

the time period discussed below) prior to the endorsed sponsor being able to disseminate them. We believe there is sufficient authority in section 1860D–31 of the Act for us to require prior submission and review of information and outreach materials. For example, section 1860D–31(d)(2) of the Act gives the Secretary the authority to identify the information necessary to be included in information and outreach materials to “promote informed choice among endorsed discount card programs.” In order to ensure that information and outreach materials are, in fact, promoting informed choice, we believe prior filing and review is necessary. Additionally, section 1860D–31(h)(8) of the Act authorizes us to craft conditions for endorsement that we believe would “protect and promote the interests of Medicare beneficiaries.” We believe that ensuring that marketing materials contain the necessary information, adequately reflect the drug discount card program, and do not violate any of our conditions for endorsement will protect Medicare beneficiaries. Our review of these materials will ensure that beneficiaries are not misled or confused about the services offered by drug discount card programs, that beneficiaries receive the information necessary to make informed choices in their selection of a drug discount card program, and that the Medicare name is not misused—for example, to advertise services unrelated to this program.

Therefore, we require in § 403.806(g)(5) of our regulations that information and outreach materials must have our review and approval (within the time period discussed in § 403.806(g)(5)(iii)) in order for them to be disseminated. We define information and outreach materials to include the same kinds of materials described in 42 CFR § 422.80(b) as well as enrollment forms, eligibility determination forms, membership cards, Web site content and any information on over-the-counter drugs (*see also* § 403.806(g)(5)(v) of our regulations). Examples of information and outreach materials that will be reviewed include, but are not limited to—

- General audience materials;
- Telephone or sales scripts for presentations;
- Presentation materials and slides;
- Membership communications, such as member handbooks and letters regarding contractual changes in benefits, procedures, or enrollment fee;
- Enrollment forms, eligibility determination forms, and membership cards;

- Information regarding over-the-counter drugs offered for a discount; and

- All forms of advertising, including television, radio, print, and Internet.

In order for us to conduct our review, our regulations provide that all information and outreach materials must be submitted to us for approval 30 days before dissemination. We will include model language in our guidelines, and materials that use that model language will receive a streamlined review process and will be approved in fewer than 30 days. Our guidelines will also include a File and Use Program, which will be another approach for streamlining the review process. Further guidance will be provided in the information and outreach guidelines regarding the criteria for the File and Use Program.

The endorsed sponsor may disseminate the information and outreach materials if we do not disapprove the initial submission of these materials by the end of the 30-day period. This rule applies only to the initial submission of materials. Resubmission of materials (that is, submissions made after receiving comments or questions on the initial submission) will not be subject to the deemed approval rule in § 403.806(g)(5)(iii) of our regulations.

Exclusive card sponsors will have a modified review process that will facilitate the coordination of their information and outreach materials with the Medicare managed care plan marketing materials. Further details on the review process will be provided in the Information and Outreach Guidelines, the solicitation, and also in the pre-application conference that will be announced in the solicitation.

#### b. Call Center

As stated in section 1860D–31(d)(2)(B) of the Act, each endorsed sponsor must have a mechanism (including a toll-free telephone number) for providing, upon request, specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to their enrollees. Therefore, in § 403.806(g)(6), we are requiring that, as a condition of endorsement, each endorsed card endorsed sponsor must maintain a toll-free customer call center to assist beneficiaries in understanding the drug discount card program offered. The call center must be open during regular business hours and must provide customer telephone service in accordance with standard business practices. We interpret this to mean that

the call center will be available at least Monday through Friday from 8 a.m. to 4:30 p.m. Eastern to Pacific Standard times for those zones in which the discount card program will operate. We also interpret the requirement that the call center will be operated in accordance with standard business practices to mean that—

- 70 percent of customer service representatives' time while on the job will be spent answering telephones and responding to enrollee inquiries;
- 80 percent of all incoming customer calls will be answered within 30 seconds;
- The abandonment rate for all incoming customer calls will not exceed 5 percent; and
- There will be an explicit process for handling customer complaints.

These standards are required or exceeded by the 1–800 Medicare call center contractors.

As stated earlier and included in § 403.806(e)(5) of our regulations endorsed sponsors are required to provide through their toll-free numbers information on the amount of available transitional assistance (section 1860D–31(d)(2)(B) of the Act).

Endorsed sponsors must also have in place a reliable means for accommodating pharmacy inquiries regarding the endorsed sponsor's program. We believe this requirement promotes and protects beneficiaries by ensuring that pharmacists can have their questions answered about the card program's drug offering on behalf of the beneficiary. Endorsed sponsors could, for example, accommodate pharmacist inquiries by incorporating a specific number in the Interactive Voice Response (IVR) for the pharmacist to select so that hold times will be minimized (many pharmacies use this already for ease of access for physicians). We are aware that endorsed sponsors, as part of their current business operations, generally have some established mechanism for responding to pharmacy inquiries. However, we do not intend to mandate a specific approach because we do not want to inadvertently force a higher cost solution. Instead, we will permit individual endorsed sponsors to decide on methods for effectively addressing pharmacy inquiries.

Endorsed discount card programs may establish additional mechanisms for communicating with enrollees and pharmacies, such as e-mail or fax.

#### c. Reduction of Medication Errors and Adverse Drug Reactions

In our regulations at § 403.806(g)(7), we require that each endorsed discount