

such as drug interaction counseling or allergy alerts;

(3) The availability of a grievance process and how it works;

(4) If applicable, any special rules for beneficiaries in long term care facilities, American Indians/Alaska Natives who use I/T/U pharmacies, as well as residents of the U.S. territories;

(5) The toll-free telephone numbers described in § 403.806(g)(6) of our regulations;

(6) A list of contracted pharmacies and prescription drugs offered for a negotiated price, how coinsurance works, and a guarantee that contracted pharmacies will provide the lower of the negotiated price or the usual and customary price;

(7) Enrollment fees (if any);

(8) A notice that drugs and prices may change or vary and a description of how the enrollee can obtain information regarding those changes and variations;

(9) A clear description of the service area in which the endorsed program is available;

(10) A privacy notice for protected health information. Further guidance will be provided in the information and outreach guidelines on the notice of privacy practices for protected health information; and

(11) A description of any circumstances and special procedures that relate to potential transitional assistance enrollee liabilities stemming from procedures endorsed sponsors have in place to manage transitional assistance against an enrollee's cap or transitional assistance balance transfer to a newly elected endorsed program.

Endorsed sponsors must also make available, upon request, the negotiated prices for prescription drugs.

In addition to the above information, section 1860D–31(d)(2)(B) of the Act provides that an individual's transitional assistance balance must be available and provided as requested by toll-free line. Because this provision also requires that the toll-free line is publicized, we will require in the information and outreach guidelines that the toll-free number be included in all media through which the sponsor communicates with beneficiaries (for example, magazines, television, newspapers, billboards, radio, pre-enrollment, or post-enrollment materials).

Section 1860D–31(d)(2)(C) of the Act requires endorsed sponsors to make available, at the point of sale, information on the remaining balance of transitional assistance. Endorsed sponsors, therefore, must explain in their information and outreach materials that, at the point of sale, enrollees can

request that network pharmacies determine—either electronically or by telephone—how much of the enrollee's transitional assistance remains.

Endorsed sponsors must also include information in the member handbook or summary of program features on how an enrollee can obtain his or her transitional assistance balance.

Additionally, in accordance with section 1860D–31(d)(3) of the Act, information and outreach materials must explain how enrollees will be informed of the differential between the price of the drug to the enrollee and the price of the lowest priced therapeutically equivalent and bioequivalent generic covered discount card drug available at that pharmacy. Our forthcoming information and outreach guidelines will provide further detail on the method for communicating this information to beneficiaries, including to beneficiaries who purchase drugs through mail order.

All information required to be included in information and outreach materials, must, as required under section 1860D–31(d)(2)(A) of the Act, be provided both through the Internet and through some tangible medium, such as mailings (see § 403.806(g)(1) of our regulations). For information provided on the Internet, endorsed sponsors must establish a process for informing members when the web page was last updated, for example, by putting a date and disclaimer on the web page to promote beneficiary understanding that the information could be dated. In their applications, we require endorsed sponsors to demonstrate how they will maintain Web sites that provide information and outreach.

In II.C.5. of this document, we discuss products and services considered inside and outside the scope of endorsement, and explain that products or services outside the endorsement may not be offered or marketed under the endorsement. We further explain in section II.C.9. of this document that marketing related to non-endorsed services will be prohibited, even if the endorsed sponsor obtains beneficiary consent to receive such marketing. In keeping with these rules, our information and outreach provisions provide that any communication provided by sponsors that would concern services outside the endorsement may not be co-mingled with information and outreach materials relating to endorsed items or services. Therefore, when endorsed sponsors are acting in their capacity as endorsed sponsors, and are using data or information they collected through the operation of their endorsed program,

they may not co-mingle information and outreach materials on endorsed features with any materials on non-endorsed features. This, however, would not prohibit entities, when they are not acting in their capacity as endorsed sponsors, from publicizing their endorsed programs or providing information about such programs. Thus, for example, an exclusive card sponsor could describe its endorsed program in its Medicare managed care plan marketing materials if those materials are CMS-approved, but it could not describe its Medicare managed care plan general features in materials which are directed solely toward its endorsed program enrollee population.

Our forthcoming information and outreach guidelines also will provide certain rules regarding the proper procedures for conducting information and outreach. For example, the guidelines will provide that, in conducting information and outreach, endorsed discount card sponsors may not engage in activities that could mislead or confuse beneficiaries or provide cash or other monetary rebates (for example, coupons or discounts on pharmacy products and services) as an incentive for enrollment.

Section 1860D–31(c)(3) of the Act provides that each endorsed sponsor must issue to each enrollee a card in a standard format specified by the Secretary that establishes proof of enrollment and that can be used in a coordinated manner to identify the endorsed sponsor, program, and beneficiary (*see also* § 403.806(g)(4) of our regulations). We will, in the information and outreach guidelines, provide guidance according to the requirements of the National Council for Prescription Drug Programs (NCPDP) for pharmacy identification cards. NCPDP is recognized as the industry standard for current prescription drug programs. We will review and approve pharmacy identification cards.

Our information and outreach guidelines will also include standards for use of a Medicare endorsement emblem. Use of the emblem may occur only after written notification of endorsement. Endorsed discount card sponsors may use the emblem on information and outreach materials such as newsletters, discount cards, stationery, and other promotional items designed to inform Medicare beneficiaries about the program.

Finally, as a condition of endorsement, we will require endorsed sponsors to file with us all information and outreach materials (*See also* § 403.806(g)(5)). These materials will require our review and approval (within