

Rules governing these exclusive card programs are discussed in section II.G. of this document.

Applicants seeking special endorsement—that is, applicants wishing to offer an endorsed program in the U.S. territories and/or applicants willing to include within their pharmacy networks' long-term care and/or I/T/U pharmacies—also are subject to special rules, as set forth in § 403.816 and § 403.817 of our regulations and discussed in sections II.I and II.J of this document.

1. Applicant Structure and Experience

Under section 1860D–31(h)(1)(A) of the Act, the Secretary is authorized to designate the type of non-governmental entities that are appropriate to act as endorsed sponsors, which may include pharmacy benefit management companies, wholesale or retail pharmacy delivery systems, insurers (including insurers offering Medicare supplemental policies), and Part C plans. Although we have the authority to limit the types of entities that may act as endorsed sponsors, the only specific structural requirement for a sponsor is that it be a non-governmental, single legal entity doing business in the United States. We choose not to impose other structural requirements at this time because our conditions for endorsement ensure that applicants, either individually or through subcontracts, will have the necessary experience and integrity to act as endorsed sponsors. Thus, as long as an applicant can meet our conditions for endorsement through subcontracting, except as stated above, we do not mandate the legal form of the endorsed sponsor.

Although only one legal entity may act as the applicant, our regulations at § 403.804(c)(1) permit applicants to combine their capabilities with other entities in order to meet the requirements for endorsement. As further discussed below, applicants must include documentation related to their legal arrangements with subcontractors.

As specified in section 1860D–31(h)(1)(B) of the Act, an applicant is eligible for endorsement under the Medicare drug discount card program if the applicant, together with its subcontractors, has demonstrated experience and expertise in operating a drug discount card or similar program and meets certain requirements related to business stability and integrity. We interpret this provision to mean that applicants, together with their subcontractors, must: (1) Demonstrate 3 years of private sector experience in pharmacy benefit management; (2)

currently serve at least 1 million covered lives; and (3) demonstrate fiscal stability and business integrity, as provided in § 403.806(a) and § 403.806(b) of our regulations. Medicare managed care organizations offering exclusive card programs, while required to comply with most of the conditions related to applicant structure, are subject to alternative requirements, as discussed in greater detail in section II.G. of this document.

a. 3 Years of Private Sector Experience

Section 403.806(a)(2) of the regulations provides that each applicant, together with its subcontractors, must have 3 years of private sector experience within the United States in the following:

- Adjudication and processing of claims at the point of sale;
- Negotiating with prescription drug manufacturers and others for rebates and discounts on prescription drugs; and
- Administration and tracking of an individual subsidy or benefit in real time.

We require that this experience must have occurred in the United States to ensure that the applicant, together with its subcontractors, is familiar with applicable Federal laws, including those enforced by the Food and Drug Administration. We believe requiring 3 years prior experience will ensure that endorsed sponsors are able to quickly establish their endorsed programs, thereby promoting implementation of the Medicare drug discount card program within 6 months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In addition, the 3 years prior experience requirement ensures that endorsed sponsors have the necessary experience and capacity to offer card enrollees quality discounts and customer service. Moreover, given the relative newness of the drug card industry and high market turnover, we believe requiring less than 3 years experience would create an untenable risk of having the Medicare name associated with less than stable and reputable organizations.

b. 1 Million Covered Lives

In addition to requiring 3 years of relevant experience, our regulations at § 403.806(a)(3) require that a single entity which is either the applicant or a subcontractor operate a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

We interpret covered lives to mean discrete individuals who have signed enrollment agreements with or paid (or have paid on their behalf) an enrollment fee or insurance premium to the applicant (or its subcontractors), or some comparable documentation. An applicant must include in its application documentation demonstrating that the applicant meets this requirement. If an applicant contracts with other entities for purposes of administering an endorsed program, the entity satisfying the 1 million covered lives requirement need not be the same entities satisfying the 3 years experience requirement. We choose not to link the 1 million covered lives requirement with the 3-year experience requirement in order to provide entities the flexibility to combine their capabilities. For example, an entity with the requisite experience may not have the enrollment capacity, but may acquire this capacity by contracting with another entity for purposes of administering the endorsed program. (A single entity, however, must meet the 1-million covered lives requirement. Therefore, an entity with 600,000 covered lives could not combine with an entity with 400,000 covered lives and meet the conditions for endorsement.)

As discussed in the impact analysis, we estimate that during the first year of the Medicare drug discount card program, over 7 million beneficiaries may wish to enroll in the program, and anticipate that endorsed sponsors should have the capacity to accept between 1 to 10 percent of this volume. This influx of Medicare beneficiaries—100,000 to several hundred thousand beneficiaries—enrolling in an endorsed program would represent a sizable expansion over most card programs' current operations. Our 6-month implementation timeline requires that endorsed sponsors be able to quickly accommodate this potentially large influx of enrollees over a relatively short period of time. Current levels of covered lives provides evidence of an applicant's immediate capacity to do so.

In examining our data on the number of covered lives served by a variety of organizations, we found that a standard of 1 million lives strikes a balance between ensuring a competitive marketplace with a number of different endorsed programs available to Medicare beneficiaries and ensuring that endorsed sponsors have the capacity to handle a large influx of card enrollees.