

exclusive card program to members of one or more of its Medicare managed care plans that include the exclusive card program as part of the plans' benefit package, the Medicare managed care organization must offer its exclusive card program to all discount card eligible individuals enrolled in those specific Medicare managed care plan(s). A Medicare managed care organization may not limit enrollment in its exclusive card program to only some discount card eligible individuals enrolled in those Medicare managed care plan(s) to the exclusion of other discount card eligible individuals because this would violate the uniformity of benefits provisions under section 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2).

We also implement the exception from pharmacy access standards in section 1860D-31(h)(9)(B)(ii) of the Act and § 403.814(b)(3)(i) of our regulations by deeming exclusive card sponsors as having met such standards if—

- The network is not limited to mail-order pharmacies; and
- The network is equivalent to the pharmacy network under any outpatient drug benefit offered under the Medicare managed care organization's Medicare managed care plan which was previously approved by us under the Medicare Part C or Section 1876 rules.

If the Medicare managed care organization does not offer a drug benefit under its Medicare managed care plan, we will evaluate whether the network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees using the same considerations we currently use to evaluate Medicare managed care plans' other provider networks under 42 CFR 422.112.

We are not applying the standards of § 403.806(f)(3) of our regulation because these standards may be impracticable for exclusive card sponsors. Medicare managed care organizations currently do not have to follow these standards in establishing their pharmacy networks. We presume that many exclusive card sponsors will wish to use the same pharmacy networks under their endorsed program as they currently use to provide prescription drugs under any prescription drug benefit they may offer to their Medicare managed care plan members. Moreover, given the size of exclusive card sponsors' service areas relative to the statewide service areas of other sponsors, the pharmacy access standards contained in § 403.806(f)(3) of our regulation may be too restrictive. In addition, Medicare managed care organizations that use plan-owned pharmacy networks would have a

difficult time meeting these access standards.

In addition to the requirements Congress specifically waived in section 1860D-31(h)(9)(B) of the Act, section 1860D-31(h)(9)(B)(iii) authorizes the Secretary to waive other endorsed sponsor requirements if those requirements are duplicative of or conflict with requirements applicable to Medicare managed care organizations under Part C (and the regulations promulgated thereunder) or section 1876 (and the regulations promulgated thereunder), as the case might be, or if waiver of the requirements would improve coordination of the benefits available under the Medicare drug discount card program and Medicare managed care plan programs. We believe the following requirements, discussed in section II.C of this document, are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations under Medicare managed care plan programs, or that waiver of such requirements would improve coordination of the Medicare drug discount card program with Medicare managed care plan benefits—

(1) The covered lives requirement in § 403.806(a)(3) of the regulations;

(2) The requirement set forth in § 403.806(e)(2) of our regulations that transitional assistance be applied only toward costs incurred for covered discount card drugs obtained through the Medicare drug discount card program. Instead, we also permit transitional assistance to be used to pay for coinsurance, copayments, or other cost-sharing charged under a Medicare managed care plan drug benefit when beneficiaries purchase covered discount card drugs.

In addition, although applicants seeking to offer an exclusive card program must meet the business integrity and financial stability requirements in § 403.806(b) of our regulations, we will not require their applications to include the documentation we generally require of applicants to demonstrate compliance with this requirement, as described in section II.C.1. of this document, because such documentation would be duplicative of what these organizations already must demonstrate to us under the provisions of Part C and section 1876 of the Act.

We believe it is appropriate to waive the 1 million covered lives requirement for exclusive card programs because 1 million covered lives is more than most Medicare managed care organizations currently enroll in their Medicare managed care plans and is far higher

than the minimum enrollment requirements for Medicare managed care organizations under 42 CFR 422.514 and 42 CFR 417.413(b). Moreover, the service area for exclusive card programs will be limited to the affiliated Medicare managed care plan service area, which could be as low as several thousand individuals for some plans. Therefore, the 1 million covered lives standard potentially would conflict with the minimum enrollment requirements for Medicare managed care plans and pose challenges for certain Medicare managed care organizations seeking to coordinate benefits under their Medicare managed care plans and newly created endorsed programs. Our failure to waive the 1 million covered lives requirement for exclusive card programs likely would have the effect of excluding from the Medicare drug discount card program small Medicare managed care organizations that might otherwise meet the endorsement requirements.

We believe it is appropriate to waive the transitional assistance requirements in § 403.806(e)(2) of our regulations. We believe exclusive card sponsors should be permitted to apply transitional assistance toward any copay, coinsurance, and deductible amounts incurred by transitional assistance enrollees for covered discount card drugs obtained under their Medicare managed care plan's outpatient drug benefit in order to improve coordination between the benefits provided under their endorsed programs and Medicare managed care plans. Because of differences between the cost-sharing structure under a Medicare managed care plan's outpatient prescription drug benefit and the coinsurance requirements under the Medicare drug discount card program, as required under section 1860D-31(g)(1)(B) of the Act, transitional assistance enrollees could be responsible for a larger portion of a drug's costs if obtained under the Medicare managed care plan drug benefit than under the Medicare drug discount card program. Allowing transitional assistance enrollees to apply transitional assistance toward any cost-sharing amounts incurred for covered discount card drugs obtained under their Medicare managed care plan drug benefit would address this problem while allowing for more seamless drug coverage.

Although applicants seeking to offer an exclusive card program must meet the business integrity and financial stability requirements under § 403.806(b) of our regulations, we believe the process for demonstrating compliance with this requirement, as