

described in section II.C.1 of this document, is duplicative of aspects of the qualification process that already exists under Part C and section 1876 of the Act. Medicare managed care organizations are currently required, under 42 CFR 422.400 or 42 CFR 417.120 and 42 CFR 417.122, to be licensed under State law as risk-bearing entities or, alternatively, to obtain certification from a State that they meet the financial solvency and other standards that the State may require for the entity to operate as a managed care plan. Under these licensure or certification requirements, Medicare managed care organizations must demonstrate a level of business stability and integrity that generally exceeds our standards for endorsed program applicants. Because exclusive card sponsors already demonstrate business stability and integrity through alternative processes, neither they nor their subcontractors will be required to present documentation demonstrating they meet the business stability and financial stability requirement set forth in § 403.806(b) of our regulations.

In addition to the aforementioned waivers, we will allow applicants seeking to offer exclusive card programs to request in their applications for endorsement that we waive or modify additional requirements applicable to endorsed sponsors. Applicants making such requests must demonstrate that the requirements at issue are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations under Part C, or that they interfere with coordination of the benefits offered under the Medicare drug discount card program with benefits provided under Part C. If we determine that waiver of any additional requirements applicable to endorsed sponsors would be appropriate with respect to exclusive card sponsors, the waivers will apply to all similarly situated exclusive card sponsors.

We are considering providing a streamlined application process for applicants seeking to offer exclusive card programs that parallel the discount cards currently offered under their Medicare managed care plans. We will provide further guidance on this issue in the solicitation.

b. Enrollment and Enrollment Fees in Exclusive Card Programs

As discussed in section II.A.3 of this document, and under section 1860D–31(c)(1)(E) of the Act, discount card eligible individuals enrolled in a Medicare managed care plan offering an exclusive card program may *only* enroll in the exclusive card program and may

not enroll in another endorsed sponsor's endorsed program. Discount card eligible individuals enrolled in Medicare managed care plans that *do not* offer an exclusive card program may enroll in any endorsed program available in their service area.

As discussed above in section II.A.3 of this document and as described in § 403.814(b)(5) of our regulations, we will allow Medicare managed care organizations offering exclusive card programs to group enroll their eligible Medicare managed care plan members into their exclusive card programs—defined as simultaneous enrollment of all or many members of a Medicare managed care plan into an exclusive card program. However, prior to doing so, an exclusive card sponsor must disclose to its Medicare managed care plan members its intent to group enroll them into its exclusive card program and provide them the opportunity to actively decline such enrollment.

c. Application Process

Section 403.804(a) of our regulations provides that only those applicants submitting their applications for endorsement of their prescription drug discount card programs by the deadline announced in the solicitation will be eligible for endorsement. However, in recognition of the advantages to members of Medicare managed care plans from improved coordination between the benefits available under the Medicare drug discount card program and their Medicare managed care plans, we will permit certain Medicare managed care organizations to apply for endorsement of their prescription drug card programs after the official application deadline.

As discussed above, section 1860D–31(h)(9)(B)(iii) of the Act authorizes the Secretary to waive requirements applicable to endorsed sponsors for exclusive card sponsors if such waiver would improve coordination of the benefits available under the Medicare drug discount card program and Medicare managed care plan programs. One of the major features of the Medicare discount drug card program is that it allows Part C organizations to offer members in their plans a prescription drug plan that integrates access to negotiated prices and transitional assistance available under a drug card with the unique package of benefits available in that Part C plan, including any prescription drug benefit. Beneficiaries who choose to enroll in a new Medicare managed care plan should have the same access to these coordinated discount card programs as members of existing Part C plans.

Therefore, as provided under § 403.804(a)(2) of our regulations, we will permit an entity that is applying to enter into a new contract with CMS under Part C to offer a new coordinated care plan or plans, as described in section 1851(a)(2)(A) of the Act, to simultaneously apply to offer an exclusive card program. We will approve such organization's application to offer an exclusive card program provided we approve its Part C application, the Part C organization demonstrates to CMS that it meets all applicable requirements for endorsement, and the Part C organization is ready to initiate enrollment in and fully operate its exclusive card program upon approval of its Part C and endorsement applications.

H. Special Rules Concerning States

1. State Pharmacy Assistance Programs

As described above in section II.A.1. of this document, under section 1860D–31(b)(1)(A)(ii) of the Act and § 403.810(a)(2) of this regulation, beneficiaries with outpatient prescription drug coverage under Title XIX (Medicaid) or a section 1115 waiver demonstration are ineligible for the Medicare drug discount card program. Conversely, beneficiaries with outpatient prescription drug coverage under certain other sources may be eligible for the program provided they meet all other eligibility criteria. For example, many State and local governments provide outpatient prescription drug coverage to individuals through State pharmacy assistance programs (SPAP). Because these programs are operated separately from Title XIX and section 1115 waiver demonstrations and are funded in whole or in part by the State or local governments, without any Federal financial participation, individuals enrolled in these programs still may be eligible for the Medicare drug discount card program. The SPAPs have flexibility in deciding how to work in partnership with endorsed programs. For example, if a State has an SPAP operated by an entity that meets the requirements for endorsement under § 403.800 through § 403.822 of our regulations, that entity could apply to become an endorsed sponsor. However, the entity would be required to meet all requirements for endorsement, including the requirement that an endorsed sponsor offer its endorsed program to all discount card eligible individuals residing in the endorsed program's service area, which may include individuals not eligible for the