor meets the above pharmacy access standard.

Exclusive card programs are not required to meet these same pharmacy access standards; rather, as discussed in greater detail in section II.G. of this document, exclusive card programs will be subject to an alternative access standard.

In accordance with section 1860D–31(e)(1)(B) of the Act, § 403.806(f)(4) of the regulations provides that endorsed sponsors will not be permitted to offer a mail order only option to their card enrollees. However, because some card enrollees may prefer to obtain their drugs from mail order pharmacies, endorsed programs will be allowed to offer a home delivery option via a mail order pharmacy, in addition to including their retail pharmacy in their networks. As discussed in greater detail in II.J. of this document, we may waive this requirement to allow mail order only in the territories for endorsed programs receiving special endorsement to operate in the territories.