

- Offer an endorsed program in all the U.S. territories.

We will select applicants for special endorsement based on a competitive process, with consideration given to which applicants can best serve these populations. Applicants seeking special endorsement also must apply and, except in specified circumstances, meet the requirements for basic endorsement; however sponsors seeking special endorsement may request waivers of requirements, allowing, for example, an applicant to apply for special endorsement solely for the purpose of long-term care pharmacy business to the exclusion of all other types of pharmacies. The requirements and procedures related to special endorsements are discussed in further detail in sections II.I. and II.J. of this document.

Except as provided in section 403.804 (c)(2) of our regulations and discussed below in section II. O.2.C. of the preamble, we anticipate that endorsed sponsors may begin information and outreach activities, as well as enrollment activities as early as Spring 2004, and expect that these activities will begin no later than 6 months from the date of enactment of the Act; we reserve the right to terminate an endorsed sponsor's endorsement if the endorsed sponsor is not ready to fully operate its endorsed program and begin information and outreach activities by the 6 month deadline. The date upon which we will permit an endorsed sponsor to begin these activities will depend on its satisfaction of certain conditions, including—

- Finalizing pharmacy network contracts;
- Negotiating manufacturer rebates or discounts;
- Entering into an endorsed sponsor contract with us;
- Operationalizing call centers;
- Entering into all subcontracts necessary to ensure full compliance with the conditions of endorsement;
- Obtaining our approval of all information and outreach materials; and
- Establishing and obtaining CMS approval of a system for conducting electronic transactions with us (or our subcontractor), including successful testing of such system.

As stated above, we expect these requirements to be met within 6 months of enactment, and may terminate an endorsed sponsor's endorsement if the requirements are not met by this time. These requirements are discussed in greater detail below.

A solicitation for applications for Medicare endorsement under the

Medicare drug discount card program will follow publication of this interim final rule. We expect to publish the solicitation on or near the date of publication of this rule. Following publication of the solicitation, potential applicants seeking clarification on the application process and requirements for endorsement may submit questions to us. In addition, we will hold a pre-application conference for potential applicants approximately 2 weeks after publication of the solicitation.

In order to ensure that we successfully implement the Medicare drug discount card program no later than 6 months after enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we anticipate that applicants will first need to submit completed applications to CMS within 45 days after the publication date of the solicitation. Applicants must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

We will require applicants to provide with their applications certain information and test files, as specified in the solicitation. Such information and files will be used by us to expedite our implementation of the data systems necessary to support enrollment in the Medicare drug discount card program, determinations of beneficiaries' eligibility for transitional assistance, and comparison of endorsed programs negotiated prices.

Medicare endorsement of a sponsor's drug discount card will be valid for the duration of the Medicare drug discount card program, which in accordance with section 1860D–31(a)(2)(C)(i)(I) of the Act will terminate on December 31, 2005. Section 1860D–31(a)(2)(C)(ii) of the Act authorizes the Secretary to issue rules governing the transition period, including rules ensuring that the balance of any transitional assistance remaining available to a transitional assistance enrollee on January 1, 2006 remain available during the transition period. Under this authority we require endorsed sponsors to continue operating their endorsed program during the transition period, including ensuring that their card enrollees have access to negotiated prices and that transitional assistance enrollees can apply any transitional assistance remaining available to them toward the cost of covered discount card drugs obtained under the program during the transition period.

See section II.F. of this document for a discussion of termination of an endorsed sponsor's endorsement.

Section 403.804(d) of our regulations specifies that as a condition of endorsement, an endorsed sponsor must sign a contract. The contract signature will certify that the endorsed sponsor will comply with all requirements set forth in the contract, will implement its endorsed program in accordance with the program description contained in its application, and will operate its endorsed program consistent with the requirements set forth in the Act, this rule, and all other applicable Federal and State laws, including administering transitional assistance for eligible enrollees and conducting information and outreach activities consistent with our guidelines.

#### *C. Sponsor Requirements for Eligibility for Endorsement Under the Medicare Drug Discount Card and Transitional Assistance Program*

Section 1860D–31(a)(1)(A) of the Act requires the Secretary to endorse qualified applicants seeking to offer endorsed discount card programs to Medicare beneficiaries. Section 1860D–31 of the Act sets forth specific requirements that applicants must satisfy to be eligible for endorsement and that endorsed sponsors must meet to retain their endorsement. In addition, section 1860D–31(h)(8) of the Act authorizes the Secretary to prescribe additional requirements of endorsement that the Secretary concludes protect and promote the interests of beneficiaries. Accordingly, we require applicants seeking endorsement under the Medicare drug discount card program to demonstrate that they meet a series of requirements related to—

- Organizational structure and experience;
- Service area;
- Pharmacy network access;
- Administering transitional assistance;
- Prescription drug offering;
- Eligibility and enrollment processes;
- Customer service, including information and outreach;
- Grievance processes;
- HIPAA administrative simplification provisions and other marketing and security provisions;
- Document retention; and
- Data reporting to CMS.

In this section of the document we describe these conditions for endorsement.

Special rules govern Medicare managed care organizations wishing to limit enrollment in their endorsed programs to members of one or more of their Medicare managed care plans.