

discount card drug. Any product or service that is either not related to a covered discount card drug, or is not a discount for an over-the-counter drug, could not be provided under the endorsement and would be considered outside the scope of a sponsor's Medicare endorsement.

Although an endorsed sponsor (and pharmacies participating in their networks) may provide products and services related to covered discount card drugs and may offer discounts on over-the-counter drugs, our regulations provide at § 403.806(h)(1) that endorsed sponsors (and pharmacies participating in their networks) may not offer any such product or service for an additional fee (nor may any of their subcontractors or pharmacies in the network charge an additional fee for services offered under the endorsement). Endorsed sponsors therefore must fund all such products and services (whether optional or required) through the enrollment fee, and, if necessary, through rebates, discounts, and other price concessions garnered from manufacturers and pharmacies. We believe that we have the authority to recognize as outside the scope of endorsement those products and services offered for an additional fee. Section 1860D–31(h)(8) of the Act charges us with protecting and promoting the interests of Medicare beneficiaries. Were we to allow endorsed sponsors to charge additional fees, we believe beneficiaries might, in effect, be charged annual enrollment fees higher than the \$30 limit mandated by section 1860D–31(c)(2)(B) of the Act, especially if endorsed sponsors were to condition enrollment in their endorsed programs on beneficiaries paying these additional fees. In addition, beneficiaries may be unable to access negotiated prices and transitional assistance, as intended by Congress, if endorsed sponsors require that they pay additional fees for optional products and services. Further, we believe permitting endorsed sponsors to charge additional fees could be confusing to beneficiaries. For example, beneficiaries may find it confusing and frustrating that endorsed sponsors can charge a diabetic an additional fee to access discounts on durable medical equipment related to drugs for diabetics when they cannot charge a case management fee related to helping the beneficiary manage his or her diabetes. Our beneficiary research has demonstrated that beneficiaries expect a discount card program to be simple to understand and easy to use (Bearing Point and Sutton Group. CMS Formative

Research on Prescription Drug Shopping Habits: Round 1 Findings, Final. April 8, 2003). We believe that the most straightforward and easily understood structure for an endorsed program is one that provides all products and services related to covered discount card drugs and discounts on over-the-counter drugs for the single enrollment fee.

We clarify that we do not intend to prohibit pharmacies from charging beneficiaries for drugs; rather, this policy concerns not the price of a drug itself, but products or services directly related to the drug and access to discounts on over-the-counter drugs. Pharmacies and endorsed sponsors therefore may charge beneficiaries negotiated prices for covered discount card drugs and discounted prices for over-the-counter drugs.

In accordance with section 1860D–31(h)(7)(B) of the Act, our regulations at § 403.813(a) and § 403.806(g)(5)(iv) provide that an endorsed sponsor's information and outreach materials may describe only those products or services within the scope of the Medicare endorsement; the information and outreach materials may not include descriptions of products or services offered by the endorsed sponsor outside the scope of the endorsement. Because only products and services that are both (1) related to a covered discount card drug or are discounts for over-the-counter drugs and (2) offered for no fee (other than the enrollment fee or negotiated prices) are considered within the scope of the Medicare endorsement, an endorsed sponsor's information and outreach materials may not include information on products or services offered for an additional fee. We interpret this to mean that endorsed sponsors may not commingle communications about endorsed sponsors' products or services offered outside the scope of endorsement with information and outreach materials describing products and services within the scope of endorsement. In addition, if endorsed sponsors offer for no additional fee non-required products and services related to covered discount card drugs or they offer discounts on over-the-counter drugs, the endorsed sponsor must describe these products and services in its information and outreach materials, which are subject to our review as described in section II.C.7. of this document.

Finally, as provided in § 403.813(a)(1) and (2) and discussed in section II.C.9. of this document, an endorsed sponsor may not use or disclose a card enrollee's individually identifiable health information created, collected, or maintained under the Medicare drug

discount card program for the purpose of marketing products or services offered outside the scope of endorsement.

#### 6. Eligibility and Enrollment Responsibilities

Sections 1860D–31(f)(1)(A) and (c)(1) of the Act direct the Secretary to establish procedures for determining beneficiaries' eligibility for the Medicare drug discount card program and transitional assistance and for enrolling eligible beneficiaries in endorsed programs. Sections 403.810 and 403.811 of our regulations set forth these procedures, which are discussed in part in section II.A. of this document. Endorsed sponsors are expected to implement these requirements as provided in § 403.806(k) of the regulations. This section discusses the obligations of endorsed sponsors related to eligibility determinations and enrollment. Section 1860D–31(c)(1)(B) of the Act also requires endorsed sponsors to use a standard enrollment form, and section 1860D–31(c)(2) of the Act permits endorsed sponsors to charge an annual enrollment fee up to, but no more than, \$30 per year. This section also discusses our rules pertaining to the standard enrollment form and annual enrollment fee.

##### a. Eligibility and Enrollment Process

An endorsed sponsor may enroll a Medicare beneficiary in its endorsed program only after we verify the beneficiary's eligibility. We require endorsed sponsors to interact with CMS's enrollment systems to ensure that only eligible beneficiaries enroll in the Medicare drug discount card program; that beneficiaries enroll in only one endorsed program at a time and with few exceptions, in only one endorsed card program per year, as required under section 1860D–31(c)(1)(C)(i) of the Act and § 403.811(a)(6) and (a)(7) of our regulations; and that members of a Medicare managed care plan offering an exclusive card program do not enroll in other endorsed programs.

Medicare beneficiaries seeking to enroll in an endorsed sponsor's program must submit information to the endorsed sponsor by completing the standard enrollment form or by providing the necessary information to the sponsor via other means (for example, telephone, internet, or facsimile), as specified by CMS and permitted by the endorsed sponsor. Beneficiaries who wish to receive transitional assistance must complete the standard enrollment form for transitional assistance and submit this