

**Medicare Prescription Drug Discount Card  
and Transitional Assistance Program**

**Information & Outreach  
Materials Guidelines**

Centers for Medicare & Medicaid Services

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## **Chapter 1 – Introduction**

The Medicare-Endorsed Prescription Drug Discount Card and Transitional Assistance Program (Rx Discount Card Program) implements section 1860D-31 of the Social Security Act (the “Act”). Section 1860D-31(d)(2)(A) of the Act requires each Endorsed Card Sponsor that offers an endorsed prescription drug discount card program (“Approved Card Program”) to make available to beneficiaries eligible to participate in the Rx Discount Card Program (through the Internet and otherwise), information that the Secretary identifies as being necessary to promote informed choice among Approved Card Programs, including information on enrollment fees and negotiated prices for covered discount card drugs. Further, in 42 CFR §403.806(g), the Centers for Medicare & Medicaid Service requires Endorsed Card Sponsors who will operate Approved Card Programs to comply with Information and Outreach guidelines and to submit materials for review.

In over 35 years of working with and developing educational materials for people with Medicare, the Centers for Medicare & Medicaid Services (CMS) has researched extensively the most appropriate and effective methods for conveying information to this population. Based on the requirements of this program in the interim final rule published December 15, 2003 (42 CFR Section 403) and this research, CMS has developed these Information and Outreach Materials Guidelines (“the Guidelines”) to assist the Rx Discount Card Program Sponsors in their efforts to educate people with Medicare.

The Guidelines are intended to meet several objectives:

- Assist Medicare-Endorsed Prescription Drug Discount Card Sponsors (“Endorsed Card Sponsors”) in developing Information and Outreach materials that appropriately educate people with Medicare about the Medicare Prescription Drug Discount and Transitional Assistance Program and the Endorsed Card Sponsor’s own Approved Card Program;
- Establish uniform standards by which to review each Endorsed Card Sponsor’s Information and Outreach materials for its Approved Card Program;
- Create review protocol and timeframes sensitive to the Information and Outreach requirements within a competitive marketplace; and
- Ensure consistent materials review across the nation.

General guidance regarding the materials review requirement and process is outlined in the following chapters. The breakdown is as follows:

Chapter 2: Privacy Provisions

Chapter 3: Materials Subject to Review

Chapter 4: The Materials Review Process

Chapter 5: Required Information and Outreach Materials

Chapter 6: Use of Medicare Name or Mark

Chapter 7: Special Guidelines

Chapter 8: Guidelines for Information and Outreach Materials

Chapter 9: Guidelines for Promotional Activities

## **Chapter 2 – HIPAA Privacy Provisions**

An Endorsed Card Sponsor is a “covered entity” under the HIPAA Privacy Rule, 45 CFR parts 160 and 164, subparts A and E. The Endorsed Card Sponsor must comply with the HIPAA Privacy Rule provisions in the same manner as health plans as described in 42 CFR §403.812 in the interim final rule for the Medicare Prescription Drug Discount Card Endorsement Program.

Endorsed Card Sponsors will be required, as a term of endorsement, to agree to protect the privacy of Medicare beneficiary information and provide beneficiaries with rights regarding this information consistent with the privacy provisions set forth in the HIPAA Privacy Rule. These include, but are not limited to, providing beneficiaries notice of the permitted and required uses and disclosures of protected health information and the Endorsed Card Sponsor's duties with respect to such information.

For more information on the HIPAA Privacy Rule requirements, see <http://www.hhs.gov/ocr/hipaa> the Office for Civil Rights website. For a discussion of the HIPAA privacy provisions as they relate to the Medicare Prescription Drug Discount and the Transitional Assistance Program, see Sections II.C.9. and II.C.10. of the drug card interim final rule (published in the Federal Register, Vol. 68, No. 240, December 15, 2003, pp. 69840-69927), as well as the regulations in Section 403.812 of this rule.

These guidelines provide some guidance to assist Endorsed Card Sponsors in assuring they remain in compliance with the HIPAA Privacy Rule and the privacy provisions required by the Medicare Prescription Drug Discount Card Endorsement.

### **Key Terms for Endorsed Card Sponsors**

Business Associate: This is a defined term under HIPAA (see 45 CFR §160.103). For Endorsed Card Sponsors, a business associate may include any entity to which an Approved Card Program discloses protected health information in order to carry out, perform, or assist in the performance of the functions of the Rx Discount Card Program.

Covered Discount Card Drug: Any of the following: (1) a drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; (2) a biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; (3) insulin described in section 1927(k)(2)(C) of the Act; (4) the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; (5) a vaccine licensed under section 351 of the Public Health Service Act; or (6) any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition excludes certain drugs. Please refer to 42 C.F.R. 403.802 for a list of drugs or agents that are excluded from the definition.

Covered Entity: A health plan, health care clearinghouse, or health care provider who transmits any health information in electronic form in connection with a transaction for which the Secretary has adopted standards, and an Endorsed Card Sponsor. See 45 CFR §160.103 and 42 CFR §403.812(a).

Endorsed Features: Prescription drug discounts, as well as additional drug-related services, such as providing information on drug interactions, drug utilization review, allergy alerts, and pharmacy counseling, that are offered without an additional fee. Also, discounts for non-prescription drugs including vitamin supplements may be considered endorsed features.

Health Information: Any information whether oral or recorded in any form or medium that is created or received by the Endorsed Card Sponsor under the Rx Discount Card Program and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. See 45 CFR §160.103.

Information and Outreach: Pre-enrollment and post-enrollment materials and communications in any medium, including but not limited to print, electronic mail, and the Internet, intended to disclose to enrollees or to those potential enrollees information about how to use the Approved Card Program, including Transitional Assistance, and any other products or services provided within the scope of the Medicare endorsement. Information and Outreach materials may not contain information about products and services outside the scope of the Medicare endorsement. For further discussion of what is inside and outside the scope of the Medicare endorsement see section II.C.5. of the drug card interim final rule (published in the Federal Register, Vol. 68, No. 240, December 15, 2003, pp. 69840-69927).

Non-Endorsed Features: (a) Products and services related to covered discount card drugs offered for an additional fee (such as disease management if offered for an additional fee; an additional discount program on prescription vitamins when such program requires an additional enrollment fee; or the purchase of Part B Supplies, since such purchase would necessarily involve an additional fee for the supply; or (b) products and services not related to covered discount drug card (such as discounts on eyeglasses or travel services) whether offered for a fee or not.

Over-The-Counter Drug: A non-prescription drug.

Protected Health Information: All individually identifiable health information transmitted or maintained by an Endorsed Card Sponsor, regardless of form. “Individually identifiable health information” is a subset of health information created or received by the Endorsed Card Sponsor that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, including demographic information collected from an individual and that is created or received by the Endorsed Card Sponsor, and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. See 45 CFR §160.103.

Treatment: The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider, with a third party; consultation between health



care providers related to a patient; or the referral of a patient for health care from one health care provider to another. See 45 CFR §164.501.

Payment: The activities undertaken by (i) an Endorsed Card Sponsor to obtain premiums, or annual enrollment fees, or to determine or fulfill its responsibility for coverage and provision of benefits under the Approved Card Program, including determinations of whether Transitional Assistance may be applied toward the cost of drugs obtained by beneficiaries receiving Transitional Assistance; or (ii) a health care provider, including a pharmacy, or Endorsed Card Sponsor to obtain or provide reimbursement for the provision of health care, including application of Temporary Assistance toward the cost of drugs obtained by beneficiaries receiving Temporary Assistance. See 45 CFR §164.501.

Transitional Assistance: A special feature of the Approved Card Program whereby Medicare beneficiaries who qualify may receive up to a \$600 annual credit to help pay for covered prescription drugs. The Endorsed Card Sponsor operating an Approved Card Program is responsible under contract with CMS to manage the Transitional Assistance.

Secretary: Secretary of the Department of Health and Human Services or his Designee.

## **General Guidelines for Endorsed Card Sponsors About Uses and Disclosures of Protected Health Information (See 45 C.F.R. §164.502)**

### Permitted Uses and Disclosures

Endorsed Card Sponsors may use or disclose protected health information for treatment, payment, and health care operations under the HIPAA Privacy Rule without individual authorization. See 45 CFR §164.506 for more information. For purposes of the HIPAA Privacy Rule, the provision of Information and Outreach activities, as provided in the Medicare-endorsed agreement, is considered within Endorsed Card Sponsors' health care operations, as are most activities relating to endorsed features. (See 45 CFR § 164.501).

For purposes of this Approved Card Program, uses and disclosures of protected health information related to products and services outside the scope of the endorsement is prohibited even if the Endorsed Card Sponsor obtains written authorization from the beneficiary. Under no circumstance may an Endorsed Card Sponsor use or disclose protected health information to market products or services outside the scope of the endorsement, nor may an Endorsed Card Sponsor ask an enrollee or potential enrollee to provide an authorization in order to market such products or services. (See 42 CFR §403.813). The marketing limitations for participation in the Approved Card Program are in addition to those under the HIPAA Privacy Rule. (See 45 CFR §164.510, 164.508(a)(3)).

Under the HIPAA Privacy Rules, an Endorsed Card Sponsor may use or disclose protected health information if it has provided the privacy notice, as discussed below, and the disclosure is:

- To the individual (or his or her personal representative);
- For treatment, payment, or health care operations as permitted by and in compliance with the HIPAA Privacy Rule and Medicare-Endorsed Prescription Drug Discount Card Program Final Rule;
- To a business associate that needs the protected health information to assist the Endorsed Card Sponsor in its operations under the Approved Card Program, if the Endorsed Card Sponsor obtains satisfactory assurance that the business associate will appropriately safeguard the information (sample business associate contract provisions are available at the HIPAA website – <http://www.hhs.gov/ocr/hipaa/contractprov.html>); or
- Pursuant to valid authorization, if applicable (an authorization may not be sought or granted to market non-endorsed products or services).

For other permissible uses and disclosures of protected health information by Endorsed Card Sponsors, under the Privacy Rule, see 45 CFR § 164.502(a).

#### Required Disclosures

Endorsed Card Sponsors are required by the Privacy Rule to disclose protected health information to the individual if the individual requests to inspect or obtain a copy of their information, as required by 45 CFR §164.524. Endorsed Card Sponsors also must disclose protected health information when required to do so by the Secretary to investigate or determine the Endorsed Card Sponsor's compliance with the HIPAA Privacy Rule. (See 45 CFR §164.502(a)(2)(ii)).

#### **Notice of Privacy Practices for Protected Health Information (45 CFR § 164.520)**

Beneficiaries in the Approved Card Program have a right to adequate notice of the uses and disclosures of protected health information that may be made by the Endorsed Card Sponsor, and of the beneficiary's rights and the Endorsed Card Sponsor's legal duties with respect to protected health information. Endorsed Card Sponsors are required to provide notice under the Privacy Rule. There are some additional requirements of the Approved Card Program as identified below.

#### A Privacy Notice must:

- Be written in plain language.
- Prominently display the following statement: "This notice describes how medical information will be used and disclosed and how to get access to this information. Please review carefully."
- Contain a description and at least one example of each of the types of uses and

disclosures that the Endorsed Card Sponsor is permitted to make for the purposes of health care operations, payment, and treatment. These descriptions must reflect any more stringent applicable law; please see 42 CFR §403.806(c).

- Contain a description of the other purposes for which the Endorsed Card Sponsor is permitted or required to use or disclose protected health information without the beneficiary's written authorization. These descriptions must reflect any more stringent applicable law; please see 42 CFR §403.806(c).
- Contain a statement that the Endorsed Card Sponsor may not use or disclose the beneficiary's protected health information to market non-endorsed products or services.
- Contain a statement that other uses and disclosures of protected health information will be made only with the beneficiary's written authorization and that the beneficiary may revoke such authorization as provided by the HIPAA Privacy Rule.
- Contain a statement that the beneficiary is not required to authorize any additional uses or disclosures of his/her protected health information.
- Contain a statement that the beneficiary has the right to (1) request restrictions on certain uses and disclosures of protected health information by the Endorsed Card Sponsor, including a statement that the Endorsed Card Sponsor is not required to agree to a requested restriction; (2) receive confidential communications of protected health information from the Endorsed Card Sponsor, as applicable; (3) inspect and copy protected health information; (4) amend protected health information; (5) receive an accounting of certain uses and disclosures of protected health information by the Endorsed Card Sponsor and its business associates; and, (6) receive the notice electronically on the Endorsed Card Sponsor's web site, if any, and by email upon agreement, and to obtain a paper copy of the notice upon request.
- Contain a statement that the Endorsed Card Sponsor is required by law to maintain the privacy of protected health information and to provide beneficiaries with notice of its legal duties and privacy practices with respect to protected health information.
- Contain a statement that the Endorsed Card Sponsor is required to abide by the terms of the Privacy Notice currently in effect and that it reserves the right to change the terms of its Privacy Notice and to make the new Privacy Notice provisions effective for all protected health information that it maintains. In addition, the statement will describe how the Endorsed Card Sponsor will provide beneficiaries with a revised Privacy Notice.
- Contain a statement that the beneficiary may complain to the Endorsed Card Sponsor, Medicare, and to the Secretary if he/she believes that his/her privacy rights have been violated, a brief description of how the beneficiary may file a complaint with the Endorsed Card Sponsor, and a statement that the beneficiary will not be retaliated against for filing a complaint.

- Contain the name, or title, and phone number of a person or office to contact for further information.
- Contain the date on which the Privacy Notice is first in effect, which may not be earlier than the date on which the Privacy Notice is printed or published.

The Endorsed Card Sponsor must distribute its Privacy Notice at or before the time the beneficiary enrolls into the Approved Card Program and within 60 days of any material change to the Privacy Notice.

#### Electronic Notices

**Website:** An Endorsed Card Sponsor that maintains a website that provides information about services to the beneficiary must prominently post its Privacy Notice on the website and make the Privacy Notice available electronically through the website.

**E-mail:** An Endorsed Card Sponsor may provide the Privacy Notice to a beneficiary by e-mail, if the beneficiary agrees to an electronic Privacy Notice and such agreement has not been withdrawn. If a Privacy Notice is delivered via e-mail, the Endorsed Card Sponsor must ensure that the names or identities of the e-mail recipients are not disclosed. The use of blind carbon copy (bcc) to e-mail recipients is one way to ensure protection of the beneficiaries' identities. If the Endorsed Card Sponsor knows that the e-mail transmission has failed, a paper copy of the Privacy Notice must be provided to the beneficiary.

A beneficiary who is the recipient of an electronic Privacy Notice retains the right to obtain a paper copy of the Privacy Notice from the Endorsed Card Sponsor upon request.

### **Other Individual Rights Under the Privacy Rule**

In addition to the right to receive a Privacy Notice, beneficiaries in the Approved Card Program have many other rights under the Privacy Rule. Generally, beneficiaries have the right to:

- Review and obtain a copy of their protected health information maintained by an Endorsed Card Sponsor. See 45 CFR §164.524.
- Have Endorsed Card Sponsors amend their protected health information. See 45 CFR §164.526.
- Obtain an accounting of the disclosures of their protected health information by an Endorsed Card Sponsor or the Endorsed Card Sponsor's business associates. See 45 CFR §164.528.
- Request that an Endorsed Card Sponsor restrict certain uses or disclosures of protected health information, or receive communications of protected health information by an alternative means or at an alternative location. See 45 CFR §164.522.

- Endorsed Card Sponsors, as covered entities under the Privacy Rule, must satisfy their obligations with regard to these individual rights. As previously discussed, Endorsed Card Sponsors will be treated as health plans for determining their compliance requirements under the Privacy Rule.

### **Administrative Requirements for Privacy (45 CFR § 164.530)**

There are additional provisions in the HIPAA Privacy Rule regarding an Endorsed Card Sponsor's duties and administrative requirements. An Endorsed Card Sponsor is required to comply with all of these provisions, in accordance with 42 CFR §403.812.

For more information regarding the HIPAA Privacy Rule, a copy of the Rule, and official guidance and interpretation of the Rule, refer to <http://www.hhs.gov/ocr/hipaa>, the HHS Office for Civil Rights website.

## **Chapter 3 – Materials Subject to Review**

Prior to use, Endorsed Card Sponsors are required to submit to CMS or its Designee all materials in any medium that describes the endorsed features of an Approved Card Program – please see 42 CFR §403.806(g). Examples of materials subject to review include, but are not limited to, general audience materials, including all advertising, telephone and sales scripts, and presentation materials and slides; membership communication materials; enrollment materials including notice of expected uses of beneficiary information, member handbook, enrollment forms, eligibility determination notices and member communications to enrollees announcing covered discount card drugs offered for a discount, including changes in the drugs offered or in the prices that reflect discount rates; information about products and services related to covered discount card drugs for no additional fee; information on discounts, if any, on over-the-counter drugs offered for no additional fee; nominal incentive gifts; and information relating to withdrawal and termination.

An Endorsed Card Sponsor is not required to submit a produced television, radio ad or story board. For review purposes, a script with any necessary disclaimers and substantiations is sufficient for the Endorsed Card Sponsor to receive an item disposition. If tapes of a produced advertisement are submitted for review, scripts must accompany the submission. Furthermore, once an approved script is produced, a tape of the finished product must be submitted to CMS or its Designee.

CMS expects that Endorsed Card Sponsors will use a variety of materials and media to describe their Approved Card Programs to Medicare beneficiaries. CMS makes a distinction between materials that are used for explaining card features to members and advertising materials that are used to attract Medicare beneficiaries and promote membership retention.

### Materials Not Subject To Review

The following items are not reviewed by CMS or its Designees: privacy notices, press releases, blank letterhead, non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of the Medicare-Approved Discount Drug Card Program (i.e., ‘Your prescription is out of refills’), and customer service correspondence that addresses issues that are unique to individual members. Additionally, Endorsed Card Sponsors releasing an updated drug list need only send a hard copy for file to CMS or its Designee.

### **Definitions**

For the purposes of the Rx Discount Card Program, the following definitions shall apply:

Covered Discount Card Drug: (from Chapter 2 of these Guidelines) Any of the following: (1) a drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; (2) a biological product described in sections

1927(k)(2)(B)(i) through (iii) of the Act; (3) insulin described in section 1927(k)(2)(C) of the Act; (4) the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; (5) a vaccine licensed under section 351 of the Public Health Service Act; or (6) any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition excludes certain drugs. Please refer to 42 C.F.R. 403.802 for a list of drugs or agents that are excluded from the definition.

**Endorsed Features:** All required features, such as information about eligibility, enrollment fees, disenrollment, switching cards, prices that reflect discounts on covered discount card drugs and Transitional Assistance; any products and services, whether required or not, directly related to covered discount drug cards for no additional fee, such as providing information on drug interactions, drug utilization review, refill reminders, allergy alerts, and pharmacy counseling; and discounts on over the counter drugs, including vitamins, if offered as a part of the Approved Card Program.

**Non-Endorsed Features:** (a) Products and services related to covered discount card drugs offered for an additional fee (such as disease management if offered for an additional fee; an additional discount program on prescription vitamins when such program requires an additional enrollment fee; or the purchase of Part B Supplies, since such purchase would necessarily involve an additional fee for the supply); or (b) products and services not related to covered discount drug card (such as discounts on eyeglasses or travel services) whether offered for a fee or not.

**Information and Outreach:** Pre-enrollment and post-enrollment materials and communications in any medium, including but not limited to print, electronic mail, and the Internet, intended to disclose to members or to potential enrollees information about how to use the Approved Card Program, including endorsed features. Information and outreach materials may not contain information about non-endorsed features. Information and Outreach materials and other advertising materials may only contain information relevant to the endorsed features. (42 CFR 403.813(a)(3)).

**Explanatory Materials:** A subset of Information and Outreach materials that includes the member handbook, enrollment and disenrollment forms, pharmacy directory, list of prescription drugs, member card, eligibility determination letters, summary of Approved Card Program features, and grievance letters. Explanatory materials may not contain information about non-endorsed features.

**Advertising Materials:** A subset of Information and Outreach materials and communications in any medium, including but not limited to print, television, radio, telephone, electronic mail, and the Internet, that is intended to attract or appeal to eligible non-members and/or to promote membership retention by disclosing general information about the Approved Card Program. The purpose of these materials is to allow the recipient the opportunity to request additional information that will assist them in making an informed enrollment decision. These materials are not meant to result in enrollment. Advertising materials may not contain information about non-endorsed features.

**Example of Advertising Materials:** Television Ads, Outdoor Advertising, Banner/Banner-like Ads, Direct Mail, Print Ads (newspaper, magazine, flyers, church bulletins, etc.) Internet Advertising, Fliers, Brochures, Posters, Pharmacists' Buttons, Window Stickers, Counter Tents, Post Stands, Radio, Newspaper, Newsletters, and Magazine Ads, Postcards, Self Mailers, Event Signage, Teaser Post-card, Home Delivery Coupons, Reply Card, and Free Standing Inserts (Newspapers, magazines, etc).

**Marketing:** Any communication or activity about a product or service outside the scope of the Medicare endorsement.

**I/T/U pharmacies:** Those pharmacies operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 USC §1603.

Any materials describing endorsed features, whether categorized as Information and Outreach materials or advertising materials, must be submitted for review.

Marketing materials may never be associated as part of the Approved Card Program, and an Endorsed Card Sponsor may not claim or imply that the non-endorsed products or services are recommended or approved by CMS and/or Medicare as part of the Approved Card Program. Therefore, marketing materials for non-endorsed features should not be submitted to CMS or its Designee for review.

### **Limitation on Distribution/Dissemination of Information and Outreach Materials**

With the exception of Endorsed Card Sponsors with approved nationwide service areas, an Endorsed Card Sponsor is not permitted to advertise outside of its defined service area. In situations in which this cannot be avoided (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area), Endorsed Card Sponsors are required to clearly disclose the areas in which their Approved Card Programs are available to beneficiaries. Outreach activities outside of an Endorsed Card Sponsor's defined service area may be the basis for intermediate corrective action or termination of Medicare endorsement.

### **Limitations on Commingling Information and Outreach Materials with Marketing Materials**

An Endorsed Card Sponsor acting solely in its capacity as an Endorsed Card Sponsor may not distribute marketing materials to its enrollees or potential enrollees per 42 CFR §403.813. This means an Endorsed Card Sponsor acting in its capacity as an Endorsed Card Sponsor may not commingle information about non-endorsed features with its Information and Outreach Materials or Advertising Materials, and may not claim or imply that their non-endorsed features are recommended or approved by CMS and/or Medicare.



When entities are not acting in their capacity as Endorsed Card Sponsors, the entity may commingle information about endorsed and non-endorsed features. These materials do not need to be submitted to CMS for review. (Entities must still comply with Section 1140 of the Social Security Act, prohibiting the misuse of the Medicare name). For example, an entity may have a link on its website homepage directing those who are interested in the Approved Card Program to the page for the Approved Card Program.

An Endorsed Card Sponsor is deemed as acting in its capacity as an Endorsed Card Sponsor when it either (1) uses beneficiaries' information created, collected or maintained under its Approved Card Program to conduct marketing, or (2) targets its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees).

An Endorsed Card Sponsor is deemed as acting in another capacity when it (1) does not use beneficiaries' information created, collected or maintained under its Approved Card Program to conduct marketing, and (2) does not target its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). For example, we will consider a Medicare Managed Care Organization as acting in its Endorsed Card Sponsor capacity if it targets its marketing to members of its plan who are also enrolled in its Approved Card Program, to the exclusion of other plan members. In contrast, we will consider a Medicare Managed Care Organization as acting in its capacity as a Medicare Managed Care Organization if it directs its marketing to all or a subset of its Managed Care Organization plan membership, including those not enrolled in its Approved Card Program, and, to the extent it uses individual information, such information was not collected or maintained under the Medicare Managed Care Organization's Approved Card Program.

### **Endorsed Card Sponsors' Co-Branding Materials**

Endorsed Card Sponsors are allowed to co-brand materials without prior permission from CMS. However, such materials must be compliant with the Guidelines (See Chapter 8). Co-branded materials may be submitted to CMS or its Designee as template materials. However, a data sheet showing all variable information that will populate placeholders upon publication, co-brand names, logos, contact information, etc, must be provided at the time of submission.

Co-brands added to previously submitted materials are not subject to re-review. However, the Endorsed Card Sponsor must submit to CMS or its Designee a list of co-branded additions for each material that is being altered. The Endorsed Card Sponsor must include the assigned material identification number and material name. Additionally, the Endorsed Card Sponsor is required to submit one printed sample of each final version for possible retrospective review to CMS or its Designee.

## **Implementation of Information and Outreach Campaign**

Endorsed Card Sponsors may not begin their Information and Outreach campaign until they have received notification from CMS that all of the Endorsed Card Sponsor's required documents for start up are approved.

CMS expects the enrollment period for the Rx Discount Card Program may begin as early as May 3, 2004. It is also expected that Endorsed Card Sponsors may begin Information and Outreach activities at the same time. If this date changes, it will be updated at <http://www.cms.gov/discountdrugs/> (the CMS Prescription Drug Discount Card website). An Endorsed Card Sponsor shall not refer to itself as Medicare-approved and its advertising campaign shall not begin until:

- 1) May 3, 2004 or the date established in the signed agreement between CMS and the Endorsed Card Sponsor; however, Exclusive Card Sponsors will be permitted to begin their advertising campaign April 1, 2004; dates are subject to change so please check at <http://www.cms.gov/discountdrugs/> (the CMS Prescription Drug Discount Card website) for any news.
- 2) CMS has approved (or deemed approved) advertising communications and/or materials. Only materials that have been approved by CMS may be used in the campaign (please see Chapter 4 for a discussion of the review process); and
- 3) The Endorsed Card Sponsor is ready to fully operate its Approved Card Program. As explained in our interim final rule, this means that the pharmacy network contracts must be finalized, manufacturer rebates or discounts must be negotiated; there must be a signed contract with us, call centers must be up and running, all subcontracts necessary to operate the Rx Discount Card Program are executed and in place and we have received the necessary information describing such contracts (explained in our solicitation), and CMS has approved the system for conducting electronic transactions with us (or our subcontractor), including successful testing of such system.

CMS anticipates that Endorsed Card Sponsors may begin Information and Outreach activities, as well as enrollment activities as early as May 3, 2004.

CMS expects that Exclusive Card Sponsors that have the required materials for start-up approved will begin marketing activities to their current membership beginning April 1, 2004.

General Card Sponsors and Special Endorsed Card Sponsors that have the required materials for start-up approved may begin marketing on May 3, 2004 and enrollment of beneficiaries may begin June 1, 2004.

CMS reserves the right to terminate an Endorsed Card Sponsor's endorsement if the Endorsed Card Sponsor is not ready to fully operate its Approved Card Program and begin Information and Outreach activities by the 6 month deadline.

## **Template Materials**

**Submission of template materials:** A “Template Material” is any advertising or outreach material that includes placeholders to be populated by variable elements. Variable elements can be specific to one sponsor or can apply to a bundle of sponsors utilizing the same base materials. If an Endorsed Card Sponsor is submitting template materials, the Endorsed Card Sponsor has to include a data sheet. This data sheet should include the information that will populate all variable fields. It should also clearly state the Endorsed Card Sponsor application numbers and identification numbers. There should be only one file submission for each template item.

If template items are submitted on multiple files they cannot be reviewed as templates as each file will need to be reviewed.

- 1) **Re-submissions of template material:** Resubmission sheets must include original material identification numbers for ALL items being resubmitted. The data sheet must include all information that will populate all variable fields.
- 2) **Extending approval to like items:** In order to do this, CMS or its Designee must receive an attestation that items being submitted are identical to approved item except for changes to name, address, phone numbers, and logos. The attestation for the documents may be sent by e-mail.

A data sheet must be included in the submission requesting extended approvals to identical items. The data sheet must include all information as noted above, including assigned material identification number for the approved item. Neither CMS nor its Designee can process documents without this information.

Note: Identical materials submitted separately and not noted as template materials are subject to separate reviews and may receive different dispositions. In this case, the most recent disposition on the identical items would be valid.

## **Endorsed Card Sponsor Changes To Approved Materials**

The following changes do not require that materials be submitted to CMS or its Designee for re-review:

- Changes made to approved materials that do not affect the Approved Card Program fee, Approved Card Program offers, Approved Card Program features, readability, required elements, and content.
- Name changes to Approved Card Programs [All Name Changes Must be Reported To CMS].
- The addition of a company alliance that is compliant with the Guidelines (See Chapter 8).

Furthermore, all changes to approved documents must be reported to CMS or its Designee. This report must include the Endorsed Card Sponsor's name, Approved Card Program number, material identification number, material name, and the changes being made. A separate document must be submitted to CMS or its Designee for each material item being changed.

Additionally, once materials are printed, one sample of each changed document must be sent to CMS or its Designee for possible retrospective review.

However, any changes made to approved materials that affect fees, Approved Card Program features, readability of required elements, contents of the item, and/or are questionable relative to CMS Guidelines requirements must be submitted for review. This submission will be categorized as an original material eligible for 30-day review.

### **Including Approved Materials Within New Material Submissions**

Endorsed Card Sponsors may include an already approved material item within a new piece of material (exp. including an approved enrollment form or drug list within a website) and not submit the prior approved material item with the new submission. However, within the new material submission form, the Endorsed Card Sponsor must provide the assigned approved material item number for the material item that the Endorsed Card Sponsor wants to be included within the new material. The prior approved material item will not receive a re-review.

## **Chapter 4 – The Material Review Process**

The materials review process has two main components, which are listed below and described in this chapter.

- **Review of Materials Submitted to CMS:** This review will fall into one of three categories, which is discussed in further detail later in this chapter:
  - ◇ **Standard 30-day Review:** Any materials that do not qualify for the Streamlined Review or File and Use, will be reviewed within 30 days of submission using the Standard Review process. Only after the material is approved, may the Endorsed Card Sponsor use the material. If materials must be resubmitted, the resubmission will be reviewed within 10 days.
  - ◇ **Streamlined 10-day Review:**
    - Materials that replicate CMS standardized documents or those that follow model documents without modification by the Endorsed Card Sponsor (and only those materials) will be reviewed within 10 days of submission using the Streamlined Review process. Only after the material is approved, may the Endorsed Card Sponsor use the material.
    - CMS will award special material review permissions to certain Endorsed Card Sponsors that agree to offer an Approved Card Program for all U.S. Territories; and/or include pharmacies serving residents in long-term care facilities; and/or I/T/U pharmacies. These "Special Endorsed Card Sponsors" will receive an expedited review process on Information and Outreach and advertising materials. In order to ensure these materials are identified, Special Endorsed Card Sponsor must indicate on their submission form that they are Special Endorsed Card Sponsors. Further, if these materials are submitted as a template with materials for entities without special endorse privileges, they will be subject to the review period as dictated by the material type.
    - File and Use: Endorsed Card Sponsors who have been granted File and Use Status (and only those Endorsed Card Sponsors) may distribute their advertising materials, as defined in these Guidelines, (and only advertising materials) five days after submission to CMS.
- **Review of Materials in Marketplace:** CMS will periodically conduct random or for-cause reviews of actual materials in the marketplace to ensure compliance with the Guidelines.

### **Review of Submitted Materials**

As mentioned above, the expectation is that Endorsed Card Sponsors will use a variety of materials and media to describe their Approved Card Programs to Medicare beneficiaries.

CMS plans to make a distinction between materials that are provided for explaining how to use the Approved Card Program and its endorsed features, and advertising materials that are used to attract Medicare beneficiaries and promote membership retention. Examples of each are provided below.

**Explanatory Materials:** A subset of Information and Outreach materials, both pre-enrollment and post enrollment materials that include, but are not limited to, the member handbook, enrollment and disenrollment forms, pharmacy directory, list of prescription drugs, member card, eligibility determination letters, pre-enrollment packet, summary of program features, and grievance letters. Explanatory materials may not contain information about non-endorsed features.

**Advertising Materials:** A subset of Information and Outreach materials and communications in any medium, including but not limited to print, television, radio, telephone, electronic mail, and the Internet, that is intended to attract or appeal to eligible non-members and/or to promote membership retention by disclosing general information about the Approved Card Program. The purpose of these materials is to allow the recipient the opportunity to request additional information that will assist them in making an informed enrollment decision. These materials are not meant to result in enrollment. Advertising materials may not contain information about non-endorsed features.

**Example of Advertising Materials:** Television Ads, Outdoor Advertising, Banner/Banner-like Ads, Direct Mail, Print Ads (newspaper, magazine, flyers, church bulletins, etc.) Internet Advertising, Fliers, Brochures, Posters, Pharmacists' Buttons, Window Stickers, Counter Tents, Post Stands, Radio, Newspaper, Newsletters, and Magazine Ads, Postcards, Self Mailers, Event Signage, Teaser Post-card, Home Delivery Coupons, Reply Card, and Free Standing Inserts (Newspapers, magazines, etc).

Both explanatory materials and advertising materials must be submitted for review. When submitting materials, the Endorsed Card Sponsor has the following responsibilities:

- Ensure materials are consistent with the Information and Outreach Materials Guidelines.
- Submit for review proposed copies of its national and local advertising and explanatory materials with a dated submission form (See Attachment A). Materials for a national audience will be comprised of materials applicable to beneficiaries nationwide, while local materials will contain information relevant to specific locations or service areas.
- For items that require revisions, review all comments by reviewers and ensure that appropriate corrections have been made. A resubmission form will be required for the revised item and the resubmission form must include the identification number assigned to the item by CMS or its Designee.

Endorsed Card Sponsors may submit materials by U.S. mail, express mail, e-mail, or by fax. Endorsed Card Sponsors should submit camera-ready copies for review. Electronic mail submissions may be in color and in Microsoft Word, PowerPoint or Adobe Acrobat PDF format. If you have a question regarding your material submission electronic format, please contact CMS or its Designee.

All e-mail communications from Endorsed Card Sponsors should indicated in the subject line if it is a submission, resubmission, or item inquiry.

RX Discount Card Contact Information:

Mailing Address: CMS Rx Discount Card Material Review  
1676 International Dr., 6<sup>th</sup> Fl.  
McLean, VA 22102

Electronic Mail: [CMS-Rx-Review@BearingPoint.com](mailto:CMS-Rx-Review@BearingPoint.com)

Telephone Number: 1-703-747-5774

Fax Number: 1-703-747-8750

The CMS material review process will utilize standardized “review protocols.” The protocols will prompt reviewers to look for specific required or unallowable language and will help to ensure that the review is both thorough and consistent.

### **Disposition Definitions**

Approved: Material submission is approved for use in its current format.

Approved with Recommendations: Material is approved for use; however, the reviewer has made suggestions for replacement language.

Approved with Stipulations: Material is approved for use after the Endorsed Card Sponsor has made the required changes detailed within the disposition letter. These materials do not have to be resubmitted for re-review. However, one hard copy of each document with its stipulated changes made must be delivered to the reviewing entity after publication for possible retrospective review.

Disapproved: The material submission is denied and cannot be used by the Endorsed Card Sponsor. The disapproval letter sent by CMS or its Designee includes required changes that must be made before the item can receive an approval. If an Endorsed Card Sponsor decides to make the required changes to a disapproved item, the Endorsed Card Sponsor must resubmit the item to CMS or its Designee to receive an item approval.

An item may not be used in the marketplace until it has received an approval from CMS or its Designee.

### Submission of Start-Up Materials

Endorsed Card Sponsors' required Information and Outreach documents for start up may be submitted with the applications by January 30, 2004. All Information and Outreach materials must be received by February 2, 2004 in order to ensure a timely review and allow sufficient time for Endorsed Card Sponsors to have these materials printed for distribution. The initial Information and Outreach material review process will begin on February 2 and continue through March 17, 2004. If all of the above deadlines are met, it is expected that Endorsed Card Sponsors may begin their Information and Outreach activities with prospective members on or about May 3, 2004. Exclusive Card Sponsors may begin to conduct Information and Outreach with their materials starting April 1, 2004. Because these dates are subject to change, please check <http://www.cms.gov/discountdrugs/> (the CMS Prescription Drug Discount Card website) for any news.

CMS will communicate any changes in these dates on the website.

Thereafter, all material should be submitted at least 30 days before their intended dissemination to Medicare beneficiaries. After the start-up phase, review of Information and Outreach material will continue throughout the year in accordance with these Guidelines.

CMS will provide several standardized and model materials for the Approved Card Program. For standardized documents, Endorsed Card Sponsors are required to use the document provided by CMS without any modifications.

For model documents, Endorsed Card Sponsors may choose to use the CMS document without any modifications, incorporate portions of the CMS document, or create their own document. Unless specially noted, Endorsed Sponsors are not required to use the same language as in the model document. They must include comparable information that meets all of the elements outlined within the Guidelines. NOTE: Only documents that replicate model documents without change are eligible for streamlined review.

The standardized and model documents are listed below.

### **Model Documents:**

- Enrollment Forms
  - ◊ Discount Card
  - ◊ Discount Card and Transitional Assistance.

Please Note: Endorsed Card Sponsors are required to use all standardized elements of the enrollment forms without modification.

- Eligibility Determination Letters
- Member Handbook



- Annual Notice of Change
- Medicare Managed Care Notification Letter
- Change of Address Letter
- Pre-Enrollment Cover Letter

**Standardized Documents:**

- Member Card

**Documents Required for Start-up of Approved Card Program:**

In order to qualify for start-up, an Endorsed Card Sponsor must have approved disposition letters from CMS or its Designee for the following items:

- Enrollment Forms (models)
  - ◊ Discount Card
  - ◊ Discount Card and Transitional Assistance
- Member Card (standardized)
- Eligibility Determination Letters (model)
- Member Handbook (model)
- Summary of Program Features and Rules
- Pharmacy Directory for Geographic Service Area
- Endorsed Card Sponsor Top 100 Discount Prescription Drug List

Standard Review

Advertising and Information and Outreach materials that are not based on model materials without modification or not based on standardized materials will be reviewed under the standard review process and an initial determination will be made within thirty (30) calendar days of submission. The timeline below outlines the standard review process. (Exhibit 1 also illustrates the review process.)

Standard Initial Review:

*Day 0:* Material received by CMS or Designee.

*Day 1:* Material is logged into the Data Entry Tracking System and given a unique identification number by CMS or its Designee. An item receipt is then sent to the Endorsed Card Sponsor via e-mail.

*Days 1-30:* Initial item review based on these Guidelines.

*Not later than Day 30:* Initial review communication sent to Endorsed Card Sponsor.

If the item is approved, the Endorsed Card Sponsor will receive final approval of item.

If the item is not approved, the Endorsed Card Sponsor will receive a letter detailing the reasons it was not approved. The Endorsed Card Sponsor may choose one of two options:

Endorsed Card Sponsor withdraws item or does not resubmit an item for which revisions were requested.

Endorsed Card Sponsor revises and resubmits material and the item undergoes the resubmission review process. A resubmission of an item must include the material name and unique identifier assigned.

If CMS has not requested revisions or given approval within 30 days of submission, the item is “deemed approved.”

For initial submission, an item is considered approved if one of the following two conditions is met: (1) the Endorsed Card Sponsor has received an approval letter for the item, or (2) CMS has not requested revisions within 30 days of initial submission (this is considered “deemed approved”). For deemed approval, Endorsed Card Sponsors should retain the original receipt letter indicating the date the item was submitted, as evidence that the 30-day initial review period has expired. Until an item is approved or deemed approved, the Endorsed Card Sponsor may not use the material in the marketplace. Once approved or deemed approved, materials remain approved until changed by the Endorsed Card Sponsor or CMS policy changes make the materials no longer compliant.

When an item is returned for revision, a letter detailing the reason(s) why the material was not approved will accompany it. The letter will indicate the specific section(s) of item that are non-compliant, as well as the section(s) of the Guidelines on which this determination is based.

If the Endorsed Card Sponsor decides to revise and resubmit the item, the item will be reviewed under a 10-day resubmission review timeline. The resubmission review will focus on (1) assessing whether the Endorsed Card Sponsor has appropriately addressed the problems identified during the initial review, and (2) ensuring that any additional changes made by the Endorsed Card Sponsor (that were not requested by the reviewer) are compliant with the guidelines.

If sections in Information and Outreach materials have been updated or added to an item that was not in the original submission, and if these sections make a significant or substantial change to the item, it will be considered an original submission and the reviewer will examine the item in its entirety for compliance with the guidelines. Further, this item will revert to its original review status. The item resubmission review process is summarized below.

Standard Resubmission Review:

*Day 0:* Material received by CMS or Designee (Resubmission only applies to items that have received a disapproval disposition).

*Day 1:* Material logged into the Data Entry Tracking System and is given a new identification number by CMS or its Designee. A receipt is sent to the Endorsed Card Sponsor via e-mail.

*Days 1-10:* Resubmission review based on these Guidelines.

*Not later than Day 10:* Resubmission review communication sent to Endorsed Card Sponsor.

If the item is approved, the Endorsed Card Sponsor will receive final approval of item.

If the item is not approved, the item will be returned to the Endorsed Card Sponsor with a letter detailing the reasons it was not approved. The Endorsed Card Sponsor may choose one of two options:

Endorsed Card Sponsor withdraws item or chooses not to resubmit the item, or

Endorsed Card Sponsor revises and resubmits material and the item undergoes the resubmission review process.

There is no deemed approval of resubmitted materials.

A resubmitted item is considered approved if the Endorsed Card Sponsor has received an approval letter for the item; *there is no deemed approval during the resubmission phase.*

Until a resubmitted item is approved, the Endorsed Card Sponsor may not use the material in the marketplace. Once approved, materials remain approved until changed by the Endorsed Card Sponsor or CMS policy change that make the materials no longer compliant.

### Streamlined Review

Information and Outreach materials that replicate CMS provided standardized or model materials without modification, may take advantage of a streamlined 10-day review process. (Note: Except for special Endorsed Card Sponsor's materials, as noted below, no advertising materials are eligible for Streamlined Review because CMS has not developed model advertising materials.)

- Enrollment forms (models)
  - ◇ Discount Card
  - ◇ Transitional Assistance

Please Note: Endorsed Card Sponsors are required to use all standardized elements of the enrollment forms without modification. Because the Approved Card Program enrollment may be conducted via telephone or the Internet, the standardized elements are mandatory and the

presentation of the elements must otherwise conform to these guidelines. Additional information may be requested provided that it is clearly indicated that providing such additional information will have no bearing on whether the beneficiary will qualify for the card and Transitional Assistance.

- Member Card (standardized)
- Eligibility Determination Letters (model)
- Member Handbook (model)
- Annual Notice of Change (model)
- Medicare Managed Care Notification (model)
- Information for people who change their residence outside of the Endorsed Card Sponsor's geographic service area (model)

Some Endorsed Card Sponsors may receive a Special Endorsement from CMS because they agree to offer an Approved Card Program for all territories (42 CFR §403.817) and/or include pharmacies serving residents of long-term care facilities (42 CFR §403.816(b)) and/or include I/T/U pharmacies (42 CFR §403.816(d)) in their networks. These "Special Endorsed Card Sponsors" will also be eligible to use the Streamlined Review process on all Information and Outreach and advertising materials including standardized materials and those model materials without modification. In order to ensure accurate material identification, Endorsed Card Sponsors must indicate on their marketing submission form that they are Special Endorsed Card Sponsors.

Under the Streamlined Review process, Endorsed Card Sponsors will receive an approval within ten (10) calendar days for materials that do not require revisions. Items must be reviewed by CMS; however, if CMS does not approve or request revisions within 30 days, the material is deemed approved. The Streamlined Review timeline is outlined below.

**Streamlined Initial Review:**

*Day 0:* Standardized or unmodified model material or material from Special Endorsed Card Sponsors received by CMS or Designee.

*Day 1:* Material logged into the Data Entry Tracking System and a receipt sent to the Endorsed Card Sponsor via e-mail.

*Days 1-10:* Initial item review based on these Guidelines.

*Not later than Day 10:* Initial review communication sent to Endorsed Card Sponsor:

If the item is approved, the Endorsed Card Sponsor will receive final approval of item.

If the item requires revision, the materials will be returned to the Endorsed Card Sponsor with comments detailing the reasons it was not approved. The Endorsed Card Sponsor may choose one of two options:

Endorsed Card Sponsor withdraws item or chooses not to resubmit the item, or

Endorsed Card Sponsor revises and resubmits material and the item undergoes the resubmission review process.

If the item is based on model materials without modification, standardized materials or materials from Special Endorsed Card Sponsors and CMS has not requested revisions within 30 days of submission, it is “deemed approved.”

When an item is returned for revision, a letter detailing the reasons the material was not approved will accompany it. The letter will indicate the specific sections of item that are non-compliant, as well as the sections of the Guidelines on which this determination is based. Reviewers may choose to include suggested text or revisions to correct the problems identified.

If the Endorsed Card Sponsor decides to withdraw the item from review, the Endorsed Card Sponsor should provide written notification that the item is being withdrawn. This letter should include the Item Tracking Number, the date of the original submission, and the assigned reviewer’s name.

If an item is resubmitted following revision, the item will be reviewed under a 10-day resubmission review timeline. The resubmission review will focus on (1) assessing whether the Endorsed Card Sponsor has appropriately addressed the problems identified during the initial review and (2) ensuring that any additional changes made by the Endorsed Card Sponsor (that were not requested by the reviewer) are compliant with the guidelines. Reviewers may also re-review portions of the original document and may request additional revisions to these sections if they identify an infraction that was overlooked during the initial review. The resubmission review process is summarized below.

*Streamlined Resubmission Review:*

*Day 0:* Material received by CMS or Designee (Resubmission status applies only to items that have previously received a disapproval disposition).

*Day 1:* Material logged into the Data Entry Tracking System and a receipt sent to the Endorsed Card Sponsor via e-mail.

*Days 1-10:* Resubmission review based on these Guidelines.

*Not later than Day 10:* Resubmission review communication sent to Endorsed Card Sponsor

If the item is approved, the Endorsed Card Sponsor will receive final approval of item.

If the item is not approved, the item will be returned to the Endorsed Card Sponsor with a letter detailing the reasons it was not approved. The Endorsed Card Sponsor may choose one of two options:

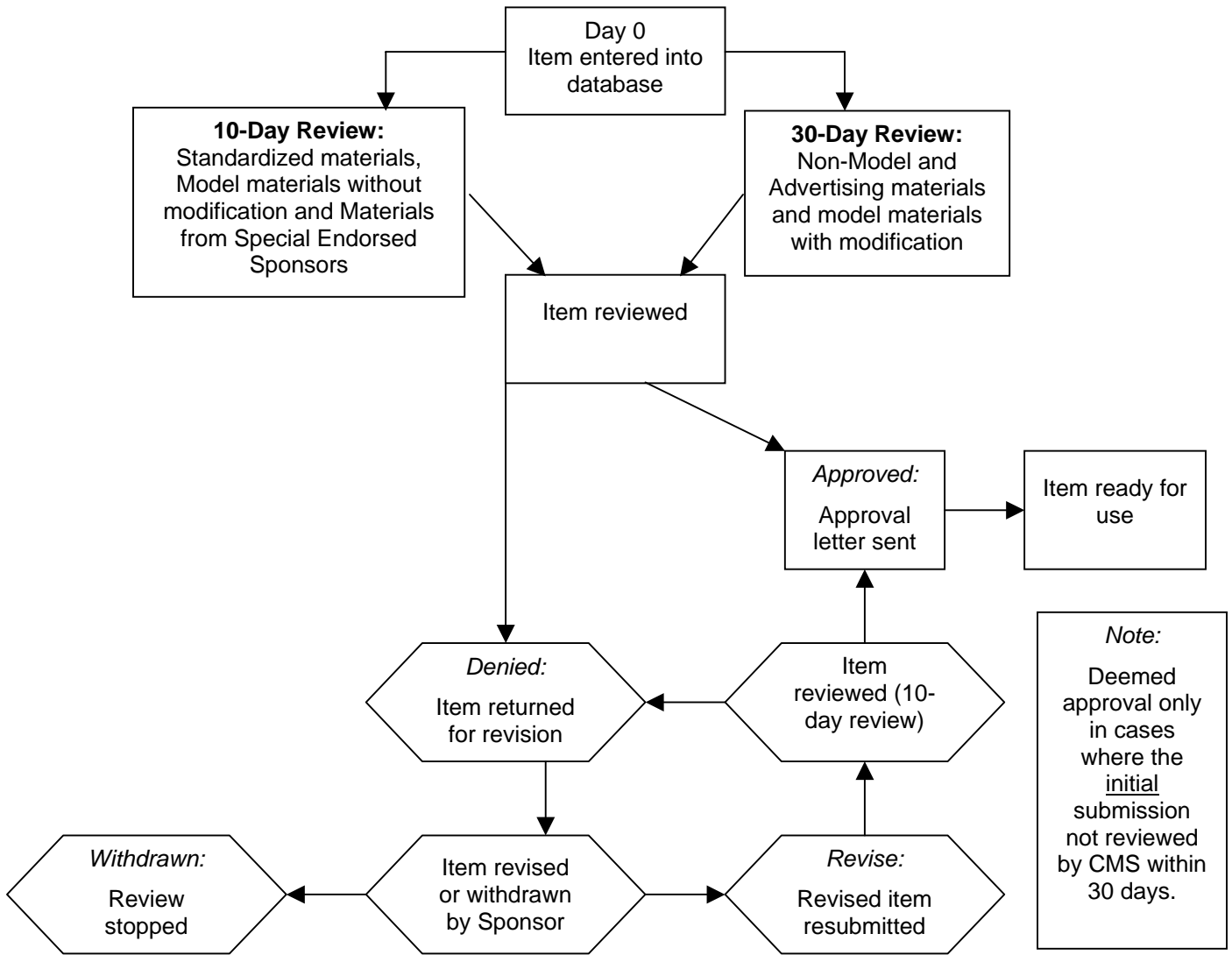
Endorsed Card Sponsor withdraws item or chooses not to resubmit the item, or

Endorsed Card Sponsor revises and resubmits material and the item undergoes the resubmission review process.

There is no deemed approval for resubmitted materials.

Until a resubmitted item is approved, Endorsed Card Sponsors may not use the materials in the marketplace; there is no deemed approval during the resubmission phase. Once a resubmitted item is approved, materials remain approved until changed by the Endorsed Card Sponsor or conditions change that make the materials no longer compliant.

**Exhibit 1: Initial Review Processes: Streamlined (10-Day) and Standard (30-Day)**



## **File and Use Privileges**

The File and Use program will be another approach for streamlining the review process. Endorsed Card Sponsors that demonstrate they can meet a particular standard of performance will be able to publish and distribute advertising materials, as defined earlier in this document, without prior CMS approval.

### *Eligibility for File and Use*

File and Use will be implemented and offered to Endorsed Card Sponsors who have been endorsed for six (6) months. After six months the Endorsed Card Sponsor must make a written request to CMS for File and Use privileges. The Endorsed Card Sponsor must obtain written approval from CMS for these File and Use privileges. CMS will select a random sample of eligible materials that the organization used in the marketplace over the prior six months. Ninety percent of these materials must be “acceptable,” according to File and Use standards set by Medicare. This means that 90 percent of these materials were approved by CMS on the initial submission.

**Eligible Materials:** All advertising communications and materials in any medium, such as brochures, flyers, direct mail pieces, will be eligible for File and Use. (Note: When an Endorsed Card Sponsor with more than one Approved Card Program submits the same advertising piece for each program, these items will only be counted as one eligible piece.) Materials not eligible for the File and Use program are materials that CMS believes pose a greater risk to a Medicare beneficiary if they are inaccurate in any way. These include any materials that are not advertising materials, such as the member handbook, annual notice of change, pharmacy directory, listing of prescription drugs and enrollment forms.

**Acceptable Materials:** All items that upon their initial submission are not materially inaccurate or misleading or otherwise make a material misrepresentation, follow the Information and Outreach guidelines delineated in this document, and need minimal or no modification. If the materials need any modification, the changes requested are minimal. This means that the changes would have no impact on a beneficiary’s decision to elect the Approved Card Program: they would not cause a member to disenroll, and/or would not cause a member to believe they could not get coverage for a covered service.

Examples of changes that would result in an item being unacceptable include failing to include a disclaimer for drug prices or benefit information.

Examples of changes that would not affect File & Use Status are not adhering to font-size requirements for an ad or to provide incorrect dates or times for a sales presentation. Persistent errors in sales presentation dates or persistent failure to adhere to font size requirements could cause CMS to begin considering an organization’s materials to be unacceptable.

## **Procedures to Follow When Using File and Use**

Endorsed Card Sponsors, who have been granted File and Use status, should follow the procedures listed below for their materials.



- 1) The Endorsed Card Sponsor must provide CMS with copies of all final materials at least five (5) calendar days before their intended distribution. Final materials are copies that will be sent to the printer, or comparable copies that are provided for reproduction. All organizations must specify the expected date of initial distribution or publication when filing materials with CMS. They must clearly indicate on the front cover of the submission that the material is being filed as a File and Use item. Upon receipt of materials CMS will log the materials into a tracking system.
- 2) If the organization submits materials under File and Use but later decides it does not want to use the materials, it **must** notify CMS in writing that it no longer intends to use them. This is to ensure that CMS does not review those materials as part of the quarterly random sample.

#### *How to Maintain File and Use Status*

Once an organization is permitted File and Use privileges, it must do the following to maintain that status:

The organization must develop and use at least five eligible advertising materials each calendar quarter in order to maintain File and Use privileges. (Note: When an Endorsed Card Sponsor with more than one Approved Card Program submits the same advertising piece for each program, the advertising material will only be counted once when calculating the five eligible pieces).

Ninety percent of the eligible materials used under File and Use during the preceding calendar quarter were determined to be “Acceptable” per File and Use standards set by Medicare. (Note: When an Endorsed Card Sponsor with more than one Approved Card Program submits the same advertising piece for each program, the advertising material will only be counted once.) For instance, an Endorsed Card Sponsor with File and Use status submits a web page for review in November. In the previous quarter ending September 30, this Endorsed Card Sponsor had submitted 20 advertising materials and 19 were approved on the initial submission (more than 90%). The web page submitted in November may be used five (5) days after submission unless CMS provides a denial notice to the Endorsed Card Sponsor.

The organization must follow the procedure outlined in the section above entitled “Procedures to Follow When Using File and Use”.

The Endorsed Card Sponsor must continue to submit for standard review materials that are not eligible for File and Use privileges and follow the Information and Outreach guidelines.

#### *Loss of File and Use Status*

An Endorsed Card Sponsor may lose File and Use privileges if it:

- Continually uses materials that do not meet the definition of “Acceptable.”
- Fails to file two or more materials at least 5 calendar days prior to distribution or publication.

- Fails to notify CMS two or more times that it has retracted materials it had originally filed under the File and Use program.
- If it is determined during random or for-cause reviews of actual materials in the marketplace that materials were never filed with CMS or that submitted materials were altered.

**NOTE:** CMS will notify the Endorsed Card Sponsor in writing if their File and Use privileges will be revoked. If these privileges are revoked, the organization may not request File and Use privileges until the following quarter. CMS will continue to review materials on the 30-day review process until privileges have been regained. A written notice will be sent to the Endorsed Card Sponsor once they again become eligible for File and Use privileges.

### **Review of Materials in the Marketplace**

CMS will randomly obtain and review Endorsed Card Sponsor Information and Outreach and advertising materials in the marketplace to ensure that these materials have not changed from what was filed with CMS and to ensure that the materials were not commingled with materials describing non-endorsed features. In addition to random reviews, CMS may complete “for-cause” reviews in response to complaints from the public. CMS will collect and review complaints information and investigate the most serious allegations. The data collected from complaints, along with other quality indicators may inform an intermediate corrective actions process, and, potentially, could cause revocation of the Medicare endorsement.

## **Chapter 5 – Required Information and Outreach Materials**

Endorsed Card Sponsors will be required to provide certain types of Information and Outreach materials prior to enrollment, following enrollment, and on an annual basis after enrollment. A description of the materials required at each of these intervals is provided below. Endorsed Card Sponsors may include additional materials provided that these meet the requirements of the Guidelines.

### **Pre-Enrollment Packet**

When Endorsed Card Sponsors send Medicare beneficiaries the pre-enrollment information packets, the packets must include at least the materials listed below and these materials must include the elements as noted. Additional materials may be included provided these meet the requirements of the Guidelines.

- A cover letter that includes the Endorsed Card Sponsor’s toll-free customer service telephone number, including a toll-free TDD/TTY telephone number, and the hours during which customer service representatives are available to answer questions or assist beneficiaries with the enrollment process. The letter must also indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227) or TTY users should call 1-887-486-2048 for more information about Medicare benefits and services.
- Enrollment instructions and forms for both the Approved Card Program and the up to \$600 credit in annual Transitional Assistance.
- A Summary of Program Features that briefly describes the Approved Card Program and must include the following information:
  - ◇ Enrollment process, enrollment fees (if any), and the consequences of non-payment of the annual fee.
  - ◇ Eligibility requirements.
  - ◇ The types of drugs available for a discount and how to get more complete information -- including visiting the Medicare price comparison website and by calling the Endorsed Card Sponsor’s customer service number.
  - ◇ A drug list that includes discounts applicable by drug.
  - ◇ The Endorsed Card Sponsor’s service area.
  - ◇ The availability of a grievance process.
  - ◇ Endorsed Card Sponsor’s customer service number, TTY Number, and physical address.

- ◇ Types of pharmacies within the Endorsed Card Sponsor's network (i.e. retail, independent, grocery, etc.) and directions on how to receive more information about the network.
- ◇ Any other endorsed features (services offered under the endorsement, related to covered discount card drugs, and offered for no additional fee). See definition of Endorsed Features in Chapter 3.
- ◇ Whether discounts on over-the-counter drugs are provided.
- ◇ An explanation of the Endorsed Card Sponsor's policy for individuals who paid an enrollment fee for a non-Medicare discount card program (for use in 2004) that became an Approved Card Program. The policy should explain whether the earlier fee will be credited to the Approved Card Program, or whether the beneficiary needs to pay the full enrollment fee. The following rules apply to Endorsed Card Sponsors who wish to apply an earlier fee to the Approved Card Program:
  - The beneficiary must already be enrolled in a non-endorsed drug discount card program sponsored by the Endorsed Card Sponsor with features similar to the design submitted and approved for Medicare endorsement. The beneficiary must have already paid a fee for the use of the card in calendar year 2004. Both programs must be in the same state.
  - If these conditions are met, the amount paid by the beneficiary *may be* applied by the Endorsed Card Sponsor to the standard enrollment fee charged for the similar Approved Card Program. A fee may not be charged to those applying for, or those who have received, Transitional Assistance.
- For beneficiaries who qualify for the Transitional Assistance, CMS will reimburse the Endorsed Card Sponsor for the full amount of the Endorsed Card Sponsor's enrollment fee charged for the Approved Card Program, and the Endorsed Card Sponsor must reimburse to the beneficiary the amount that the Endorsed Card Sponsor credits beneficiaries who do not receive Transitional Assistance.
- The Endorsed Card Sponsor must implement this policy uniformly. That is, it would apply to all beneficiaries who paid the fee for use of the card in 2004.
- However, it is a choice whether the Endorsed Card Sponsor implements this policy or decides not to recognize the prior fee paid if the Endorsed Card Sponsor's program meets the conditions stated above.
- A description of mail order services offered by the Approved Card Program (if available) must include the maximum expected turnaround time for the processing and shipment of all mail orders and telephone numbers (including TTY) to call if there are questions. It must also describe the process for enrollees to obtain a prescription if a mail order shipment is delayed.
- A disclaimer that some drugs, and the discounted prices for those drugs, are subject to change as frequently as weekly, depending on whether the cost of purchasing the drugs from the manufacturer has changed, and that prices will be reported at least weekly.

- A disclaimer, if it applies, that drugs offered and their discounted prices vary by beneficiary characteristic (such as by income) and geographic area.
- A disclaimer targeted at travelers, particularly “snowbirds,” people who reside in two different places during the year, for Approved Card Programs that do not include the entire United States about the lack of access to discounted prices and Transitional Assistance when traveling outside the Endorsed Card Sponsor’s service area.
- A description about how enrollees will be informed of the differential between the price of the prescription drug to the enrollee and the price of the lowest priced therapeutically equivalent and bio-equivalent generic covered discount card drug available at that pharmacy.
- A description of “Transitional Assistance,” including a description of eligibility standards set by Medicare, benefits, and the enrollment process. This description should highlight the advantages of applying and qualifying for Transitional Assistance, and how it works, such as the amount available in 2004 and 2005 (including a note about proration if they do not choose to become eligible until 2005, using the information in Table 1, in Section II.A.4. of the interim final rule), that any balance of the unused assistance rolls over each year including into 2006.
- Clearly disclose information on enrollment and disenrollment rules, including special election periods (SEP) and the annual enrollment period in 2005, specifically the conditions of enrollment and potential consequences of disenrollment for enrollees in the Approved Card Program and for those who qualify for Transitional Assistance, particularly if they do not disenroll during the annual enrollment period or under a SEP.
- Annual Coordinated Election Period – November 15<sup>th</sup> through December 31, 2004. If a beneficiary chooses to enroll in a new Approved Card Program during this time, the effective date of their disenrollment from the Endorsed Card Sponsor’s Approved Card Program and enrollment in the new Approved Card Program will be January 1, 2005.
- Explain that any \$600 credit remaining when a beneficiary enrolls in a new Approved Card Program during the annual coordinated election period or during a SEP will follow the beneficiary to their new Approved Card Program and may be used toward the cost of prescription drugs obtained using the new Card.
- Explain to the beneficiary that when s/he disenrolls from one Approved Card Program and enrolls in another s/he may be charged a new annual enrollment fee for the newly joined Approved Card Program.
- Explain that if a beneficiary disenrolls for specific reasons (i.e. moves out of Approved Card Program service area, enters or leaves a skilled nursing facility, etc.), s/he will be given a Special Election Period and will be allowed to enroll in another Approved Card Program at any time until December 31, 2005.
- Explain that if a member disenrolls for non-approved reasons, s/he will lose any remaining \$600 credit. The beneficiary will also have to reapply, and Transitional Assistance may be

prorated depending on the application date in 2005.

- A description of the automatic disenrollment policy if joining a Medicare Managed Care plan offering an Exclusive Card Program, as beneficiaries in such Medicare Managed Care plans are not allowed to participate in other Approved Card Programs.
  - ◊ Disclosure of the coverage period of the Rx Discount Card Program relative to the Part D drug benefit implementation, and that the enrollee will receive information sometime in 2005, before Part D enrollment period begins in 2006, about how he/she may transition into the Part D drug benefit.
- A Privacy Notice (see Chapter 2 for more information about Privacy Notices);

NOTE: Enrollment Forms, Cover Letter, Summary of Program Features, and Privacy Notice can be submitted as a Pre-enrollment Packet. However, if an Endorsed Card Sponsor wishes to submit only a Pre-Enrollment Packet, this must be indicated on the item submission form in order for the Endorsed Card Sponsor to receive acknowledgment of submission of all required documents.

### **Post-Enrollment Package**

Within seven (7) days of receipt of a completed enrollment form, Endorsed Card Sponsors are required to mail the enrollee a letter indicating that the Endorsed Card Sponsor has received the enrollment form and is in the process of making an eligibility determination. Within five (5) days of receiving the eligibility determination, Endorsed Card Sponsors must mail the enrollee an eligibility determination letter and, if the individual has enrolled in the Rx Discount Card program, a post-enrollment package. A reasonable effort should be made by the Endorsed Card Sponsor to provide the post-enrollment package by the first day of the month following the date the completed enrollment form was provided. The post-enrollment package must include at least the materials listed below and may include additional materials provided these materials meet the requirements of the Guidelines.

- Cover letter that includes the Endorsed Card Sponsor's toll-free customer service telephone number, including a TDD/TTY telephone number, and the hours during which customer service representatives are available to assist beneficiaries. The letter must also indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227) or TTY users should call 1-887-486-2048 for more information about Medicare benefits and services;
- Prescription drug discount membership card (see Chapter 8, Section 4 for more information about membership cards);
- Member Handbook that provides:
  - ◊ Information about how to use the Approved Card Program to obtain prescription drugs at discounted prices and that prices are subject to change.
  - ◊ An explanation of the Approved Card Program costs including the enrollment fee (if any) and the required coinsurance for Transitional Assistance enrollees.

- ◇ A description of the Approved Card Program’s service area, including special enrollment and disenrollment provisions for people who reside in two different places during the year (“snowbirds”) if the Approved Card Program’s service area is smaller than the entire U.S.
- ◇ A summary of the Transitional Assistance feature including a description of eligibility standards set by Medicare, benefits, and the enrollment process; the summary should include details on how to determine the balance of the assistance amount available to the member, either at the pharmacy or by contacting the Endorsed Card Sponsor; it should also include a description of any circumstances and special procedures that relate to potential Transitional Assistance enrollee liabilities stemming from procedures Endorsed Card Sponsors have in place to manage Transitional Assistance against an enrollee’s cap or Transitional Assistance balance transfer to a newly elected Approved Card Program.
- ◇ If applicable, in keeping with §403.816, special rules for beneficiaries accessing Transitional Assistance through pharmacies serving residents in long-term care facilities or I/T/U pharmacies.
- ◇ If applicable, in keeping with §403.817, special rules for residents of the U.S. Territories.
- ◇ A detailed description of the grievance process.
- ◇ Endorsed Card Sponsor must provide information about other prescription drug quality services or drug-related services offered at no additional fee, including medication therapy as required or discounts on over-the-counter drugs. Endorsed Card Sponsors can also include in their Approved Card Program products or services that are related to covered discount card drugs but which do not fit into a category of required services. An example might be a piece of DME related to a discount drug. All Endorsed Card Sponsors must also implement and provide information on programs designed to reduce medical errors and adverse drug interactions. Any product or service not related to a covered discount card drug, other than a discount on an over-the-counter drug, could not be provided under the Medicare endorsement and would be considered outside the scope of the endorsement.
- ◇ A description of mail order services offered by the Approved Card Program (if available) must include; the maximum expected turnaround time for processing and shipment of all mail orders, a description of the process for enrollees to obtain a prescription if a mail order shipment is delayed, and the telephone number (including TTY) to call if there are questions.
- ◇ A description of how enrollees will be informed of the differential between the price of the prescription drug to the enrollee and the price of the lowest priced therapeutically equivalent and bio-equivalent generic covered discount card drug available at that pharmacy. It must also indicate that contracted pharmacies will always provide the lowest of the discounted price or the usual and customary price

- (i.e., the price that the pharmacy would charge a customer who does not have any form of prescription drug coverage).
- ◇ Information about discounts on over-the-counter drugs if offered.
  - ◇ Endorsed Card Sponsor must describe consequences of disenrollment without being eligible for a Special Election Period (i.e., beneficiary must re-qualify for the drug card and/or Transitional Assistance; enrollment will not be effective until January 1, 2005 at the earliest; Transitional Assistance enrollee loses any remaining balance of the Transitional Assistance and it will not roll over to the next year. If Transitional Assistance enrollee applies for Transitional Assistance in 2005, the Transitional Assistance may be prorated depending upon date of application.
  - ◇ Endorsed Card Sponsor must describe how disenrollment occurs if enrollee fails to pay enrollment fee [§403.811(b)(6)].
  - ◇ Exclusive Endorsed Card Sponsors must specify that members could be group enrolled, an enrollee must actively decline enrollment, and an Exclusive Endorsed Card Sponsor's enrollee may not enroll in another Approved Card Program.
  - ◇ Endorsed Card Sponsor must describe the rules for getting a Special Election Period. [§403.811(b)(2)].
  - ◇ Information about how and where to report fraud and abuse.
- Pharmacy Provider Directory (see Chapter 8 for more information);
  - Discount drug list applicable to the member's income and geographic area (see Chapter 8 for more information about formularies) with the disclaimer that prescription drugs listed in the discount drug list are subject to change; and
  - A Privacy Notice (see Chapter 2 for more information about Privacy Notices).

## **Annual Mailings**

In the second year of the Approved Card Program, Endorsed Card Sponsors must send all members either an Annual Notice of Change (ANOC) or, an Annual Notification Letter (ANL) stating there are no changes to the Approved Card Program.

An ANOC must clearly detail all changes to the Approved Card Program and inform the member of what to do if the member wishes to remain enrolled in the program or enroll in another Approved Card Program. The ANOC should also include information regarding where to find additional information about other Approved Card programs and dates of the Annual Election Period. In addition, the Endorsed Card Sponsor must send all members revised member handbooks that reflect these changes, which impact the features and benefits of the program.

If there are no changes to the Approved Card Program, the ANL must clearly state there are no changes, and inform the member what to do if the member wishes to remain enrolled in the Approved Program or enroll in another Approved Card Program. As mentioned previously, the



Sponsor must disclose where to find information about other Approved Card Programs and the dates of the Annual Election Period. Members should also be informed how to request a replacement handbook. Model documents for both of the ANOC and ANL are available on the CMS Sponsor website.

Additionally, upon a member's request, an Endorsed Card Sponsor must send a mailing that includes the materials listed below. Additional materials may be included provided these meet the requirements of the Guidelines.

- Cover letter that includes the Endorsed Card Sponsor's toll-free customer service telephone number, including a TDD/TTY telephone number, and the hours during which customer service representatives are available to assist beneficiaries. The letter should also indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227) or TTY users should call 1-887-486-2048 for more information about Medicare benefits;
- Member Handbook with information specified above;
- Pharmacy Directory (see Chapter 8, Section 2 for more information about provider directories);
- Discount drug list applicable to the enrollee's geographic area (see Chapter 8 for more information about formularies) with the disclaimer that prescription drugs and discounted prices were last updated on what date and could change by what future date. Discounted prices of prescription drugs and a statement that prices and drugs are subject to change. It must also indicate that contracted pharmacies will always provide the lowest of the discount price or the usual price (i.e., the price the pharmacy would charge a customer who does not have any form of prescription drug coverage);

## **Internet Information and Outreach**

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. This requirement may be satisfied by one of the following:

- (1) Providing ALL Information and Outreach materials on the Endorsed Card Sponsor's website for its Approved Card Program;

OR

- (2) Providing ALL Information and Outreach materials to members or prospective members via e-mail;

OR

(3) Providing the following:

(a) Through CMS' price comparison website, an Endorsed Card Sponsor must report the following information:

- (i) Customer service hours;
- (ii) Customer service contact information;
- (iii) Approved Card Program Web site.

AND

(b) Provide all other Information and Outreach material to members or prospective members via e-mail.

For information provided on the Internet on the Endorsed Card Sponsor's website, the Endorsed Card Sponsor must establish a process for informing members when the web page was last updated, for example, by putting a date and disclaimer on each web page to promote beneficiary understanding that the information might not be current. Information available on or through the internet is subject to these Guidelines and should be the same as information provided in hard copy. If an Endorsed Card Sponsor chooses to provide its Information and Outreach materials on its own website (option 1 above), the information it submits to CMS for the price comparison website must be consistent to avoid confusion.

At a minimum, an Endorsed Card Sponsors' Approved Card Program Internet pages must include the following items. If the Endorsed Card Sponsor does not have a website, it must have the capability to send Medicare beneficiaries all of the information listed below via e-mail.

- Approved Information and Outreach materials. This includes both pre-enrollment and post enrollment materials.
- Toll-free customer service telephone number, including a TDD/TTY telephone number, and the hours during which customer service representatives are available to assist beneficiaries.
- Toll-free 1-800-MEDICARE (1-800-633-4227) telephone number for more information about Medicare benefits and services or TTY users should call 1-887-486-2048.
- Information about how to apply for Transitional Assistance (up to \$600 annually to help pay for prescription drugs) and that those receiving Transitional Assistance and enrolled in the Endorsed Card Sponsor's Approved Card Program may use the Endorsed Card Sponsor's toll-free telephone (and other communications means if appropriate) to track the amount of Transitional Assistance available to them at any given time.
- Beneficiaries MAY apply to enroll in the Approved Card Program on the Endorsed Card Sponsor's website by checking the appropriate box.
- Beneficiaries MAY NOT apply for Transitional Assistance on the Endorsed Card Sponsor's website. A signature is required. Endorsed Card Sponsor websites should be programmed so the enrollment forms for Transitional Assistance can be printed and then either mailed or

faxed to the Endorsed Card Sponsor.

- Complete list of contracted pharmacies.
- Complete list of drugs and discounted prices, including when these were last changed and when any changes will be posted again. Prices can change weekly depending on the cost of purchasing drugs from manufactures. NOTE: The prices on the Endorsed Card Sponsor's website must be in agreement with the prices posted on the Medicare Price Comparison website. It is the responsibility of the Endorsed Card Sponsor to provide regular updates to this website to assure prices agree.
- Differentiation of drugs and price by characteristics and income.
- Participation rules, including:
  - ◇ Special rules for Endorsed Card Sponsors serving beneficiaries in long-term care facilities, if applicable,
  - ◇ Service area,
  - ◇ Special rules for American Indians/Alaska Natives using I/T/U pharmacies, if applicable,
  - ◇ Special rules for Endorsed Card Sponsor's serving only U.S. Territories.
  - ◇ As discussed in Chapter 2, in certain circumstances, Endorsed Card Sponsors will be allowed to commingle information about endorsed features and non-endorsed features on their Websites. An organization's Web pages listing its full range of products and services, including but not limited to its Approved Card Program, are deemed as targeting the public at-large. For example, in these cases, the Endorsed Card Sponsor's organization's web page may, for example, include a link to the Web page(s) describing the Approved Card Program(s). However, Web pages specifically describing the Approved Card Program and targeting current or potential discount card enrollees, may not include information about non-endorsed products and/or services. Endorsed Card Sponsors also may not imply that any non-endorsed features are approved by CMS or Medicare (see section 1140 of the Social Security Act).

## **Chapter 6 – Use of Medicare Name or Medicare-Approved Seal**

Endorsed Card Sponsors may not under any circumstances use the Medicare name or Medicare-approved seal (the “seal”) to promote any product or service other than those covered within the Medicare-Endorsed Prescription Drug Discount Program. In addition, Endorsed Card Sponsors may not claim or imply that their non-endorsed features are recommended or approved by CMS and/or Medicare.

Section 1140 of the Social Security Act, 42 USC §1320b-10 prohibits the use of the Department’s name and logo, the agency’s name and identity seal, and the word “Medicare” or “Medicaid” in a manner which would convey the false impression that such item is approved, endorsed, or authorized by CMS or DHHS, or that such person has some connection with, or authorization from, CMS or DHHS.

### **Agency**

Department of Health and Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), Center for Beneficiary Choices (CBC).

### **Summary**

This notice provides information and instructions to all Medicare-Endorsed Prescription Drug Discount Sponsors (“Endorsed Card Sponsors”) on the use of the Medicare-Endorsed Prescription Drug Discount Card Program (“Approved Card Program”) name and seal.

EFFECTIVE DATE: May 2004

### **Authorized Users**

The Medicare-Endorsed Prescription Drug Discount Card Program authorizes Endorsed Card Sponsors to use the name and seal only after written notification of approval into the Approved Card Program. Approved Card Program entities may use the name and seal after review and approval of marketing materials, such as stationery, posters, recruitment literature, newsletters and other promotional items designed to inform persons with Medicare about the Approved Card Program.

Those entities that are Exclusive Endorsed Card Sponsors are required to use the Medicare-approved seal. For Exclusive Card Sponsors that are Medicare managed care organizations wanting to use a single card, it is a requirement that the seal is included on the member identification card. If Medicare managed care organizations offering an exclusive card want to use two cards (one for the Approved Card Program and one for the approved Part C program), then the seal only has to be on the Approved Card Program member identification card.

## **Use of Medicare-Approved Name or Seal on Items for Distribution**

Only Endorsed Card Sponsors may use the Medicare-Endorsed Prescription Drug Discount Card Program name and seal on items they distribute, provided the item follows guidelines for Nominal Gifts, as stated in Chapter 9 of these guidelines. Items with the Medicare-Endorsed Prescription Drug Discount Card Program name or seal cannot be sold.

## **Approval**

Requests to distribute items bearing the Medicare-Endorsed Prescription Drug Card Program name or seal must be submitted at least thirty (30) days prior to the anticipated date of distribution. Approved requests will be effective for a period not to exceed one year *or* at the time of termination from the Approved Card Program and only for those items for which such written approval was granted.

Requests for approval to use the Medicare seal should be sent to: CMS Public Affairs Office/Visual and Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03. *The approval to use the Medicare-approved seal is a separate process from the Material Review process but does not require the submission of materials. Approved Endorsed Card Sponsors will be sent detailed instructions regarding this procedure.*

## **Restrictions on Use of Medicare Name or Medicare-Approved Seal**

Unless otherwise approved, all unauthorized individuals, organizations, and/or commercial firms may not distribute materials bearing either the Medicare-Endorsed Prescription Drug Card Program name or seal.

Unauthorized use of the Medicare name or Medicare-Approved seal should be reported immediately so that appropriate legal action can be taken. Reports of unauthorized use should be referred to CMS' Public Affairs Office at 7500 Security Blvd., C1-16-03, Baltimore, MD 21244-1850, or by telephone to 410-786-7214.

## **Prohibitions**

Article 42 USC §1320b-10 prohibits the misuse of the Medicare name or seal. In general, it authorizes the Inspector General of DHHS to impose penalties on any person who misuses the term Medicare or other names associated with DHHS in a manner which the person knows or should know gives false impression that it is approved, endorsed, or authorized by DHHS.

Offenders are subject to fines of up to \$5,000 per violation or in the case of a broadcast or telecast violation, \$25,000.

## **Seal Guidelines**

Positive Certification Seal

The Medicare-approved seal is comprised of two elements that appear in an unchangeable fixed relationship: the Medicare oval element and the typographic element.



The typographic element created for the Medicare-approved seal is under and conforms to the shape of the oval element.

The seal cannot be altered in any way, including the translation of any part of it into a language other than English.

### **Obtaining and Use of the Medicare Seal**

An Endorsed Card Sponsor that has received approval to use the Medicare seal from the CMS Public Affairs Office must always use reproducible art available electronically. Do not attempt to recreate the seal. Artwork will be supplied in EPS, TIF, or JPG format. File formats are available from CMS' Office of Public Affairs for other media (e.g., TV) upon request. Endorsed Card Sponsors may also obtain the Medicare seal by accessing:

- <http://www.cms.hhs.gov/images/rxseal/rxlogo.asp>

General guidelines for use of the Medicare seal include:

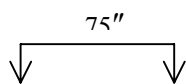
- The Medicare-approved seal is not to be reversed out in white.
- Do not attempt to recreate the Medicare-approved seal.

### **Approved Colors**

The Medicare-approved seal may only appear in 1 color. Approved colors are: 100% Black and 100% PMS 287 (blue) at 100%.

### **Size**

To maintain clear legibility of the seal, never reproduce it at a size less than .75" wide. The seal must be legible.





### Clear Space Allocation

The clear space around the Medicare-approved seal prevents any nearby text, image or illustration from interfering with the legibility and impact of the seal. The measurement “x” can be defined as the height of the letter “M” in “Medicare” in the seal. Any type or graphic elements must be at least “x” distance from the seal as shown by the illustration.



“x”		“x”
“x”		“x”

Detail showing space allocation.

### Bleed Edge Indicator

The Medicare-approved seal may not bleed off any edge of the item. The seal should sit at least 1/8” inside any edges of the item.

## **Incorrect Use**

- Do not alter the position of the certification seal elements.
- Do not alter the aspect ratio of the certification seal. Do not stretch or distort the seal.
- Always use the seal as provided.
- Do not rotate the seal or any of its elements.
- Do not alter or change the typeface of the seal.
- Do not alter the color of any of the seal elements.
- Do not position the seal near other items or images. Maintain the clear space allocation.
- Do not position the seal to bleed off any edge of the item. Maintain 1/8" safety from any edge.



## **Chapter 7 – Special Guidelines**

### **Anti-Discrimination**

Endorsed Card Sponsors may not discriminate based on race, ethnicity, religion, gender, sexual orientation, health status, or geographic location within the service area. All items and services that comprise the Medicare endorsement will be available to all eligible beneficiaries in the service area with the following exceptions:

- There may be additional eligibility standards set by Medicare for Transitional Assistance.
- Endorsed Card Sponsors may offer on a voluntary basis alternative covered discount card drug lists and discounted prices, recognizing certain beneficiary characteristics, such as income, and geographic location.
- Discounted prices on covered discount card drugs may vary geographically.
- Certain non-required products and services related to covered discount card drugs may be available on a voluntary basis to enrollees with certain diagnoses, i.e., medically necessary provisions of items and services. Service areas must not be designed to discriminate based on health status or socio-economic status of potential enrollees in the program. An Endorsed Card Sponsor may target such products and services in a limited geographic portion of their service area if utilization data or medical indicators indicate a need for intervention.
- Endorsed Card Sponsors who are Managed Care organizations offering an exclusive Approved Card Program may serve only their members enrolled in one or more of their Medicare Managed Care plans. However, these Medicare Managed Care organizations may not limit enrollment in its exclusive Approved Card Program to only some discount card eligible individuals enrolled in such health plans. (42 CFR §403.814).
- Endorsed Card Sponsors who qualify for a special endorsement to serve residents of long-term care (LTC) facilities are permitted to limit the drug card offering to Transitional Assistance only, and certain waivers of Approved Card Program requirements apply as provided in (42 CFR §403.816(b)).
- Endorsed Card Sponsors who qualify for special endorsement to serve American Indians/Alaska Natives who use I/T/U pharmacies (those operated by the Indian Health Service, tribes and tribal organizations, and/or urban Indian organizations) are permitted to limit the drug card offering to Transitional Assistance only, and certain waivers of the Approved Card Program requirements apply as provided in (42 CFR §403.816(d)).
- Endorsed Card Sponsors who qualify for a special endorsement to service residents of the territories are required to provide discounted prices, but not Transitional Assistance, and certain waivers of Approved Card Program requirements apply as provided in 42 CFR §403.817.

## **Guidelines for Managed Care Organizations**

Entities offering coordinated care plans under Medicare Advantage (including Medicare Advantage Health Maintenance Organizations) (HMOs), with and without Point of Service options, and Preferred Provider Organizations (PPOs) as well as Medicare cost plans may offer an Exclusive Approved Card Program. These entities will be referred to as Exclusive Card Sponsors and the rules are provided in 42 CFR §403.814.

The Exclusive Approved Card Program will be a new category of “benefits” under which Exclusive Card Sponsors may offer an Approved Card Program to only enrollees of one or more of their health plans.

- A Medicare Managed Care Organization (MCO) may subsidize the enrollment fee (or offer the Approved Card Program for no fee) for drug card eligible Medicare managed care plan members and, if it chooses to do so, the MCO must include the Approved Card Program as an additional benefit under its Adjusted Community Rate (ACR) filing.
- If a Medicare MCO charges a fee that is not subsidized by the plan to eligible Medicare managed care plan members for its Approved Card Program, then the benefit would be considered an optional supplemental benefit.

Please see Chapter 3 on page 9 for a discussion about commingling Information and Outreach materials related to an Approved Card Program and other marketing materials.

An Exclusive Endorsed Card Sponsor’s members are not eligible to enroll in any other Approved Card Program and this information must be disclosed to members.

A Medicare Managed Care Organization may also be a non-exclusive Endorsed Card Sponsor, in which case, they are subject to all of the rules pertinent to any other Endorsed Card Sponsor.

In order to effectively coordinate the Medicare Managed Care Marketing Review and the Rx Materials Review, CMS has developed the following guidelines. These guidelines are meant to assist MCOs in determining under which of the review processes their materials must be approved.

Those Medicare Managed Care Organizations that are Exclusive Endorsed Card Sponsors will submit their Approved Card Program Information and Outreach materials to their designated CMS Regional Office contact for material review.

Those Medicare Managed Care Organizations that are *NOT* Exclusive Endorsed Card Sponsors will submit their Approved Card Program Information and Outreach materials per the instructions in Chapter 4 of these guidelines. Any materials concerning their Medicare Managed Care business (considered non-endorsed services for the purposes of the Approved Card Program) would continue to be sent to their designated CMS Regional Office contact.

Exclusive Card Sponsors are required to use the Medicare-approved seal. Exclusive Card Sponsors who wish to use a single card must include the seal on the member identification card. If Exclusive Card Sponsors wish to use two cards (one for the Approved Card Program and one

for the approved Medicare Managed Care program), then the seal need only be on the Approved Card Program member identification card.

Medicare Managed Care Organizations are permitted to endorse a General Approved Card Program. However, any information developed by the General Approved Card Sponsor for outreach materials to MCO members must (a) indicate that the members may choose a general Approved Card Program that is not endorsed by the Medicare managed care organization; and (b) explain that the 1-800-Medicare number, as well as the [www.medicare.gov](http://www.medicare.gov) website are means of acquiring comparative information about other Approved Card Programs. Additionally, any materials developed by a Medicare managed care organization intended for use by the General Approved Card Sponsor must be submitted first to CMS or its Designee for Information and Outreach material review under these Guidelines.

### **Dual Purpose Marketing Materials**

Any materials developed by a Managed Care Organization intended for use by their Exclusive Card Program and by their General Card Program must be submitted first to CMS or its Designee for the Information and Outreach material review under these Guidelines. Secondly, the Managed Care Organization's program manager will then submit it to the appropriate CMS Regional Office for review.

### **Guidelines for Medigap Insurers**

Approved Card Programs offered by Medigap (Medicare Supplemental) insurers will need to submit advertising and Information and Outreach material intended only for members who have been enrolled or members who are being solicited to enroll in the Approved Card Program. As with Medicare Managed Care Organizations, materials that describe the Approved Card Program and/or its endorsed features and do not include information about the other Medigap insurance features must be submitted for Rx Materials Review only. However, if the Endorsed Card Sponsor is sending materials to all of its insured/members, it may commingle its program materials and information about the existence of its Approved Card Program.

For example, if a Medigap insurer Endorsed Card Sponsor is sending materials to only its members enrolled in its Approved Card Program, the Medigap insurer must follow all rules pertaining to that program, and it must not commingle any materials, even if approved by CMS, concerning non-endorsed features of the Approved Card Program. This prohibition would include any materials related to the Medigap product that are unrelated to the Approved Card Program endorsement. However, if the Medigap insurer is sending materials to all of its plan members, it may commingle Medicare-approved information about the Approved Card Program with its other materials.

### **Guidelines for Programs Endorsed by Entities in Addition to Medicare**

Health plans or other organizations that add their own "endorsement" to a Medicare-endorsed Approved Card Program may add their own brand in addition to, but not instead of, the Endorsed Card Sponsor's label for the Medicare-endorsed Approved Card Program. The Endorsed Card Sponsor will be required to ensure that other "endorsing" organizations label the actual card and

make reference to the Approved Card Program in a manner that is consistent with the CMS Information and Outreach guidelines.

Organizations adding an endorsement cannot imply that they themselves are Medicare-endorsed. Endorsed Card Sponsors must notify CMS when such additional endorsements are being added to the card as well as to Information and Outreach materials about whom the additional entity is, and attest that the additional entity was provided with the Information and Outreach guidelines and that the additional entity agreed to follow these guidelines.

The Endorsed Card Sponsor's name must appear in all Information and Outreach materials in the marketplace, so that Medicare beneficiaries will understand that the additional endorser is not the Endorsed Card Sponsor.

**In all endorsed materials, a disclaimer is required directing the beneficiary to 1-800-Medicare or [www.medicare.gov](http://www.medicare.gov) for the purpose of gathering comparative information.**

## **Guidance Regarding Accommodating Special Needs**

### Non-Native English Speakers

Although CMS does not require that Endorsed Card Sponsors provide Information and Outreach materials in other languages, it is highly encouraged. If an Endorsed Card Sponsor wishes to submit a non-English version of the Information and Outreach material, it should be submitted with the English version (translation) of the piece and a letter of attestation from the Endorsed Card Sponsor that both pieces convey the same information. Endorsed Card Sponsors may be subject to verification monitoring review and associated penalties for violation of this CMS policy. This provision applies to those who are visually impaired.

In addition, call centers must be able to accommodate non-English speaking/reading beneficiaries. Endorsed Card Sponsors should have appropriate individuals or translation services available to call center personnel to answer questions non-English speaking/reading beneficiaries may have concerning aspects of the Approved Card Program.

### Persons with Disabilities

We also encourage Endorsed Card Sponsors to make their Approved Card Programs accessible and appropriate to persons eligible for Medicare because of a disability. When a customer service telephone number is referenced in materials, a toll-free TTY/TDD or relay number to accommodate the hearing impaired must accompany it.

Endorsed Card Sponsors are also encouraged, although not required, to provide materials in alternative formats such as large print or Braille. If an Endorsed Card Sponsor wishes to submit a Braille version of the Information and Outreach material for review, it should be submitted with the text version of the piece and a letter of attestation from the Endorsed Card Sponsor that both pieces convey the same information. Endorsed Card Sponsors will be subject to verification monitoring review and associated penalties for violation of this CMS policy.

## **Guidance for the Welcome Kit for SPAP Enrollees**

When a SPAP is acting as a beneficiary's authorized representative (as defined under State law) the SPAP may enroll the beneficiary into an Approved Card Program and CMS will defer to the SPAP on the materials that should be sent to the SPAP enrollees in the welcome kit. States may choose to have the Endorsed Card Sponsor include only a letter from the State with the membership card, or they may decide that the Endorsed Card Sponsor should include additional, specific "welcome kit" materials designated by the State.

## **Chapter 8 – Guidelines for Developing Information and Outreach Materials**

This section provides Endorsed Card Sponsors with general instructions and a matrix describing required language and prohibited language (i.e., “Must Use/May Not Use” chart) for all Information and Outreach and advertising materials. These guidelines are shaped by two principal factors: (1) language that should be used when conducting Information and Outreach to Medicare beneficiaries, and (2) the need to strike a balance between the desire to educate Medicare beneficiaries and the ability of Endorsed Card Sponsors to operate in a competitive, private sector environment.

The Must Use/May Not Use chart, which begins on the following page, includes guidance on many topics, including but not limited to the following:

### **Program Description / Limitations**

- Use of the Medicare Name and Medicare-Approved Seal
- Eligibility Standards set by Medicare
- Enrollment Fee
- Enrollment Protocol
- Contact Information
- Typeface / Readability
- Notice of “Use of Beneficiary-specific Information” and Beneficiary Consent

NOTE: All approved Information and Outreach or advertising materials must include the date the item was approved by CMS for use, except for those items submitted under the File and Use process.

NOTE: All Information and Outreach materials, including pre-enrollment and post-enrollment materials, with the exception of advertising materials and membership identification cards, are required to include the appropriate disclaimers. Membership identification cards are only required to display the “This is not a Medicare insurance card.” disclaimer.

NOTE: Advertising materials may require use of a disclaimer or declaratory statement (i.e. actor portrayal or paid endorsement). Please see Advertising Must Use/Must Not Use Chart.

NOTE: Non-compliance with the Information and Outreach Materials Guidelines and intentional distribution of Information and Outreach materials that either mislead Medicare beneficiaries or misrepresent the Approved Card Program or Medicare approval, could lead to intermediate sanctions and/or termination of the Medicare endorsement.

NOTE: Endorsed Card Sponsors may include in Information and Outreach materials additional savings offered through pharmaceutical companies. To extend the additional savings to beneficiaries, Endorsed Card Sponsors may request additional income information for use by pharmaceutical companies. However, this additional information request must comply with these Guidelines, the provision of such information must clearly be voluntary, and the request must state its exact purpose (See Must Use/May Not Use Chart – Row 9).

**Section 1-A: Must Use / May Not Use Chart for Information and Outreach Materials**

The following chart provides guidance about the language that Rx Discount Card Programs must use and may not use in Information and Outreach materials. Unless otherwise stated, the requirements outlined within the chart are applicable to ALL Information and Outreach materials including pre-enrollment materials. NOTE: The language in quotation marks in the “Must Use” column is required verbatim.

See Section 1-B for the Must Use/May Not Use Chart for Advertising Materials.

**Must Use / May Not Use Chart for Information and Outreach Materials**

	<b>Subject</b>	<b>Must Use</b>	<b>May Not Use</b>	<b>Reason</b>
1.	<b>Program Description</b>	<p>All Information and Outreach materials (except for membership cards) must include the following statements:</p> <ul style="list-style-type: none"> <li>• “[Program name] is a prescription drug discount card program that is approved by Medicare but it is not a Medicare benefit.”</li> <li>• “[Program name] is not intended to replace prescription drug benefits obtained through participation in insurance plans including a Medicare Advantage plan, a Medigap policy, Medicaid, or an employer or retiree plan.”</li> <li>• Define the service area.</li> <li>• Statement that enrollee must use network pharmacies.</li> </ul> <p>NOTE: Endorsed Card Sponsors must clarify in advertising and Information and Outreach materials, the difference between drug insurance coverage (including under Medicare), discounted prices, and Transitional Assistance offered in Approved Card Programs. Medicare beneficiaries should first determine if their insurance plan applies and if not, then determine if the drug can be purchased using the Approved Card Program.</p>	<p>The term “comprehensive” may not be used when describing Approved Card Program features.</p>	<p>To ensure that Medicare beneficiaries use discount cards appropriately, they must be informed that the Approved Card Program does not replace Medicare coverage or any other medical insurance plan.</p> <p>The term “comprehensive” is vague. No single discount drug list is likely to be comprehensive for all people as it equates to, or at least infers, all-inclusive.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
1.a	<b>Membership Card</b>	<p>Membership card must state that it is a <i>discount card</i>.</p> <p>Membership card must state: "This is not a Medicare insurance card."</p> <p>The membership card should include the Endorsed Card Sponsor's customer service telephone number and the Medicare-approved seal.</p> <p>Note: All Endorsed Card Sponsors are required to use the Medicare-approved seal. Those entities that are Exclusive Endorsed Card Sponsors are also required to use the Medicare-approved seal. For Exclusive Card Sponsors that are Medicare managed care organizations wanting to use a single card it's a requirement that the seal is included on the member identification card. If Medicare managed care organizations offering an exclusive card want to use two cards (one for the Approved Card Program and one for the approved Part C program) then the Medicare-Approved seal only has to be on the Approved Card Program member identification card.</p>		<p>Medicare beneficiaries must be informed that the Rx Discount Approved Card Program does not replace Medicare coverage or any other medical insurance plan.</p>
1.b	<b>Drug Retail Price Comparisons</b>	<p>Drug Retail Price Comparative information must include the retail price and the discounted prices (expressed in dollars) for the most commonly used drugs. Discounted prices should be identified as applicable to generic, brand, or mail order prescription drugs and must include rebates paid at point of sale and dispensing fees. The discounted price should be the maximum price an enrollee will pay.</p> <p>The comparative information about prescription drug prices will be available on the CMS website:  <a href="http://www.medicare.gov">http://www.medicare.gov</a> on the Internet.</p>		<p>Comparative information of the most commonly used drugs will allow beneficiaries to make an informed choice that best meets their needs.</p> <p>NOTE: At a minimum, comparative data includes all therapeutic drug classes, groups and subgroups (identified in Attachment C of the Solicitation).</p>



**Must Use / May Not Use Chart for Information and Outreach Materials**

<b>Subject</b>		<b>Must Use</b>	<b>May Not Use</b>	<b>Reason</b>
<b>1.c</b>	<b>Program Comparisons</b>	Endorsed Card Sponsors are not permitted to include within their materials price comparisons of drugs offered by their Approved Card Program versus the same or similar drugs offered by other Approved Card Programs.		This prohibition is due to Endorsed Card Sponsors' obligation not to engage in activities that may mislead or confuse beneficiaries. The prices of prescription drugs change frequently; therefore it is not possible for information materials to have the most up to date information. Information materials that claim to have information on the prices charged by other Approved Card Program might give Medicare beneficiaries inaccurate or incomplete information. Furthermore, Endorsed Card Sponsors are required to provide beneficiaries accurate and complete information.

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
1.d	<b>Discounts on Prescription Drugs</b>	<p>Information on how to find Endorsed Card Sponsor's negotiated prices (expressed in dollars) for the most commonly used drugs. Discounted prices should be identified as applicable to generic, brand, or mail order prescription drugs and must include rebates paid at point of sale and dispensing fees. This information must be available via customer service options and the Internet.</p> <p>Note: need to also include that this information is available through the CMS price comparison website. Also need to note that discounts on prescription drugs must be provided on all drug lists, including the Top 100 by volume, dosage and supply to which the price applies.</p> <p>Any descriptions about discounts on prescription drugs must:</p> <ul style="list-style-type: none"> <li>• Include a guarantee that enrollees will receive at the point of sale, for all prescription drugs included under the Approved Card Program, the lower of the discounted price available through the program or the price that the pharmacy would charge a customer who does not have any form of prescription drug coverage, including special prices offered by the pharmacy for promotional purposes</li> <li>• Indicate that discounts and drugs are subject to change. Note-need to include the date for when changes were made including references to the Endorsed Card Sponsor's website.</li> <li>• Indicate that discounts may vary based on geographic location or enrollee characteristics.</li> </ul>		<p>Providing beneficiaries with information regarding drug discounts assists them in identifying an appropriate Approved Card Program and helps ensure that enrolled individuals receive the discounted price at the point-of-sale.</p> <p>The Endorsed Card Sponsor must ensure that Medicare beneficiaries receive the lower of the negotiated Approved Card Program price or the pharmacy's lowest price to other cash paying customers.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject	Must Use	May Not Use	Reason
<p><b>2.</b></p> <p><b>Contracted Network Pharmacies</b></p>	<p>All Information and Outreach materials (except for membership cards) must include one of the following statements:</p> <p>“Enrollees must use [Approved Card Program]’s network pharmacies in [service area] to obtain the prescription discount we offer and to apply Transitional Assistance to the prices of your drug. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used.”</p> <p>--Or --</p> <p>“In order to receive a discount through [Approved Card Program], the prescriptions must be filled at a [Approved Card Program] network pharmacy in [service area]. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used.”</p> <p>NOTE: This information may be either in the text of the piece or in a disclosure paragraph at the bottom of the piece.</p> <p>NOTE: This requirement does not apply to mail order operations the Approved Card Program may use.</p>	<p>The term “Participating Pharmacy(s)” may not be used, without the name of the Approved Card Program.</p>	<ul style="list-style-type: none"> <li>Enrollees may <i>incorrectly</i> assume that their discount card will automatically work at any pharmacy.</li> </ul> <p>Approved Card Programs must maintain adequate retail pharmacy networks meeting specific standards as described in § 403.806 (f).</p> <ul style="list-style-type: none"> <li>Using “participating pharmacies” without including the Approved Card Program name may lead beneficiaries to assume that they may receive the Approved Card Program discounts at a pharmacy participating in other Approved Card Programs.</li> </ul>
<p><b>2.a</b></p> <p><b>Travel</b></p>	<p>Reference must be made to the fact that, when traveling, the enrollee must use a network pharmacy in order for the Approved Card Program to be effective.</p> <p>Regional Approved Card Programs must make clear that the service area is limited (by specifying the states, counties, or zip codes served).</p> <p>Information and Outreach materials must be clear about rules pertaining to members who move outside the authorized geographic service area or who reside in two different service areas during the year.</p>		<p>Enrollees may incorrectly assume that the discount card price will be available at non-network pharmacies when they are traveling.</p> <p>Some Medicare beneficiaries live in two places during the year, such as “snowbirds” that live in the southern states to escape winter in the north.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
3.	<b>Mail Order</b>	<p>Information and Outreach Materials that include description of mail order services offered by the Approved Card Program must state:</p> <p>(1) the maximum expected turnaround time for processing and shipment of all mail orders</p> <p>(2) describe the process for enrollees to obtain a prescription if a mail order shipment is delayed, and</p> <p>(3) telephone number (including toll-free TTY) to call if there are questions.</p>		<p>In order to avoid or limit unnecessary breaks in a prescription regimen, enrollees need to be able to anticipate how long it will take to receive their Rx mail order.</p>
4.	<b>Use of the Medicare Name and Seal</b>	<p>Endorsed Card Sponsors may use the term “Medicare-approved” to describe their product in the Information and Outreach materials.</p> <p>Endorsed Card Sponsor shall notify enrollees if their program is no longer approved by Medicare and indicate that the program will remain available for 90 days from the date of notification. Endorsed Card Sponsors must inform beneficiaries that they may enroll in another Medicare-endorsed Approved Card Program. The Endorsed Card Sponsor must inform enrollees that they may call 1-800-MEDICARE for information about other Approved Card Programs. See also Section 1 of this chart and Chapter 6 of these Guidelines.</p> <p>Additional requirements are forthcoming regarding the Medicare Seal. All Endorsed Card Sponsors will be required to use the seal.</p> <p>Those entities that are Exclusive Endorsed Card Sponsors are also required to use the Medicare-approved seal. For Exclusive Card Sponsors that are Medicare managed care organizations wanting to use a single card it's a requirement that the seal is included on the member identification card. If Medicare managed care organizations offering an exclusive card want to use two cards (one for the Approved Card Program and one for the approved Part C program) then the Medicare-Approved seal only has to be on the Approved Card Program member identification card.</p>	<p>Endorsed Card Sponsors may not use “Medicare” in their program name.</p> <p>Neither the Medicare name nor Medicare-approved seal may be used in the promotion of non-prescription drug related services (e.g., dental, vision, massage, or chiropractic services). With the exception of discounts on over-the-counter drugs.</p> <p>Neither the Medicare name nor Medicare-approved seal may be used in the promotion of other prescription drug related services that are associated with a fee beyond the initial one-time enrollment fee.</p>	<p>The word “Medicare” in the program name may be misleading to beneficiaries.</p> <p>Medicare does not offer its approval beyond the prescription discount program, associated prescription drug-related services, and discounts on non-prescription drugs offered at no additional fee. It is misleading and improper to foster the impression that approval extends to non-endorsed services offered by or through the Approved Card Program.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

	Subject	Must Use	May Not Use	Reason
5.	<p><b>Descriptions of the Approved Card Program’s Products and Services related to Covered Discount Card Drugs</b></p>	<p>Endorse Card Sponsors may not use superlatives or unsubstantiated claims within the Information and Outreach materials.</p>	<ul style="list-style-type: none"> <li>• <u>Unsubstantiated claims</u> (e.g., “no limit to the savings,” “impressive” savings or discounts, etc.).</li> <li>• <u>“Superlatives”</u> (e.g., best, most, highest, etc.).</li> <li>• Unsubstantiated discounts rates, like “savings up to 65%”.</li> <li>• <u>Direct, negative statements</u> about other Approved Card Programs including individual statements from enrollees or former enrollees.</li> <li>• The term <u>“comprehensive”</u> may not be used when describing Approved Card Program features.</li> </ul>	<p>Superlatives and unsubstantiated claims may be misleading and prevent enrollees from assessing the validity of the statement.</p> <p>NOTE: Direct comparisons of one Approved Card Program with other Approved Card Programs are not permitted.</p> <p>The term “comprehensive” is vague. No one discount drug list is likely to be comprehensive for all people as it equates to, or at least infers, all-inclusive.</p>
6.	<p><b>Studies or Statistical Data</b></p>	<p>Approved Card Programs may refer to results of studies or statistical data in relation to customer satisfaction, quality, etc. If such studies or data are mentioned, Approved Card Programs must provide the following study details: source, dates, sample size, and number of respondents.</p> <p>If Approved Card Programs use study data that includes information on several other Approved Card Programs, they must disclose the number of programs included in the study.</p>		<p>Study details allow potential enrollees to better evaluate the Approved Card Programs claims and the significance of the study results.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
7.	<b>Drawings / prizes / giveaways</b>	<p>Any “give away” or door prize must be of nominal value (i.e., retail price less than \$15.00).</p> <p>NOTE: See also Section 9.a. of this chart, below, and Chapter 9 for additional requirements regarding prizes and giveaways.</p>	<p>The word “Free” may not be used unless in reference to the annual enrollment fee or qualified to indicate there is a cost for the prescription drugs.</p> <p>Cash gifts and charitable contributions made on behalf of a member or prospective member are also prohibited.</p>	<p>The term “Free” is misleading unless appropriately qualified. Potential and/or current enrollees may incorrectly assume that there is no cost for the prescription drugs.</p>
8.	<b>Eligibility</b>	<p>All Information and Outreach materials (except for membership cards) must include the following statement:</p> <p>Approved Card Sponsor Name] is available to all Medicare beneficiaries in [service area] except for those who have prescription drug coverage under their state’s Medicaid (Medical Assistance) program or those who are enrolled in a Medicare Managed Care Plan that offers its own Exclusive Approved Card Program.</p> <p>Enrollees in Exclusive Approved Card Programs offered by Managed Care Organizations are not eligible for any card but the one offered by their plan.</p> <p>Regional Approved Card Programs must identify geographic service area.</p> <p>NOTE: Eligibility is limited to those people with Medicare whom live within the Approved Card Program service area approved by CMS and who do not have prescription drug coverage through Medicaid.</p>	<p>The following may not be used:</p> <ul style="list-style-type: none"> <li>• “Seniors,” unless the term appears with “...and other eligible Medicare beneficiaries.”</li> <li>• “A prescription Approved Card Program specifically designed for Seniors”</li> <li>• “Individuals age 65 and over are eligible for this program.”</li> <li>• Words or phrases, such as “golden” that imply that the program is only for beneficiaries over age 65.</li> </ul>	<p>Eligibility for the Approved Card Program must be available and promoted to ALL beneficiaries in the service area who qualify based on age, disability status, and ESRD.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

	<b>Subject</b>	<b>Must Use</b>	<b>May Not Use</b>	<b>Reason</b>
9.	<p><b>Enrollment</b></p> <p><b>See also Chapter 7 of these Guidelines.</b></p>	<p>“You may be enrolled in only one Medicare-approved Rx Discount Approved Card Program at one time.”</p> <p>Must explain that enrollees may disenroll from [Rx Discount Card name] at any time but that they will not be able to enroll in a new Approved Card Program until January 1, 2005 unless special circumstances apply. Must explain that enrollees may disenroll by mail or via the Internet.</p> <p>Beneficiaries who have not previously enrolled in an Approved Card Program may enroll at any time during the year.</p> <p>Clearly describe if enrollment date is different from the effective date for access to discounts.</p> <p>Reference must be made to the Annual Election Period (AEP) Nov. 15 through Dec. 31, 2004, and that the effective date will be January 1, 2005 for those who enroll during the AEP.</p> <p>Enrollment form must include all elements from CMS’ standardized Approved Card Program enrollment form.</p> <p>Explain consequences for Transitional Assistance if the beneficiary voluntarily disenrolls, including the following:</p> <p>An individual receiving Transitional Assistance who voluntarily disenrolls from an endorsed discount card program other than for one of the reasons listed in §403.811(b)(2) will forfeit any Transitional Assistance remaining available to the individual on the date of disenrollment, and, if he or she disenrolls in 2004, must re-apply for Transitional Assistance for 2005 in order to receive Transitional Assistance in 2005.</p> <p>Endorsed Card Sponsor must clearly explain pro-ration of Transitional Assistance.</p>	<p>An Endorsed Card Sponsor may ask for more information but it must be clear that any such disclosure by the enrollee is voluntary and not required, and for what purpose the information is being requested and that the eligibility for the drug card and Transitional Assistance is in no way affected by whether the beneficiary has provided the information.</p>	<p>Potential and/or current enrollees may <i>incorrectly</i> assume that:</p> <ol style="list-style-type: none"> <li>1) They can be enrolled in more than one Approved Card Program at one time,</li> <li>2) Approved Card Program enrollment negates other prescription drug benefits for which they are qualified, and/or</li> <li>3) They can enroll in a new Approved Card Program at any time.</li> </ol> <p>A drug discount card enrollee who disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph §403.811(b)(2) will no longer be determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, if he or she disenrolls in 2004, must re-apply for the Medicare Prescription Drug Discount Card and Transitional Assistance Program should he or she wish to enroll in another endorsed discount card program for 2005, the second enrollment year.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

<b>Subject</b>		<b>Must Use</b>	<b>May Not Use</b>	<b>Reason</b>
<b>9.a</b>	<b>Enrollment Fee</b>	<p>If the Approved Card Program enrollment fee or enrollment cost is mentioned, a statement of the fee amount must accompany it.</p> <p>If no enrollment fee is required, it should be clearly stated in the materials. The materials must clearly indicate that there is a cost for the prescription drugs.</p> <p>When appropriate, “free” or “no cost” may be used to describe enrollment. The materials must clearly indicate that there is a cost for the prescription drugs.</p> <p>(Note that disenrollees from one Program may have to pay another annual enrollment fee when enrolling in a new Program.)</p>		<p>In order to assist beneficiaries in making informed choices regarding their Approved Card Program, all program costs must be clearly stated.</p> <p>The term “Free” is misleading unless appropriately qualified. Potential and/or current enrollees may incorrectly assume that there is no cost for the prescription drugs.</p>
<b>10.</b>	<b>Use of Information</b>	<p>When the Endorsed Card Sponsor initially collects protected health information from the beneficiary, the beneficiary must be provided the Endorsed Card Sponsor’s privacy notice. This information may be used by the Endorsed Card Sponsor for Information and Outreach activities and other activities necessary in the operation of the Approved Card Program</p> <p>The sharing of beneficiary information must comply with applicable state/federal privacy laws, e.g., HIPAA, as described in 42 CFR 403.812 and 403.813, and the privacy provisions outlined in these guidelines. Please See Chapter 2 of these Guidelines.</p> <p>Should the Endorsed Card Sponsor reserve the right to change, modify, add or remove portions of their Use of Information statement, they must provide the enrollee advance notice of any changes.</p> <p>Please see Chapter 2 of these Guidelines and the HIPAA Final Privacy Rule for more about the use of protected health information.</p>	<p>Endorsed Card Sponsors are not permitted to obtain enrollee authorization to conduct marketing as provided in 42 CFR 403.813. See Section 11.a. of this chart, below</p>	



**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
11.	<b>Member Consent for Non- Program Information and Outreach Materials</b>	Endorsed Card Sponsors are not permitted to use or disclose protected health information collected through operation of the program from program enrollees to market any products or services that are not approved by Medicare as part of the approved drug card program.	The “Initial” enrollment packet (or web page) and/or periodic Information and Outreach materials must not commingle Information and Outreach materials with marketing materials regarding any non-drug-related services or drug-related services offered for an additional fee.	Medicare approval cannot be associated with non-endorsed features.
12.	<b>Contact Information</b>	<p>All Information and Outreach materials must include the Endorsed Card Sponsor’s name and physical address, a toll-free phone number, a toll-free TTY/TDD number, in the same font and style, along with hours of operation for customer service.</p> <p>Materials should indicate that beneficiaries with questions or complaints should contact the Endorsed Card Sponsor’s Customer Service Center.</p> <p>The material should also indicate that beneficiaries may contact 1-800-MEDICARE and/or Medicare’s TTY/TDD for more information about Medicare benefits.</p>		<p>Potential and/or current enrollees need access to a customer service representative and the option to request additional information from the Approved Card Program.</p> <p>Endorsed Card Sponsors should attempt to resolve enrollee’s complaints or answer enrollee’s questions.</p>

**Must Use / May Not Use Chart for Information and Outreach Materials**

Subject		Must Use	May Not Use	Reason
13.	<b>Typeface &amp; “Readability”</b>	<p>A minimum 12-point font or larger must be used for all Information and Outreach materials except the membership identification card</p> <p>The font size on Approved Card Websites must be in at least 12 point and in Times New Roman style or its equivalent.</p> <p>NOTE: This includes any footnoted information.</p> <p>Foreground/Background contrast must not prevent the average person from being able to read the message.</p> <p>Note: There is an exception of the 12-point font requirement for the Medicare Rx Discount Membership Card, inter-codes, website navigation text, taglines, and CMS Approval Dates.</p>		<p>The use of serif fonts, such as Times New Roman is encouraged since market testing reveals Medicare beneficiaries have difficulty with sans serif fonts, such as Arial.</p> <p>NOTE: CMS experience suggests that reading material be prepared at no higher than a sixth grade reading level. There is software available commercially that assesses reading level.</p>
14.	<b>Transitional Assistance</b>	<p>Endorsed Card Sponsor must clearly indicate eligibility rules and consequences of disenrollment. See (8) and (9) in this table and 42 CFR §403.800-403.822.</p> <p>Materials must refer to the Transitional Assistance amount as up to a \$600 credit toward the cost of prescription drugs.</p>	<p>May not require enrollee to provide information beyond what is required on Enrollment form</p>	<p>Referring to the TA amount as \$600 credit reduces potential confusion that beneficiaries will receive a \$600 payment.</p>
15.	<b>CMS Approval Date Placeholder</b>	<p>All materials submitted for review must have a CMS Approval Date placeholder. The date included in the placeholder is the date the Endorsed Care Sponsor receives an approval letter.</p> <p>The required format of the place holder is:</p> <p>CMS Approval mm/yyyy</p>		<p>Requiring the CMS Approval Date on Information and Outreach materials establishes integrity within the discount drug program and reduces the probability of fraud.</p>
16.	<b>Assigned Material ID Number</b>	<p>Endorsed Card Sponsors must include the material identification number assigned by CMS or its Designee on all printed Information and Outreach materials used in the marketplace. The approved format is simply the material number. The only material exempt is member identification cards.</p>		<p>Requiring the assigned material identification number on the printed materials released in the market place reinforces the integrity of the material review process.</p>
17.	<b>Inbound Telephone Scripts</b>	<p>Hold time messages (recorded information played to caller while waiting on hold) within inbound telephone scripts may only discuss endorsed features.</p>		<p>Hold time messages Telephone Scripts are considered marketing and Information and Outreach materials.</p>

## **Section 1-B: Must Use / May Not Use Chart for Advertising Materials**

Advertising Materials: A subset of Information and Outreach materials and communications in any medium, including but not limited to print, television, radio, telephone, electronic mail, and the Internet, that is intended to attract or appeal to eligible non-members and/or to promote membership retention by disclosing general information about the Approved Card Program. The purpose of these materials is to allow the recipient the opportunity to request additional information that will assist them in making an informed enrollment decision. These materials are not meant to result in enrollment. Advertising materials may not contain information about non-endorsed features.

Example of Advertising Materials: Television Ads, Outdoor Advertising, Banner/Banner-like Ads, Direct Mail, Print Ads (newspaper, magazine, flyers, church bulletins, etc.), Internet Advertising, Fliers, Brochures, Posters, Pharmacists' Buttons, Window Stickers, Counter Tents, Post Stands, Radio, Newspaper, Newsletters, and Magazine Ads, Postcards, Self Mailers, Event Signage, Teaser Post-cards, Home Delivery Coupons, Reply Cards, and Free Standing Inserts (Newspapers, magazines, etc).

### **The following definitions apply to some of the ads addressed in this section:**

**Outdoor Advertising (ODA):** ODA is marketing material that captures the quick attention of a mobile audience passing the outdoor display (e.g. billboards, signs attached to transportation vehicles). It is designed to influence and capture the beneficiary to call for additional detailed information.

**Banner Advertising:** "Banner" advertisements are used in television ads, and flash information quickly across a screen with the sole purpose of enticing a prospective enrollee to call the organization for more information.

**Banner-like Advertisements:** A "banner-like" advertisement can be ODA and is usually in some form of media other than television, it is intended to be very brief and intended to alert someone that information is forthcoming or to entice a prospective enrollee to call the organization for more information.

The following guidelines apply to advertising materials, which are designed to generate request for more program information. Advertising materials may not be designed to generate enrollment. In order to ensure that the potential enrollee has been given the information necessary to make an informed decision, all material submissions that seek enrollment or contain an enrollment form will be designated as Information and Outreach and must meet the requirements of pre-enrollment information.

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
1.	<b>General Requirements</b>	<p>All advertising materials should be clearly stated, comprehensive and in no way misleading to the reader.</p> <p>Confusing language and layouts are to be avoided</p>		
2.	<b>Graphic Requirements</b>	<p>A minimum 12-point font or larger must be used for all advertising materials except for CMS Approval date, internal codes, tag lines that are incorporated into logos, and navigational links on internet pages.</p> <p>NOTE: This includes any footnoted information.</p> <p>Foreground/Background contrast must not prevent the average person from being able to read the message.</p>		
3	<b>Required Information</b>			
3a.	<b>Eligibility</b>	<ul style="list-style-type: none"> <li>• “[Approved Card Program name] is available to all Medicare beneficiaries in [service area] except for those who have prescription drug coverage under their state’s Medicaid (Medical Assistance) program” or those who are enrolled in a Medicare Managed Care plan that offers its own Exclusive Approved Card Program.</li> <li>• Medicare beneficiaries may be enrolled in only one Approved Card Program at a time</li> </ul>		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>3b.</b>	<b>Enrollment Fee</b>	<p>If an enrollment fee is charged, it must be mentioned.</p> <p>If no enrollment fee is required, it must be clearly stated in the materials. And materials must clearly state that there is no fee for enrollment but there is a cost for the prescription drugs.</p> <p>When appropriate, “free” or “no cost” may be used to describe enrollment. But, the materials must clearly indicate that there is a cost for the prescription drugs.</p>		
<b>3c.</b>	<b>Contact Information</b>	<p>All Advertising Materials must include the Endorsed Card Sponsor’s name, a toll-free phone number, TTY number, in the same font and style, and hours of operation for customer service.</p> <p>Radio and TV ads are only required to include toll-free number, TTY number. Web site is optional.</p> <p>ODA, Banner, and Banner-like advertising are required only to have a 1-800 number that interested beneficiaries may call to receive additional information about the Approved Card Program. Hours of operation are not required for these materials</p>		
<b>3d.</b>	<b>CMS Approval Date Placeholder</b>	<p>All materials submitted for review must have a CMS Approval Date placeholder. The date included in the placeholder is the date the Endorsed Card Sponsor receives an approval letter.</p> <p>The required format of the place holder is: CMS Approval mm/yyyy</p>		<p>Requiring the CMS Approval Date on outreach and advertising materials establishes integrity within the discount drug program and reduces the probability of fraud.</p>

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>3e.</b>	<b>Assigned Material ID Number</b>	<p>Endorsed Card Sponsors must include the material identification number assigned by CMS or its Designee on all printed program materials used in the marketplace.</p> <p>The approved format is simply the material number. Example: [XXXX]</p> <p>The only material exempt is member identification cards.</p>		<p>Requiring the assigned material identification number on the printed materials released in the market place reinforces the integrity of the material review process.</p>
<b>3f.</b>	<b>Required Program Descriptions</b>	<ul style="list-style-type: none"> <li>• [Program name] is a prescription drug discount card program that is approved by Medicare but it is not a Medicare benefit.”</li> <li>• “[Program name] is not intended to replace prescription drug benefits obtained through participation in insurance plans including a Medicare Advantage plan, a Medigap policy, Medicaid, or an employer or retiree plan.”</li> </ul>		<p>Endorsed Card Sponsors must clarify, the difference between drug insurance coverage (including under Medicare), discounted prices, and transitional assistance offered in Approved Card Programs.</p> <p>People with Medicare should first determine if their insurance plan applies and if not, then determine if the drug can be purchased using the Approved Card Program.</p>

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>4.</b>	<p><b>Required Disclaimers</b></p> <p>(The disclaimers below and on the following pages must be applied if the information noted in this column is referenced in advertising materials.)</p> <p><b>If mentioned/used in advertising materials:</b></p>	<p><b>Advertising Materials Must include:</b></p>		
<b>4a.</b>	<p><b>Participating Network Pharmacies</b></p>	<p>If the term ‘participating pharmacy’ is used, it must be used with the Approved Card Program name.</p>		
<b>4b.</b>	<p><b>Product Endorsement/ Testimonial</b></p>	<p>If a non-enrollee actor or celebrity is used to promote the Approved Card Program, this must be clearly stated (i.e., “paid endorsement”).</p> <p>If a Medicare beneficiary offers endorsement, the individual must be a current program enrollee.</p> <p>The speaker must identify the Approved Card Program by name.</p> <p>If an actor is utilized to portray a fictitious situation, the ad must clearly state it is a “Paid Actor Portrayal.”</p>	<p>Cannot use anonymous or fictitious quotes by physicians, healthcare provider and/or Medicare beneficiaries.</p>	
<b>4c.</b>	<p><b>Mail Order Pharmacy</b></p>	<p>Advertising materials that mention Mail Order service must provided a means for the recipient to obtain more information.</p>		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>4d.</b>	<p><b>Drug Savings/ Discounts Statements on Prescription Drugs</b></p> <p><b>NOTE:</b> Any discussion of discounts or savings requires the following copy.</p>	<ul style="list-style-type: none"> <li>Indicate that discounts and drugs are subject to change.</li> <li>Indicate that beneficiaries can visit either the Endorsed Card Sponsor's website or Medicare website for specific pricing references to the Endorsed Card Sponsor's website.</li> </ul> <p>"Enrollees must use [Approved Card Program]'s network pharmacies in [service area] to obtain the prescription discount we offer and to apply Transitional Assistance to the prices of your drug. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used."</p> <p>- Or -</p> <p>"In order to receive a discount through [Approved Card Program], the prescriptions must be filled at a [Approved Card Program] network pharmacy in [service area]. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used."</p> <ul style="list-style-type: none"> <li>Indicate that discounts may vary based upon geographic location or enrollee characteristics.</li> </ul>		



**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>4e.</b>	<p><b>Quantitative or Qualitative Drugs Savings Claims</b></p> <p><b>For example:</b></p> <p>(a) An estimate of the percent discount is mentioned (e.g., savings up to 35%).</p> <p>(b) When a claim about the extent of the drug list (e.g., we cover the majority of drugs) is referenced.</p>	<p><b>Required Disclaimer Language Equivalent:</b></p> <p>'Discounts vary by drug. Contact [Program name] to find out if your prescription drug is covered and the discounted price.'</p> <ul style="list-style-type: none"> <li><b>Must also include disclaimers within 4(d)</b></li> </ul>		
<b>4f.</b>	<p><b>Price Comparisons</b></p>	<p>Price Comparative information must include discounted prices (expressed in dollars) from the Endorsed Card Sponsor's top 100 drugs. The comparison should be between the Endorsed Card Sponsor's discount price and the retail price of the drug. Discounted prices should be identified as applicable to generic, brand, or mail order prescription drugs and must include rebates paid at point of sale and dispensing fees. The discounted price should be the maximum price an enrollee will pay.</p>	<p>Note: Inter-sponsor comparative information is only permitted on the Medicare price comparison web site. Endorsed Card Sponsors are not allowed to advertise based on price comparisons between competing Programs and the Endorsed Card Sponsor</p>	

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>4g.</b>	<b>Use of the Medicare Name and Seal</b>	Endorsed Card Sponsors may use the Medicare seal on advertising materials, but it must be compliant with usage regulations, please see Chapter 6.	<p>Endorsed Card Sponsors may not use “Medicare” in their program name.</p> <p>Neither the Medicare name nor Medicare-approved seal may be used in the promotion of non-prescription drug related services (e.g., services including: dental, vision, massage, or chiropractic services), with the exception of discounts on over-the-counter drugs.</p> <p>Neither the Medicare name nor Medicare-approved seal may be used in the promotion of other prescription drug related services that are associated with a fee beyond the initial one-time enrollment fee.</p>	
<b>4h.</b>	<b>Studies or Statistical Data</b>	<p>Advertising materials may refer to results of studies or statistical data in relation to customer satisfaction, quality, etc. If such studies or data are mentioned, programs must provide the following study details: source, dates, sample size, and number of respondents.</p> <p>If Approved Card Programs use study data that includes information on several other Approved Card Programs, they must disclose the number of programs included in the study.</p>		
<b>4i.</b>	<b>Drawings / Prizes / Giveaways</b>	<p>Any “give away” or door prize must be of nominal value (i.e., retail price less than \$15.00).</p> <p>NOTE: See Chapter 9 of the Guidelines for additional requirements regarding prizes and giveaways.</p>	<p>The word “Free” may not be used unless in reference to the annual enrollment fee or qualified to indicate there is a cost for the prescription drugs.</p> <p>Cash gifts and charitable contributions made on behalf of a member or prospective member are also prohibited.</p>	
<b>4j.</b>	<b>Transitional Assistance</b>	If Transitional assistance is mentioned, it must be clear that it is a \$600 credit.		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
5.	<b>PROHIBITED TERMINOLOGY and STATEMENTS</b>		<ul style="list-style-type: none"> <li>• “Seniors,” unless the term appears with “...and other eligible Medicare beneficiaries.”</li> <li>• “A prescription Approved Card Program specifically designed for Seniors”</li> <li>• “Individuals age 65 and over are eligible for this program.”</li> <li>• Words or phrases, such as “golden” that imply that the program is only for beneficiaries over age 65.</li> <li>• <u>Unsubstantiated claims</u> (e.g., “no limit to the savings,” “impressive” savings/discounts.)</li> <li>• <u>“Superlatives”</u> (e.g., best, most, highest, etc.).</li> <li>• Unsubstantiated discounts rates, like “savings up to 65%”</li> <li>• <u>Direct, negative statements</u> about other Approved Card Programs including individual statements from enrollees or former enrollees</li> <li>• The term “<u>comprehensive</u>” may not be used when describing Approved Card Program features</li> </ul>	
6.	<p><b>Exceptions / Special Situations:</b></p> <p>The materials/advertising vehicles listed below are either exempt from select required language, or require additional language/ disclaimers.</p>			
6a.	<b>Business Reply Mail Envelopes (BRM’s)</b>	As long as no copy has been added to USPS provided template, no review is needed		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>6b.</b>	<b>Materials Used by Prescription Drug Providers</b>	<p>Materials used by prescription drug providers informing their clientele about specific Approved Card Programs must refer potential enrollees to <a href="http://www.medicare.com">www.medicare.com</a> or 1-800-Medicare where they can gather comparative information.</p> <p>Letters to the clientele of the providers of prescription drugs, informing them about the Endorsed Card Sponsor's Approved Card Program, must be in the voice of the prescription provider. Not the Endorsed Card Sponsor.</p> <p>When enlisting a provider, including a pharmacy, to promote an Endorsed Card Sponsor's Approved Card Program, the Endorsed Card Sponsor can develop materials for the provider to disclose to beneficiaries. Provider materials may include benefits and features of the Endorsed Card Sponsor's Approved Card Program</p>	<p>Endorsed Card Sponsors cannot require the provider to encourage enrollment in a particular Approved Card Program.</p>	
<b>6c.</b>	<b>Outbound Telemarketing</b>	<p>Endorsed Card Sponsors may contact a beneficiary only if the beneficiary has requested this contact through such vehicles as a response to a direct mail advertising piece or an advertisement.</p>	<p>Cold solicitations such as cold calling or e-mailing are NOT permitted. In addition, as part of the contact, the Endorsed Card Sponsor may discuss only endorsed features. Non-endorsed features may not be discussed or raised</p>	

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>6d.</b>	<p><b>Outdoor Advertising, Banners and Banner-Like Advertising</b></p> <p>I.e., Banner ads, teaser copies, casual mentions (i.e. any advertisement that gives only a phone number for more information), buttons, tent cards, stickers, posters, post stand, etc, etc.</p>	<p>If only contact information is listed (For more information about our Medicare Approved Discount card, call 1-800-xxx-xxx) no additional information is required.</p> <p>However, if details are given regarding the program or its features, the requirements noted in section 1, 2, 3, 4, 5 and 7 of these Guidelines must be followed.</p>		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>6e.</b>	<b>Radio and TV Spots</b>	<p>RADIO Ads:</p> <ul style="list-style-type: none"> <li>• The only contact information required is the Endorsed Card Sponsor's toll free number. TTY Numbers are not required.</li> <li>• They do not have to mention CMS approval date.</li> </ul> <p>If disclaimers are required, they can be worked into the script. (I.e. savings claims, actor portrayal)</p> <p>Television Ads:</p> <ul style="list-style-type: none"> <li>• The only contact information required is the Endorsed Card Sponsor's toll-free number. This information can be displayed on the crawl or banner. The TTY number can be a different size or font so it is clearly differentiated.</li> <li>• Ad does not need to mention CMS Approval Date.</li> <li>• If disclaimers are required, they can be worked into the script or shown on the crawl (i.e. savings claims, service area, actor portrayal)</li> <li>• Medicare contact information is not required.</li> <li>• The only item required for approval is the script. If storyboards or tapes are submitted they will be reviewed – however they are not required.</li> <li>• Sponsors must submit produced copies of ads for possible retrospective review.</li> </ul>		

**Must Use / May Not Use Chart for Advertising Materials**

	<b>SUBJECT</b>	<b>MUST USE</b>	<b>MAY NOT USE/RESTRICTED LANGUAGE or ACTIVITY</b>	<b>REASON</b>
<b>7.</b>	<p><b>Specialized Materials</b></p> <p>In addition to meeting all applicable requirements for advertising materials included in this Chart, the specialized information discussed in this section must be used in the specialized materials discussed below.)</p>			
<b>7a.</b>	<p><b>Sales Presentations:</b></p> <p><b>Flyers and Invitations</b></p>	<p>A Sales Presentation is any group session with the intent of enrolling the attending individuals.</p> <p>Flyers and invitations to sales presentations must state:</p> <p>“an informational representative will be present with information and enrollment forms.</p>		
<b>7b.</b>	<p><b>Sales Presentations:</b></p> <p><b>Response Cards</b></p>	<p>A Sales Presentation is any group session with the intent of enrolling the attending individuals.</p> <p>Response cards where the beneficiary’s telephone number is requested must state:</p> <p>“An informational representative may call”</p>		
<b>7c.</b>	<p><b>Sales Scripts</b></p>	<p>Sales scripts must be reviewed and approved by CMS prior to use. (Please note: Endorsed Card Sponsors are not required to adhere to a specific format for submission, such as verbatim text or bullet points, however required information must be included.)</p>		

**Additional guidance for pharmacy directories and discount drug list are provided within the sections below:**

**Section 2: Guidance for Pharmacy Directories**

Endorsed Card Sponsors are required to provide a pharmacy directory. This directory shall be provided to each card enrollee that at a minimum includes the pharmacies in the beneficiary's geographic area within five (5) days of their enrollment in the program, as well as upon request either before or after their enrollment. Pharmacy directories must include at least the information described below.

- A regional pharmacy directory must include the contracted pharmacy name, address, and telephone number.
- A description of the Approved Card Program's service area.
- Endorsed Card Sponsors may also develop a chain pharmacy directory that lists the name of the pharmacy within the Endorsed Card Sponsors' network. The chain pharmacy directory must give the Endorsed Card Sponsors toll-free customer service and TTY/TTD numbers where beneficiaries can find the nearest chain pharmacy location. Endorsed Card Sponsors may also include chain pharmacy locators on their websites.
- Telephone numbers for the Endorsed Card Sponsor's customer service or appropriate contact information (including the hours of service) for enrollees who have questions or require assistance in selecting a participating pharmacy. The document should also indicate that beneficiaries may contact 1-800-MEDICARE and/or Medicare's TTY/TDD number for more information about Medicare benefits
- A general disclaimer that indicates that the directory is current as of a particular date and that a pharmacy listing in the directory does not guarantee that the pharmacy is still in the network. Endorsed Card Sponsors must indicate that enrollees may receive current pharmacy network information by calling the Endorsed Card Sponsor's customer service telephone number, and the Endorsed Card Sponsor may elect to provide up-to-date pharmacy directories on their website.
- A description of mail order services, if available, including a description of the process for filling a mail order prescription, the maximum expected turnaround time for processing and shipment of all mail orders, a telephone number (if different than the customer service center telephone number), and the process for enrollees to obtain a prescription if a mail order shipment is delayed.



**Figure 1. Example of Regional Pharmacy Directory**

Welcome to [Discount Drug Program]. Below is a list of [Discount Card Program] network pharmacies in your area. You must present your Drug Discount Card to the pharmacist to receive the discounted price.		
ABC Pharmacy 1114 Broad Street Anytown, VA 22201 703-555-1111	Central Drug, Inc. 1060 Broad Street Anytown, VA 22201 703-222-1111	Brooks Pharmacy 1850 Broad Street Anytown, VA, 22201 703-555-1212
123 Pharmacy 2100 Broad Street Anytown, VA 22201 703-555-7777	Middle Drug, Inc 2500 Broad Street Anytown, VA 22201 703-441-1212	River Pharmacy 3000 Broad Street Anytown, VA 22201 703-444-2222

### Section 3: Guidance Regarding the Discount Drug List

Endorsed Card Sponsors may offer a discounted price on all covered discount card drugs. Alternatively, an Endorsed Card Sponsor may limit the offering of discount drugs to a formulary provided that it meets the requirements of 42 CFR §403.806(d)(2) and (d)(3).

A discount drug list must include the Endorsed Card Sponsor’s top 100 drugs for Medicare beneficiaries. The Endorsed Card Sponsor’s top 100 discount drug list is required to be derived from the 209 categories of prescription drugs found on Table 2 of the preamble to our interim final rule. See 68 Fed. Reg. 69840, 69855 (Dec. 15, 2003).

An Endorsed Card Sponsor also has the option to tier discounted prices—a preferred list—either within the formulary or for selected drugs while offering a minimum discount on all covered discount card drugs.

If an Endorsed Card Sponsor uses a formulary or preferred list, Information and Outreach materials must disclose this and how to use it to the beneficiary’s benefit. It must also be noted that regardless of the formulary or preferred list, Transitional Assistance applies to all covered discount card drugs carried by the pharmacy where the purchase is taking place.

**Please Note:**

Endorsed Card Sponsors releasing an updated drug list need only to send a hard copy for file to CMS or its Designee.

Endorsed Card Sponsors are responsible for updating the drug prices displayed on their websites. Likewise, Endorsed Card Sponsors are responsible for submitting and updating prices to the CMS website for program comparisons. Further, it is the Endorsed Card Sponsor’s responsibility to insure that prices posted to the CMS website match those posted on the Endorsed Card Sponsor’s website

**The Discount Drug List must also include the following:**

- Top 100 drugs (note see language from prior references/ refer to Row 1B).
- An explanation of the potential value of generic drugs, and an example of at least one offering.
- Endorsed Card Sponsors are required to include drug prices within their discount drug list. Exclusive Card Sponsors may request a waiver from listing drug prices within their discount drug list from CMS.
- How to obtain a complete list of drugs offered, and the most up to date discounted price list, including from Medicare price comparison.
- When the drug list and discounted prices was last updated and when it could be updated again.
- Telephone numbers for the Endorsed Card Sponsor's customer service or appropriate contact information (including the hours of service) for enrollees who have questions or require additional information. The document should also indicate that beneficiaries might contact 1-800-MEDICARE for more information about Medicare benefits.

**Section 4: Substantiation Documentation**

Endorsed Card Sponsors must provide CMS or its Designee with documentation that supports certain promotional claims at issue within the material submitted for review.

Claims that require a substantiation document include, but are not limited to, amount of actual discount rates, pharmacy network size, or customers served. If one substantiation document is to be applied to multiple materials, the Endorsed Card Sponsor must indicate that the document applies to multiple items and name the documents within the substantiation document.

Endorsed Card Sponsor's submitting substantiation for denied materials, must reference the material identification number assigned by CMS or its Designee as designated in the item receipt or disapproval letter. Endorsed Card Sponsors must also resubmit a new version of the material for CMS or its Designee to review. If no other changes were required in the disapproval, then the Endorsed Card Sponsors may resubmit the same material again. CMS or its Designee will reassign a new material identification number to the resubmitted material.

Substantiation documents are kept on file with CMS and its Designee. However, when an Endorsed Card Sponsor is submitting new material or a resubmission, the Endorsed Card Sponsor must indicate on the item submission/resubmission form that a substantiation document is on file for the claims made within the current material. Nevertheless, if there is a claim within the new material submission that is not addressed in the substantiation document on file, the Endorsed Card Sponsor will have to provide another substantiation document.

**A substantiation document must include:**

For Drug Discounts:

- 3 to 10 Examples
- Name of Drugs
- Dosage and Quantity Applied to Discount
- Retail Price
- Actual Discount

For Pharmacy Networks:

- Statement of collaboration
- Statement detailing number of signed agreements or letters of intent
- Number of chain pharmacies within alliance
- Number of franchise or independent pharmacies within alliance
- Number of unaffiliated independent pharmacies within alliance.

## **Section 5: Membership Cards**

CMS requires as provided in 42 CFR 403.806(g)(4) that an Endorsed Card Sponsor must provide to each enrollee a card that complies with the National Council on Prescription Drug Program's (NCPDP) "Pharmacy ID Card Standard." This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled, Identification Card - Health Care Identification Cards. Thus, there will be references in the discussion below to INCITS 284. Copies of ANSI INCITS 284-1997 may be ordered from American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036 or through the Internet at <http://www.ansi.org> website.

### **Membership Card Design**

- The Medicare Approved Seal must be used on the member ID cards.
- Usage of the Medicare Approved Seal must follow guidelines.
- On the card, the Medicare Seal must be positioned within the bottom third of the card.
- The following disclaimer must be included on the front of the card: "This is not a Medicare insurance card." The disclaimer must be in no smaller than 10-point type and should be

positioned at the bottom center of the card. The type must not bleed and it must be legible.

- Included on the card must be the words: “Prescription Discount Card.” It must be in no smaller than 10-point type and should be positioned within the top third of the card. The type must not bleed and it must be legible.
- CMS Approval date can be on back of card.

**Required NCPDP Data Elements**

The NCPDP implementation of INCITS 284 suggests different data element labeling for some of the data elements in order to better meet the needs of the pharmacy industry. The data element listing in sections 6.1 of INCITS 284 are mapped, where appropriate, to NCPDP data elements in Table 5.1. Please note the location and mandatory requirements in INCITS 284 section 6.1 and the order of first name and last name in section 6.4.3.

**Table 5.1**

<b>INCITS 284 Description</b>	<b>NCPDP Description(s)</b>	<b>INCITS 284 Label</b>	<b>NCPDP Label</b>	<b>NCPDP v5.1 Maximum Field Size</b>
Card issuer name or logo	Card issuer name or logo	None required	None required	N/A
Card issuer identifier	Card issuer identifier	“Issuer (80840)”	“Issuer (80840)” <sup>1</sup>	TBD
Cardholder identification number	Cardholder ID	“ID”	“ID”	20 <sup>2</sup>
Cardholder identification name	Cardholder first name, middle initial, cardholder last name	“Name”	“Name”	First Name=12; Middle Initial=1; Last Name=15
Account number(s)	BIN, Processor Control Number, and Group ID <sup>3</sup>	“Account”	“RxBIN”, “RxPCN”, and “RxGrp” or “Grp” <sup>4</sup>	RxBIN=6; RxPCN=10; RxGrp=15
Claims submission name(s) and address(es)	Claims submission name(s) and address(es)	A suitable label	A suitable label	N/A
Telephone number(s) and name(s)	Help Desk Telephone number(s) and name(s)	A suitable label	A suitable label	N/A

<sup>1</sup> In the label “Issuer (80840),” the number “80840” represents the international identifier for USA.

<sup>2</sup> The INCITS 284 standard specifies a maximum of 19 alphanumeric characters for the cardholder identification number. This guide allows an exception in order to comply with the maximum of 20 as defined in the NCPDP data dictionary and to comply with the pharmacy transaction standard adopted under HIPAA.

<sup>3</sup> Since INCITS 284, section 6.4.4, makes reference to transaction routing information under the definition of “Account Number(s),” this guide maps the pharmacy industry’s transaction routing data elements with INCITS 284’s data element, “Account Number(s).” See Table 3.2 of this implementation guide for further information on RxBIN, RxPCN, and RxGrp.

<sup>4</sup> “Grp” is only acceptable when the ID card is a combination health care card and the group number is identical for all health care services identified to the cardholder.

In the absence of a single national issuer identifier used for transaction routing, this guide requires additional data elements used in the pharmacy industry for transaction routing. Table 5.2 lists three data elements related to transaction routing: BIN (ANSI IIN), processor control number, and Group ID.

**Table 5.2**

<b>Information Element</b>	<b>Standard Label</b>
BIN (ANSI IIN)	"RxBIN"
Processor Control Number	"RxPCN"
Group ID	"RxGrp" or "Grp"

"RxGrp" ("Grp" is acceptable when the ID card is a combination health care card and the group number is identical for all health care services identified to the cardholder.)

Please note that the use of the BIN (ANSI IIN), processor control number, and Group ID data elements may be for an interim period until a time at which wide use of a HIPAA adopted national issuer identifier is evident.

## **Data Element Placement**

### Mandatory and Situational Data Elements

#### Essential Window Information

As indicated in section 6.3 of INCITS 284, there is an essential information window that must be left justified on the front side of the ID card. The vertical placement may be anywhere along the left margin of the card as long as it does not interfere with the placement of other data elements described in this document.

To conserve vertical space on the ID card, the BIN (ANSI IIN) and Processor Control Number may be printed on the same line. The order of the data elements must be as follows and no other data may be interspersed between these data elements:

#### Situational Data Elements

BIN (ANSI IIN)

Group ID

Process Control Number

Effective Date of Card

Mandatory Data Elements

Card Issuer Identifier (Sponsor Program D Number – Assigned by CMS)

Cardholder ID

Cardholder Name (Sequence of name is: given names and initials, surname, and name suffix. Name should not contain punctuation such as periods or commas.

Figure 5.3 illustrates the “essential window information” for the pharmacy ID card.

**Figure 5.2**

RxBIN	999999 (optional)
RxPCN	ABC9999999 (optional)
RxGRP	ABC999999999999 (optional)
Effective Date	mm/dd/yyyy (optional)
Issuer ID	(D Number)
ID	123456789
Name	JOHN Q PUBLIC JR

**Card Issuer Name or Logo**

The card issuer name or logo is a required data element for the pharmacy ID card. Its placement should be along the top margin on the front side of the card; preferably, the upper left corner.

**INFORMATION ON THE BACK OF THE MEMBER ID CARD**

**Claims submission name(s) and address(es)**

“Claims submission name(s) and address(es)” is a required data element for the pharmacy ID card. Its placement must be one of the lowermost elements on the backside of the card. See Figures 4.5 and 4.6 for examples.

**Help Desk Telephone number(s) and name(s)**

“Help Desk Telephone number(s) and name(s)” is a required data element for the pharmacy ID card. Its placement must be on the back of the card near the “claim submission name(s) and address(es)” and as one of the lowermost data elements. It must be clearly labeled (e.g., “Help Desk”, “Customer Service”, “Pharmacy Services”, etc.). See Figures 4.5 and 4.6 for examples.

**Medicare Contact Information**

Medicare contact information is required to enable beneficiaries to obtain information regarding the extent of their Medicare Benefits. Include 1-800 Medicare and 1-800-486-2048 TTT/TDD, on the back of the card.

**Table 5.3**

<b>Mandatory Data Elements</b>		
<b>Information Element</b>	<b>Location</b>	<b>Notes</b>
Card issuer name or logo	Front, top margin	Reference 3.2.1.2. Upper left corner preferred.
BIN (ANSI IIN)	Front, left side	Reference 3.2.1.1.
Card Issuer Identifier	Front, left side	Reference 3.2.1.1. The value, “80840” in the label, “Issuer (80840),” represents an international identifier for the United States of America. The issuer ID must be an authorized identifier. At the time of this guide’s release, this identifier has not yet been enumerated. The most likely candidate for the issuer ID will be the “Plan ID” adopted by CMS as a result of the 1996 Health Insurance Portability and Accountability Act. Although this identifier does not yet exist, the label must be included on the ID card to be compliant with the INCITS 284 standard.
Cardholder ID	Front, left side	Reference 3.2.1.1.
Cardholder Name	Front, left side	Reference 3.2.1.1.
Claims submission name(s) and address(es)	Back, bottom	Reference 3.2.1.3.
Help Desk Telephone number(s) and names(s)	Back, bottom	Reference 3.2.1.4.

### Situational Data Elements

This guide identifies mandatory data elements and specifies the placement of situational data elements. In general, situational data elements are mandatory only when certain specified conditions exist.

#### *Processor Control Number*

The processor control number is mandatory when it is required for properly routing electronic claim transactions.

#### *Group ID*

The Group ID is mandatory when it is required for properly routing electronic claim transactions.

### Excluded Data Elements

Several data elements used by the pharmacy industry have been purposely excluded from this guide. The reasons for exclusion may be due to the physical limitations of standard-size ID cards; the fact that the standard is simply for an identification card and nothing more; the frequent changes of a particular data element; the industry cost (both issuer and provider) to implement; and more. Listed below are several data elements considered and excluded:

- Date of Birth
- Effective Date
- Expiration Date
- Co-insurance or Co-payments

### **Data Element Embossing**

Refer to Annex E of INCITS 284.

### **Machine-Readable Formats**

#### Magnetic Stripe

Capacity restrictions with the magnetic stripe standards are such that the magnetic stripe is not a feasible option for a pharmacy ID card implementation. As such, an alternative technology is to be used for a machine-readable pharmacy ID card.

The alternative technology adopted by NCPDP is the Uniform Symbology Specification - PDF417 2-dimensional bar coding standard. Therefore, this guide instructs card issuers to disregard the INCITS 284 requirement that, at a minimum, a magnetic stripe must be included if any other machine-readable format is implemented.



## PDF417

NCPDP has adopted the standard, as the standard machine-readable format for the Pharmacy ID Card. PDF417 is a multi-row, two-dimensional bar coding symbology or image. The technology was created by Symbol Technologies, Inc.

Its footprint or image size varies depending upon defined user parameters. The data capacity of the image is also determined by the user parameters and the type and order of encoded characters. Alphanumeric characters require more space in the image than numeric characters.

To find more information regarding the PDF417 standard, please refer to Table 5.4.

**Table 5.4**

PDF417 Information	Organization	Web Site
Complete, official specifications	AIM International	<a href="http://www.aimglobal.org">http://www.aimglobal.org</a>
2-Dimensional bar code basics and PDF417 symbology overview; white papers; applications; case studies; etc.	Symbol Technologies, Inc.	<a href="http://www.symbol.com">http://www.symbol.com</a>
2-Dimensional bar code basics and PDF417 symbology overview	Autoid.org	<a href="http://www.autoid.org">http://www.autoid.org</a>

## PDF417 Data Record

Only the data elements needed to identify the cardholder and the card issuer is defined in this implementation of the PDF417 standard. They are:

- BIN (ANSI IIN)
- Processor Control Number
- Group Number
- Card Issuer Identifier (anticipated HIPAA Plan ID – future use)

Table 5.5 describes the PDF417 data record layout including the five key data elements that identify the cardholder and the card issuer.

**Table 5.5**

INCITS Field	NCPDP Mapped Data	Maximum Length	Comments/Values
Start of Text	n/a	1	"%"
Format Character	n/a	1	"H"
Card Issuer	Reserved for future use	18	Anticipated HIPAA Plan ID.
Field Separator	n/a	1	"^"
Cardholder ID	Cardholder ID	20	
Field Separator	n/a	1	"^"
Elec Trans Phone	n/a	15	This data element is generally not populated since it is rarely used or is not applicable.
Field Separator	n/a	1	"^"
Reserved Field	Not used	0	
Field Separator	n/a	1	"^"
Qualifier Code	n/a	2	"BN"
Qualified Data	BIN	6	
Field Separator	n/a	1	"^"
Qualifier Code	n/a	2	"PC"
Qualified Data	PCN	10	
Field Separator	n/a	1	"^"
Qualifier Code	n/a	2	"GR"
Qualified Data	Group ID	15	
End of Text	n/a	1	"?"
	Total Maximum Characters	99	

**Example PDF417 Data Record:**

%H^12345678901^^^BN123456^PC1234567890^GR12345678901234

Extraction of the five key fields from this encoded string would be as follows:

- Card Issuer ID <no value>
- Card Holder ID 12345678901
- BIN (ANSI IIN) 123456
- PCN 1234567890
- Group ID 123456789012345

**PDF417 Image Placement**

The PDF417 image, if printed, must be printed as the uppermost item on the back of the ID card. No label for the PDF417 image is necessary.

**Pharmacy ID Card PDF417 Technical Specifications**

The parameters defined in Table 5.6 allow for a PDF417 image to print in at least the same amount of space that is typically required for a magnetic stripe while maintaining enough capacity to accommodate the PDF417 data record defined in 3.4.2.1. PDF417 parameter definitions and value ranges may be found in software or hardware/printer manuals. Readers of this guide may also want to consult with their relevant printer vendors. Table 3.8 includes images generated from the sample data record in 3.4.2.1 using the specifications defined in Table 5.7.

**Table 5.6**

<b>Specification</b>	<b>NCPDP Valid Values</b>	<b>Comments</b>
Error Correction Level	4	
Aspect Ratio (Symbol Height to Width)	3:1	
Printer Resolution	≥ 240 dots per inch	
Module Width <sup>5</sup> (X-dimension)	240 dpi → 0.0083 inches (8.333 mils) 300 dpi → 0.0100 inches (10.000 mils) 400 dpi → 0.0100 inches (10.000 mils) 600 dpi → 0.0100 inches (10.000 mils)	Estimated Max Text Characters 234 110 110 110
Max Data Rows	10	
Max Data Columns	12	
Truncate	No	

<sup>5</sup> Most laser scanners/readers are limited to module widths greater than or equal to 6.67 mils.

**Table 5.7**

<b>PDF417 Image Sizes (Images represent data record example above.)</b>	
<b>DPI</b>	<b>Sample Image</b>
240	
300, 400, 600	

**INCITS 284 Standard Exception**

Section 3.4 of this guide specifies the use of the PDF417 standard for pharmacy ID cards. With respect to the INCITS 284 standard, some of the specifications in this section do not comply with the standard for various reasons. The modifications are as follows:

The PDF417 bar code standard is not currently included in the annexes of the INCITS 284 standard. The technologies annexed in the INCITS 284 standard were voted by NCPDP to be either not feasible or too expensive to implement.

This guide recommends in section 3.4.1 that card issuers disregard the INCITS 284 requirement that, at a minimum, a magnetic stripe must be included if any other machine-readable format is implemented. NCPDP has determined that the capacity limitations of the magnetic stripe make this requirement unreasonable.

In section 7 of the INCITS 284 standard, machine-readable information is defined. The maximum length specification of the cardholder identification number is 19. NCPDP’s data dictionary specifies that the cardholder identification number have a maximum length of 20. Therefore, this guide differs from the INCITS 284 standard and specifies a maximum length of 20 for the cardholder ID.

At the time of this release, NCPDP has made a formal written request to INCITS to 1) remove the magnetic stripe requirement for the reason indicated in section 3.4.1 and 2) to add the PDF417 2-dimensional bar coding symbology to the INCITS 284 list of machine-readable formats. NCPDP will make a future request to INCITS to increase the cardholder ID maximum length to 20.

## Sample Pharmacy ID Cards

Please refer to Chapter 6 for the proper use of the Medicare name and Medicare-approved seal.

### Front of Card

Figure 5.3

A diagram of a Prescription Discount Card. At the top left is a logo with 'Rx' in a mortar and pestle. To its right is a box containing the text 'PRESCRIPTION DISCOUNT CARD'. Below this is a table with two columns. The left column contains: RxBIN 999999, RxPCN ABC1234567, RxGrp ABC123456789, Issuer (80840), ID 12345678901, and Name JOHN Q. The right column contains: SPONSOR NAME/LOGO and a Medicare logo with 'APPROVED' below it. At the bottom left, a box contains the text 'This is not a Medicare insurance card.'

The basic format.

Note although the Issuer ID.

May not be available, the label must be on the card to meet the INCITS 284 Standard.

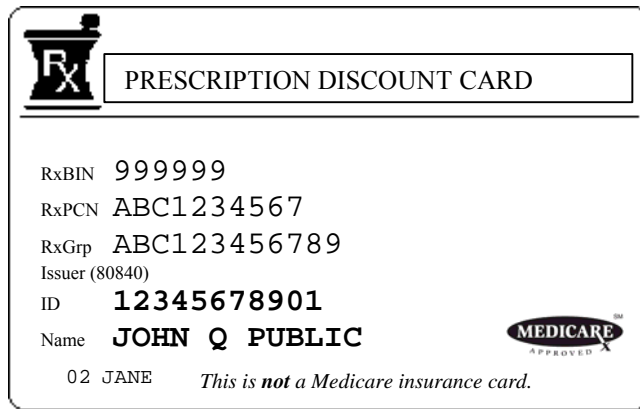
Figure 5.4

A diagram of a Prescription Discount Card. At the top left is a logo with 'Rx' in a mortar and pestle. To its right is a box containing the text 'PRESCRIPTION DISCOUNT CARD'. Below this is a table with two columns. The left column contains: RxBIN 999999, RxPCN ABC1234567, RxGrp ABC123456789, Issuer (80840), ID 12345678901, and Name JOHN Q PUBLIC. The right column contains: SPONSOR LOGO NAME and a Medicare logo with 'APPROVED' below it. At the bottom left, a box contains the text '02 JANE' and 'This is not a Medicare insurance card.'

An implementation with situational data elements.

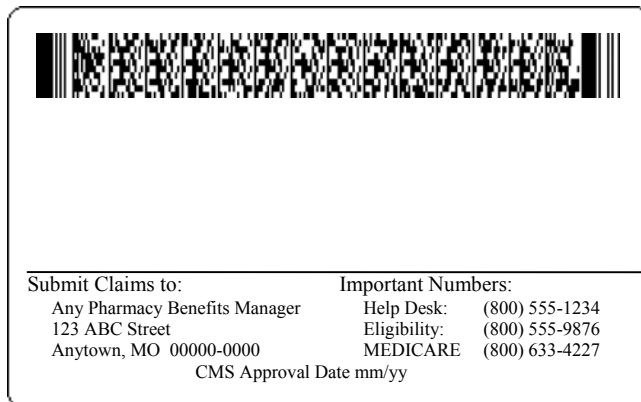
Note the location of the dependents.

**Figure 5.5**



Back of Card

**Figure 5.6**



The basic format for the back of the card.  
The phone number and address are required data elements and their placement is in the lower half of the card.

## **Chapter 9 – Guidelines for Promotional Activities**

This chapter reviews the use of promotional activities relating to the enrollment and retention of enrollees in Approved Card Programs. The following sections are included to help eliminate any unintentional violations.

### **Section 1: Nominal Gifts**

Some Endorsed Card Sponsors may choose to offer gifts to potential enrollees if they attend a presentation or as an enrollment gift. This practice is permitted, though not encouraged, as long as the gifts are of nominal value, are not cash or cash instruments, and are provided whether or not the individual enrolls in the Approved Card Program. Nominal value is defined as an item worth \$15 or less, based upon the retail purchase price of the item.

### **Section 2: Referral Programs**

The following general guidelines apply to referral programs under which Endorsed Card Sponsors solicit leads from existing enrollees for new enrollees. These include gifts that would be used to thank enrollees for devoting time to encouraging enrollment.

- Endorsed Card Sponsors may not use cash promotions as part of a referral program.
- Endorsed Card Sponsors may offer thank-you gifts of up to \$15 nominal value (e.g., thank you note, calendar, pen, key chain) when an enrollee responds to a solicitation for referrals.

### **Section 3: Materials Used by Prescription Drug Providers**

Endorsed Card Sponsors are permitted to have arrangements with Prescription Drug Providers (e.g., pharmacies) where the Provider offers Information and Outreach materials on the Endorsed Card Sponsor's Approved Card Program to Provider's clientele.

An example of such an arrangement is a business relationship between an Endorsed Card Sponsor and a pharmacy, whereby the pharmacy enrolls beneficiaries into the Endorsed Card Sponsor's Approved Card Program at pharmacy locations. However, any provider materials discussing a specific Approved Card Program must inform beneficiaries about resources available to beneficiaries to learn about other Approved Card Programs as well as the Prescription Discount Drug Program in general.

Specifically, when an Endorsed Card Sponsor allows a provider to offer Information and Outreach about an Endorsed Card Sponsor's approved Card Program, the Information and Outreach materials should meet the following requirements:

- Materials must include the address of the Medicare website, [www.medicare.gov](http://www.medicare.gov), and the Medicare toll-free number.
- Any enrollment meeting should be held within common areas of the setting, if possible.

For example: a mall, common area within an office building, or public areas within a pharmacy. Membership enrollment can take place at the provider level.

- Letters to pharmacy clients informing individuals about the Endorsed Card Sponsor's Approved Card Program should be in the voice of the provider. Not the Endorsed Card Sponsor.
- When enlisting a provider, including a pharmacy, to promote an Endorsed Card Sponsor's Approved Card Program, the Endorsed Card Sponsor can develop materials for the provider to disclose to beneficiaries. Provider materials may include benefits and features of the Endorsed Card Sponsor's Approved Card Program. However, the Endorsed Card Sponsor should not require the provider to endorse a specific Medicare-Approved Program. By Endorse, we mean that the Endorsed Card Sponsor cannot require the provider to encourage enrollment in a particular Approved Card Program, although a provider may elect to endorse a particular Approved Card Program consistent with applicable federal and state laws and may encourage enrollment in the overall Prescription Discount Card Program in general.
- An Endorsed Card Sponsor must submit an affidavit by CMS or its Designee stating that it is submitting the materials used by the provider, on behalf of the provider and the Endorsed Card Sponsors, that the Endorsed Card Sponsor did not and does not have access to the provider's clients PHI, and that both the Endorsed Card Sponsor and provider are acting in compliance with HIPPA privacy standards.

**Endorsed Card Sponsors should also refer to the Office of Inspector General's Guidance on Education and Outreach Arrangements Between Medicare-Endorsed Discount Drug Card sponsors and their Network Pharmacies Under the Anti-Kick Back Statue (available at [www.oig.hhs.gov](http://www.oig.hhs.gov)).**

#### **Section 4. Telemarketing:**

NOTE: Endorsed Card Sponsors may not conduct any outbound telemarketing activities. Telemarketing activities include solicitation through phone calls and emails.

Endorsed Card Sponsors may contact beneficiaries, only if the beneficiary requests contact through such vehicles as a response to a direct mail advertising piece or an advertisement.

Exclusive Card Sponsors that are presently conducting telemarketing activities on behalf of their Medicare Managed Care Organization will also be prohibited from conducting telemarketing activities for their Approved Card Program(s).

Therefore, when Exclusive Card Sponsors are acting in the capacity of a Medicare Managed Care Organization and engaging in telemarketing activities, they may not disclose any information regarding the Approved Card Program unless asked to do so by a beneficiary, or his/her representative, during the telemarketing activity.



## **Section 5: Door-to-Door Solicitation:**

Endorsed Card Sponsors may NOT engage in any door-to-door solicitation to individuals with Medicare.

## **Section 6: Unsolicited E-mail Policy**

An Endorsed Card Sponsor may not send e-mails to a beneficiary, unless:

1) The Medicare beneficiary agrees to receive e-mails from a Endorsed Card Sponsor and the beneficiary has provided their e-mail address to the Endorsed Card Sponsor

- ◇ Endorsed Card Sponsors are prohibited from renting e-mail lists to distribute information about the Medicare Approved Drug Program
- ◇ Endorsed Card Sponsors may not acquire e-mail addresses through any type of directory.

2) The Medicare beneficiary is doing business with the Endorsed Card Sponsor or a co-branded entity, and has requested to receive e-mails from that Endorsed Card Sponsor or co-branded entity. Only then may an Endorsed Card Sponsor e-mail that beneficiary.

## **Section 7: Media Kits**

Endorsed Card Sponsor Media Kits that consist of press releases, company profiles, contact information, and other documents that may lead to news media coverage do not need to be reviewed by CMS or its Designee. Likewise, information that provides the history of the Prescription Drug Program in general can be included and does not require review. However, these items must be sent to the Designee for file only.

However, if any document within the media kit will be used as an advertising material directed at Medicare beneficiaries, or includes specific information about the Approved Card Program, that material will have to be reviewed by CMS or its Designee for approval.

## **Section 8: URL Guidelines**

All sponsors operating a website must have a unique website for the Medicare-approved drug discount card. The websites should include the name of the sponsor and clearly identify that the sponsor is Medicare-approved. The Medicare-approved seal should appear on the sponsor website.

Web pages that are specifically designed for the Medicare-approved drug discount card should be accessed either directly from the browser or from the sponsor's homepage. All materials must include a web address that links the beneficiary directly to the sponsor's Medicare-approved website. Therefore published addresses should not link beneficiaries to the sponsor's corporate website or homepage. Medicare-approved websites may not link the beneficiary to products and services outside the scope of the endorsement. This also includes promoting access to prescription drugs offered through foreign pharmacies.

## Attachment A – Information and Outreach Material Submission Form

Revised 5/26/04

Item Submission Form  
Date of Submission: \_\_\_\_\_

<b>Sponsor Name:</b>	<b>Special Endorsement:</b>
<b>Sponsor Application Number:</b>	<b>D Numbers:</b>
<b>Contact Name:</b>	<b>E-mail:</b>
<b>Phone Number:</b>	
<b>If item is a template or in a foreign language, indicate here:</b>	

<p><b>Does this submission contain elements pertaining to an exclusive card program?</b> _____</p> <p><b>If yes, please supply the following: Regional Office Reviewer’s name:</b> _____</p> <p><b>RO Reviewer’s email:</b> _____ <b>RO Reviewer’s Phone Number:</b> _____</p> <p><b>NOTE: This means that you, the sponsor, have submitted materials that will be used by both your exclusive and general card programs for information and outreach efforts.</b></p>
--

**Item Information:**

Sponsor’s Material ID	Sponsor’s Material Name	Category Code	D Number	Follows Model?	Comments

**Please use the following Material Category Codes and Descriptions:**

1001: Summary of Program Features	2000: Enrollment/Disenrollment	3003: Radio
1002: Member Handbook	2001: Denial of Enrollment	3005: TV
1003: Provider Directory	2002: Disenrollment Form	3006: Billboard/Banner
1005: ANOC	2003: Notification of Invol. Disenroll.	3007: Internet Web Page
1006: Membership Card	2004: Failure to Pay Premium–Initial	3008: Marketing Posters
1007: Surveys/Assessments	2005: Failure to Pay Premium–Final	3009: Sales/Presentations
1008: Other Member Materials	2006: Grievance Forms/Letters	4001: Newsletters
1009: Discount Drug List	3001: Direct Mail Pieces	4002: Fliers
1010: Change of Address Letter	3002: Newspaper	5000: All Others

Please send the item resubmission form and your revised item(s) via one of the following methods:

*Email:*  
CMS-Rx-Review@BearingPoint.com

*Regular or express mail:*  
BearingPoint  
Attn: CMS Rx Review  
1676 International Drive  
McLean, VA 22102

If you have any questions, you may reach the BearingPoint review team at 703-747-5774.

### Attachment B: Resubmission Form

Revised 5/26/04

Item Resubmission Form  
Date of Resubmission: \_\_\_\_\_

<b>Sponsor Name:</b>	<b>Sponsor Application Number:</b>
<b>Contact Name:</b>	<b>E-mail:</b>
<b>Phone Number:</b>	

**Does this submission contain elements pertaining to an exclusive card program?** \_\_\_\_\_  
**If yes, please supply the following: Regional Office Reviewer's name:** \_\_\_\_\_  
**RO Reviewer's email:** \_\_\_\_\_ **RO Reviewer's Phone Number:** \_\_\_\_\_  
**NOTE: This means that you, the sponsor, have submitted materials that will be used by both your exclusive and general card programs for information and outreach efforts.**

**Item Information:**

Original BearingPoint ID	Sponsor's Material ID	Sponsor's Material Name	Comments

Please send the item resubmission form and your revised item(s) via one of the following methods:

*Email:*  
CMS-Rx-Review@BearingPoint.com

*Regular or express mail:*  
BearingPoint  
Attn: CMS Rx Review  
1676 International Drive  
McLean, VA 22102

If you have any questions, you may reach the BearingPoint review team at 703-747-5774.

## **Attachments: Model & Standardized Materials**

### **Model and Standardized Materials will be provided by CMS separately**

- Enrollment Forms (model)\* -- one for Discount Card only and one for Transitional Assistance. Endorsed Card Sponsors are required to use all standardized elements of the enrollment forms without modification.
- Member identification card (standardized)\*
- Eligibility determination letters (model)\*
- Pre-Enrollment Cover Letter (model)
- Change of Address Letter (model)
- Member Handbook (model)\*
- Annual Notice of Change (model) (currently being developed and consumer tested)
- Group Enrollment Notification Letter (model) (currently being developed and consumer tested)
- Information for people who change their address to outside Endorsed Card Sponsor's geographic service area (model)
- Pre-Enrollment Cover Letter- (model)
- Medicare Advantage Managed Care Notification Letter (model) (currently being developed and consumer tested)