

cost of outpatient drugs, with a few exceptions. In directing us to establish the Medicare drug discount card program, Congress sought to provide Medicare beneficiaries—particularly those lacking outpatient drug coverage—with access to negotiated prices on prescription drugs through enrollment in Medicare-endorsed drug discount card programs operated by endorsed sponsors. In addition, to help low-income beneficiaries meet their drug costs, Congress authorized up to \$600 of annual transitional assistance that eligible beneficiaries may apply toward the cost of covered discount card drugs purchased under the program.

The Medicare drug discount card program is designed to increase beneficiaries' access to low-cost prescription drugs by building upon best practices in the private drug benefit market today.

C. Relationship to Medicare-Endorsed Prescription Drug Card Assistance Initiative

On September 4, 2002, we published a final rule (67 FR 56618) establishing the Medicare-Endorsed Prescription Drug Card Assistance Initiative based primarily on the educational and assistance authority in section 4359 of the Omnibus Budget Reconciliation Act of 1990 (OBRA) (Pub. L. 101-508). Similar to the Medicare drug discount card program, this initiative called for us to endorse private sector prescription drug card programs that met certain criteria, including offering Medicare beneficiaries discounted drug prices through retail pharmacy networks that met our access standards. On January 8, 2003, we posted a solicitation of application.

On January 23, 2003, the Federal Court for the District of Columbia enjoined us from proceeding with the initiative. In accordance with the court order, we withdrew the solicitation, ceased all work on the initiative, and neither received any applications nor made any endorsements on the basis of the September 4, 2002 rule.

The Medicare drug discount card program described in this rule is based on entirely different statutory authority—the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—than the 2002 initiative and has significantly different features than the earlier initiative, most notably the provision of transitional assistance to eligible beneficiaries. Therefore, parties interested in the implementation and operation of the Medicare drug discount card program should not refer to the September 4, 2002 final rule or the January 8, 2003 solicitation for

guidance on the program that we will implement under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Also, by publishing this interim final rule with comment under the authority of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we hereby withdraw the regulation and solicitation published September 4, 2002 and January 8, 2003, respectively.

II. Provisions of the Interim Final Rule With Comment Period

A. Eligibility and Enrollment

Sections 1860D-31(b)(1) and (2) of the Act establish the eligibility criteria for the Medicare drug discount card program and for transitional assistance, which we have incorporated into § 403.810(a) and § 403.810(b) of our regulations. Section 1860D-31(f)(1)(A) of the Act directs the Secretary to specify the procedures for determining a beneficiary's eligibility for the Medicare drug discount card program or transitional assistance and section 1860D-31(c)(1) directs the Secretary to establish a process for eligible beneficiaries enrolling in, and disenrolling from, an endorsed program. Sections 403.810 and 403.811 of our regulations set forth these procedures. The obligations of endorsed sponsors related to eligibility determinations and enrollment are discussed in section II.C.6 of this document.

1. Eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program

In accordance with section 1860D-31(b)(1) of the Act, a Medicare beneficiary is eligible for the Medicare drug discount card if the beneficiary is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B, and does not already receive drug coverage through a State medical assistance plan under either a Title XIX program or under a demonstration program that is approved by us under sections 1115(a)(1) and (2) of the Act, hereinafter referred to as a "section 1115 waiver demonstration."

The benefit package available to beneficiaries enrolled in section 1115 waiver demonstrations varies, with some demonstrations offering comprehensive outpatient prescription drug coverage and others offering more limited or no outpatient drug coverage. Section 1860D-31(b)(1)(B) of the Act provides that beneficiaries entitled to "any" medical assistance for outpatient prescribed drugs under a section 1115 waiver demonstration are ineligible for

the Medicare drug discount card program. We interpret this section as rendering ineligible for the program all beneficiaries enrolled in a section 1115 waiver demonstration program with some outpatient drug coverage, even if limited coverage. Beneficiaries enrolled in a section 1115 waiver demonstration that does not provide outpatient drug coverage are eligible for the program provided they meet all other eligibility criteria. Similarly, beneficiaries enrolled in Medicaid under title XIX of the Act who do not receive outpatient drug coverage may be eligible for the program.

We have the authority to establish procedures for eligibility determinations under section 1860D-31(f)(1)(A) of the Act. Under this authority and in the interest of promoting efficient administration of the program, we specify in § 403.810(d) of our regulations that beneficiaries determined eligible for the program will remain eligible for the entire period of their enrollment. We therefore provide in section 403.810(a) of the regulations that a beneficiary is eligible for the Medicare drug discount card program if he or she satisfies the above requirements at the time of applying to enroll in the program. Consequently, once a beneficiary has been determined eligible for the Medicare drug discount card program, he or she will remain eligible for the duration of the program unless he or she disenrolls from an endorsed program and is ineligible for a special election period that would allow the individual to enroll in another program in accordance with § 403.811(b)(2) of the regulations, as discussed below in section II.A.6, or if involuntarily disenrolled as provided in § 403.811(b)(6). If, after such a disenrollment from the Medicare drug discount card program in 2004, a beneficiary wishes to later re-enroll in the program, he or she must re-apply and re-qualify for the program for 2005.

Section 1860D-31(b)(4) directs the Secretary to issue appropriate rules addressing the eligibility of medically needy beneficiaries, as described in section 1902(a)(10)(C) of the Act, for the Medicare drug discount card program. Medically needy beneficiaries will be treated the same as all other beneficiaries applying for the program and therefore will be eligible for the program if at the time of applying for the program they meet the eligibility criteria set forth in § 403.810(a) of the regulations.

Medicare beneficiaries residing in the U.S. territories, which include American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto