

MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM

MARKETING MATERIALS GUIDELINES
FOR
MEDICARE ADVANTAGE–PRESCRIPTION
DRUG PLANS (MA-PDs)
AND
PRESCRIPTION DRUG PLANS (PDPs)

DRAFT

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1. INTRODUCTION: MMA AND PART D

Acceptable PDP Plan Names

Joint Enterprise

Organizations that are licensed by a State as a risk-bearing entity can jointly enter into a single contract with CMS to offer a single MA-PD or PDP in a multi-state region. The participating organizations would contract with each other to create a single “joint enterprise” and would be considered an “entity” for purposes of offering a MA-PD or PDP. Joint Enterprises are expected to:

- Market the Plan under a single name throughout a region; and
- Provide uniform benefits, formulary, enrollee customer service, and appeal and grievance rights throughout the region.

Marketing materials for the joint enterprise may only be distributed where one or more of the contracted health plans creating the single entity is licensed by that State as a risk-bearing entity.

All marketing materials must be submitted under the joint enterprise’s contract number and must follow the appropriate marketing guidelines.

Multi-Contract Groups

Organizations may submit more than one Solicitation Application for the same corporation due to state licensing requirements. As a result of this process, CMS will have more than one contract with an organization that may have the same marketing materials with only minor differences. Please refer to Chapter 5, Template Materials, for further information.

2. GUIDANCE FOR TRANSITIONING BENEFICIARIES FROM DRUG CARD TO PART D PLANS

Guidance for transitioning beneficiaries from the Medicare-Approved Discount Drug Card Program to Part D Plans may be found at the CMS Web site.

Please continue to check the CMS Web site for updates:
<http://www.cms.hhs.gov/discountdrugs/infooutreach.asp>.

5. OVERVIEW

Definitions

Marketing Materials

Advertising

Advertising materials are primarily intended to attract or appeal to a potential Part D Plan enrollee. Advertising materials are intended for quick view; thus, they do not contain the same level of detail expected in other marketing materials. Outdoor advertising, banner advertising, and banner-like advertising are materials designed to catch the attention of a person and influence them to call for detailed information on the product being advertised. Examples of advertising materials include:

<Continues in Installment I>

Value Added Items and Services (VAIS)

Value-Added Items and Services (VAIS) are items and services offered to Part D Plan members by a Plan that do not meet the definition of benefits under the Part D program and involve only administrative or minimal cost. VAIS may not be funded by Medicare program dollars.

Health-Related VAIS

Health-related VAIS are intended to maintain or improve the health status of enrollees, where Plans incur an administrative or minimal cost that is not included within the Plan's bid to CMS. Examples of health-related VAIS are discounts on eyeglasses and health clubs. Plans are permitted to contact Medicare beneficiaries about VAIS health-related items and services provided by the Plan without prior written authorization to the extent permitted under the HIPAA Privacy Rule.

Non Health-Related VAIS

Non health-related VAIS are not intended to improve or maintain the health status of enrollees, and the cost incurred by the Plan is usually only administrative and is not included within the Plan's bid to CMS. Furthermore, to the extent required under the HIPAA Privacy Rule, Plans generally must receive prior written

authorization from Medicare beneficiaries before contacting them regarding VAIS non health-related items and services.

Co-Branding Requirements

Co-branding information added to previously approved template materials is not subject to re-review, as long as the changes are limited to the variable fields (e.g., organization name, logos, or contact information).

Template Materials

Submission of Template Materials

A “template material” is any marketing material that includes placeholders to be populated by variable elements. Variable elements can be specific to one Part D Plan or can apply to multiple Plans within the same organization that utilize the same base materials.

Examples of variable elements would include: date and location information for sales presentations, benefits that may vary between Plans, etc.

Template materials must show how the placeholders will be populated (e.g., <date>), or populate the placeholder fields with all variables (e.g., <benefit x/benefit y>). Template materials will have only one marketing identification number regardless of the number and combination of variable elements.

A Part D Plan may not add **new** variables to placeholder fields within approved template material unless it has submitted the material to CMS for review under a new marketing identification number. For example, including benefit information that has not been previously approved must be submitted to CMS under a new marketing identification number. However, changes to date or location of variable elements are not required to be submitted as new material.

NOTE: *Identical materials submitted separately and not noted as template materials are subject to separate reviews.*

6. MARKETING MATERIAL DEVELOPMENT GUIDELINES

Model / Standardized Materials

Directory of Model Documents

Below is a partial list of model materials that CMS will be developing. It is anticipated that these model documents will be released beginning summer 2005.

Marketing Material Model Documents

- Standard Summary of Benefits
- Model EOC for PDP
- Model Language for MA-PD EOC
- Model Pharmacy Directory for PDP
- Model Language for MA-PD Pharmacy Directory
- Annual Notice of Coverage PDP
- Annual Notice of Coverage MA-PD
- Model Explanation of Benefits (EOB)
- Model Comprehensive Formulary
- Model Abridged Formulary
- Model Formulary Change Form
- Model Appeals and Grievance Documents
- Model Enrollment and Disenrollment Documents

Advertising

Guidelines for Advertising Materials

The guidelines in this section apply to all Part D Plan advertising materials. This section is divided into two subsections:

- Guidelines on advertising materials
- The “Must Use/Must Not Use” chart for advertising materials (Forthcoming)

Part D Plans are prohibited from comparing their organization/Plan to another organization/Plan by name.

Advertising materials are defined as materials that are primarily intended to attract or appeal to a potential enrollee. They are intended to be viewed quickly by a potential enrollee and are short in length/duration. Specifically, these advertisements are:

- Television ads;
- Radio ads;
- Banner/banner-like ads;
- Outdoor advertising;
- Direct mail (as long as it does not include the enrollment form);
- Print ads (newspaper, magazine, flyers, etc.); and
- Internet advertising.

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

- **Outdoor Advertising (ODA):** ODA is marketing material intended to capture the quick attention of a mobile audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles, etc.). ODA is designed to catch the attention of a person and influence them to call for detailed information on the product being advertised.
- **Banner Advertisements:** “Banner” advertisements are typically 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. This type of ad does not contain benefit or cost sharing information.
- **Banner-like Advertisements:** A “banner-like” advertisement can be ODA and is usually in some media other than television, is intended to very brief and to entice someone to call the organization or to alert someone that information is forthcoming and, like a banner ad, does not contain benefit or cost sharing information.

Required Disclaimers

Advertising Marketing Material Language Requirements

Disclaimers/Disclosures:

1. For banner ads, banner-like ads and ODA, Plans are not required to include **any** disclaimers or disclosures (e.g., premium information) on the ads.
2. For all other advertising materials not listed in #1 above, Plans must include the statement that the organization contracts with the Federal government. Refer to the “Must Use/Must Not Use” chart for advertising materials for statements a Plan may use.
3. In addition to the disclaimers required in # 2 above, flyers and invitations to sales presentations that are used to invite beneficiaries to attend a group session with the intent of enrolling those individuals attending must also include the following two statements:
 - a. “A sales representative will be present with information and applications.”
 - b. “For accommodation of persons with special needs at sales meetings, call [insert phone number].”

Claim Forms and Paperwork

If a material addresses claim forms or paperwork, Plans are allowed to say:

- Virtually no paperwork
- Hardly any paperwork.

Plans cannot say:

- No paperwork
- No claims or paperwork / complicated paperwork
- No claim forms

Hours of Operation

Part D Plans must list the hours of operation for customer service in all places where phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the Plan lists the 1-800-MEDICARE number (24 hours a day/7 days a week). This requirement does not apply to any numbers included on advertising materials for persons to call for more information.

TTY/TDD Numbers

With the exceptions listed below, TTY/TDD numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. Part D Plans can use either their own or State Relay Services, as long as the number included is accessible from TTY/TDD equipment.

Exceptions

- TTY/TDD numbers need not be included on ODA and banner/banner-like ads or in radio ads that include a telephone number.
- In television ads, the TTY/TDD number need not be the same font size/style as other phone numbers since it may result in confusion and cause some prospective enrollees to call the wrong phone number. As an alternative, Plans are allowed to use various techniques to sharpen the differences between TTY/TDD and other phone numbers on a television ad (such as using a smaller font size for the TTY/TDD number than or the other phone numbers).
- TTY/TDD numbers are not required in radio ads.

Reference to Studies or Statistical Data

Part D Plans may refer to the results of studies or statistical data in relation to customer satisfaction, quality, cost, etc., as long as specific study details are given. At a minimum, study details that need to be included are the

source and dates. Upon submitting material to CMS for review, unless the study that is referenced is a CMS study, the Plan must provide the study sample size and number of Plans surveyed for review purposes.

Plans are prohibited from using study or statistical data to directly compare their Plan to another Part D Plan.

If a Part D Plan uses study data that includes aggregate marketplace information on several other Part D Plans, they will not be required to submit data on all of the organizations included in the study. However, the study details, such as the number of Plans included, must be disclosed.

Qualified superlatives (i.e., “one of the best,” “among the highest rank,” etc.) may be used. Absolute superlatives (i.e., “the best,” “highest ranked,” “rated number one,” etc.) may only be used if they are substantiated with supporting data.

Pharmacies

1. If the number of pharmacies is used in an ad, the ad must include only those pharmacies available to Plan enrollees.
2. Print ads and direct mail materials:
 - a. If a total number of pharmacies is used in the ad, it must separately delineate the number of preferred versus non-preferred pharmacies.
 - b. If the Plan uses the name and/or picture of a pharmacist and/or pharmacy to market the Plan, the information may **only** be used within the context of informing beneficiaries of pharmacies that are associated with the Plan’s delivery system.

Formatting Requirements

Font Size Rule

With the exception listed below, for all written advertising materials footnotes must be the same size font as the majority of the text of the advertisement. The text

size is left to the discretion of the Plan and can be smaller than size 12-point font, but the majority of the text of the advertisement and footnotes must be the same size font.

Exception

- Information contained in brochures and direct mail pieces must be no smaller than Times New Roman 12-point or equivalent font.

Font Size Rule for Internet Advertising

Unless an exception regarding font size is noted above, any advertising materials that a Plan places on its Web site must be a minimum of 12-point Times New Roman equivalent font. Neither CMS nor the Plan has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the Plan codes the font for the Web page, not how it actually appears on the user's screen.

Submission and Review Requirements

Other Requirements

Logos/Tag Lines

CMS recognizes the difference of purpose and intent between company logos/product tag lines and other advertising or marketing materials. The guidelines regarding the use of unsubstantiated statements that apply to advertising materials do not apply to logos/tag lines. Part D Plans may use unsubstantiated statements in their logos and in their product tag lines (e.g., "Your health is our major concern," "Quality care is our pledge to you," "XYZ Plan means quality care," etc.). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. Notwithstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., "XYZ Plan means the first in

quality care” or “XYZ Plus means the best in managed care”).

Pre-Enrollment Materials

Guidance for Pre-Enrollment Materials

Required Disclaimers

Language Requirements

Enrollment Limitations

Part D Plans must include a statement indicating that members may enroll in a Part D Plan during specific times of the year. Plans may either describe all enrollment periods (i.e., the annual election period, special election period and the initial election period) in detail or refer eligible individuals to the Plan’s customer service to obtain more information.

Network Limitations

Part D Plans must include a statement that indicates that they must use network pharmacies to access their prescription drug benefit. If members utilize pharmacies outside of the network, Plans must also include a statement that indicates that the member may obtain their prescriptions from pharmacies outside the network at a reduced benefit.

Hours of Operation

Part D Plans must list the hours of operation for customer service in all places where phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the organization lists the 1-800-MEDICARE number (24 hours a day/7 days a week).

Identification of All Plans in Materials

Where organizations may submit multiple bids and Plan Benefit Packages (PBPs) to cover the same region/service area, there is no requirement that all Medicare Plans be identified in all of the organization’s marketing materials.

At their discretion, organizations may identify or mention more than one Plan in a single marketing piece.

TTY/TDD Numbers

TTY/TDD numbers must appear in conjunction with all other phone numbers in the same font size and style as the other phone numbers. The TTY/TDD number must also include the hours of operation. Part D Plans can use either their own or State relay services, as long as the number is accessible from TTY/TDD equipment.

Availability of Alternative Formats

To ensure that beneficiaries have access to beneficiary education materials in alternative formats (e.g., Braille, foreign languages, audio tapes, large print), Part D Plans must provide a disclosure on pre-enrollment materials indicating the document is available in alternative formats.

Claim Forms and Paperwork

If a material addresses claim forms or paperwork, Plans are allowed to say:

- Virtually no paperwork
- Hardly any Paperwork

Plans cannot say:

- No paperwork
- No claims or paperwork / complicated paperwork
- No claim forms

Reference to Studies or Statistical Data

Part D Plans may refer to the results of studies or statistical data in relation to customer satisfaction, quality, cost, etc., as long as specific study details are given. At a minimum, study details that need to be included are the source and dates. Upon submitting material to CMS for review, unless the study that is referenced is a CMS study, the Plan must provide the study sample size and number of Plans surveyed for review purposes.

Plans are prohibited from using study or statistical data to directly compare their Plan to another Part D Plan.

If a Part D Plan uses study data that includes aggregate marketplace information on several other Part D Plans, they will not be required to submit data on all of the organizations included in the study. However, the study details, such as the number of Plans included, must be disclosed.

Qualified superlatives (i.e., “one of the best,” “among the highest rank,” etc.) may be used. Absolute superlatives (i.e., “the best,” “highest ranked,” “rated number one,” etc.) may only be used if they are substantiated with supporting data.

Product Endorsements/Testimonials

Product endorsements and testimonials must adhere to the following guidelines:

- Content of product endorsements and testimonials, including statements by Plan members, must comply with CMS marketing guidelines.
- Speaker must identify the Part D Plan by name.
- If an individual is paid to promote a Part D Plan, this must be clearly stated (i.e., “paid endorsement”).
- If an individual is paid to portray a real or fictitious situation, the ad must clearly state it is a “Paid Actor Portrayal.” However, non-members cannot say they belong to the Plan. This requirement only applies to product endorsements / testimonials.
- If a Medicare beneficiary offers endorsement, the individual must be a current Plan enrollee offering the endorsement in their capacity as a Medicare beneficiary, as opposed to an actor paid to portray a fictitious situation or a celebrity paid for his or her endorsement who also happens to be a Medicare beneficiary.

Product endorsements and testimonials cannot:

- Use negative testimonials about other Plans
- Use quotes by physicians and other health care providers
- Use anonymous or fictitious quotes by Medicare beneficiaries

Formatting Requirements

Font Size Rule for Member Materials

All pre-enrollment materials must be printed with a 12-point font size or larger. CMS is cognizant of the fact that, when actually measured, 12-point font size may vary among different fonts with the result that some font types may be smaller than others. Therefore, if Plans choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12-point.

Font Size Rule for Materials on the Internet

Any pre-enrollment materials that a Part D Plan places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor the Part D Plan has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the Plan codes the font for the Web page, not how it actually appears on the user's screen.

Font Size Rule for Footnotes and Subscripts

The 12-point font size or larger rule described above also applies to any footnotes or subscript annotations in notices.

Footnote Placement

Part D Plans must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. For example, the Plan cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

Submission and Review Requirements

Sales Scripts

Sales scripts, both for in-home and telephone sales use, must be reviewed by CMS prior to use. However, Part D Plans are not required to adhere to a specific format for submission (i.e., verbatim text or bullet points).

Other Requirements

Logos/Tag Lines

CMS recognizes the difference of purpose and intent between company logos/product tag lines and other advertising or marketing materials. The guidelines regarding the use of unsubstantiated statements that apply to advertising materials do not apply to logos/tag lines. Part D Plans may use unsubstantiated statements in their logos and in their product tag lines (e.g., “Your health is our major concern,” “Quality care is our pledge to you,” “XYZ Plan means quality care,” etc.). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. Notwithstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., “XYZ Plan means the first in quality care” or “XYZ Plus means the best in managed care”).

Pharmacy Network Information

Plans must provide, at a minimum, a toll-free customer service number and a toll-free TTY/TDD number for Part D eligible individuals to obtain the names and address of a Plan’s network pharmacies. A Web site listing is optional.

Online Enrollment Center for MA-PDs and PDPs

PDPs and MA-PDs can choose to facilitate enrollment into their Plan through CMS’s Online Enrollment Center (OEC).

Plans that opt to participate in the OEC can promote this enrollment feature in their pre-enrollment materials and direct Part D eligible individuals to www.medicare.gov for further information. Plans facilitating enrollment into their Plan through OEC must state the following disclaimer in pre-enrollment materials: “Medicare beneficiaries may enroll in <Plan Name> through the Centers for Medicare and Medicaid Services Online Enrollment Center, located at <Web site>. For more information contact the <Plan Name> at <Plan Phone Number>.”

Availability of Medicare Subsidy Information

All Part D Plan pre-enrollment marketing materials detailing eligibility requirements for Part D benefits must include the following language:

“Beneficiaries interested in available Medicare Part D subsidies may contact [Plan Name] customer service at [Plan toll-free telephone number and toll-free TTY/TDD], 1-800-MEDICARE (TTY/TDD users call 877-486- 2048), their State Medicaid Office, or local Social Security Administration Office.”

Low-Income Subsidy Premium Disclaimer

In all marketing materials where PDP monthly premium and other member costs are described, the PDP sponsor must include the following language with any such discussion:

“If you have qualified for additional assistance for your Medicare Prescription Drug Plan costs, the amount of your premium and cost at the pharmacy will be less. Once you have enrolled in [name of PDP], Medicare will tell us how much assistance you are receiving, and we will send you information on the amount you will pay. If you are not receiving this additional assistance, you should contact 1-800-MEDICARE (TTY/TDD users call 877-486- 2048), your State Medicaid Office, or local Social Security Administration Office to see if you might qualify.”

Medigap Disclaimer

Plans must include the following disclaimer regarding Medigap in all pre-enrollment materials:

“If you have a Medicare Supplement (Medigap) policy that includes prescription drug coverage, you must contact your Medigap Issuer to let them know that you have joined a Medicare Prescription Drug Plan. If you decide to keep your current Medigap supplement policy, your Medigap Issuer will remove the prescription drug coverage portion of your policy and adjust your premium. Under certain circumstances, you can also buy a different Medigap policy without prescription drug coverage sold by your Medigap Issuer. Your Medigap Issuer cannot charge you more based on any past or present health problems. Call your Medigap Issuer for details.”

Specific Guidance

Summary of Benefits

Permitted Changes to Summary of Benefits Language and Format

PDPs are only permitted to make changes to the benefit matrix or Hard Copy Summary of Benefits on a limited basis. **Any changes** must be approved by CMS. Please refer to the section below on *PDP Requests to Change Hard Copy Summary of Benefits*, for further detail.

PDP Requests to Change Hard Copy Summary of Benefits

NOTE: *The following guidance applies to PDPs only. MA-PDs should follow the hard copy change process detailed in Chapter 3 of the Medicare Managed Care Manual.*

CMS will allow an organization to make changes to hard copy SBs on a very limited basis. The organization must receive approval from CMS prior to making any changes. Any approved changes will NOT result in changes in Medicare Personal Plan Finder, nor will they result in

changes to the Plan Benefit Package. However, requests may be considered for future changes to the Plan Benefit Package.

What types of Changes will be Permitted?

The only changes that will be permitted are those that would correct inaccurate or misleading information presented to beneficiaries in the hard copy SB. For example, if the front-end deductible applies to brand drugs only, a change **may** be permitted to add “brand drugs only” to the sentence defining the deductible.

What types of Changes will NOT be Permitted?

Requests for changes in which the existing sentences are accurate will not be permitted. PDPs will NOT be permitted to add additional sentences in Section 2 of the Summary of Benefits in order to further explain their benefits. Plans may be permitted to add a sentence to describe partial coverage in the gap. CMS will not allow changes in wording, based on individual preferences.

How to Request a Change?

To request a change to the hard copy SB, PDPs should send an e-mail to SummaryofBenefits@cms.hhs.gov. The subject line in the request must read: “Hard Copy SB Change Request.” In the body of the e-mail, PDPs should provide:

- The S number and Plan ID – each S number and Plan ID should be in a separate e-mail;
- The existing standardized Summary of Benefits language;
- An explanation of why the existing standardized language is inaccurate; and
- A modified sentence.

How will CMS Review the Requests?

A cross-functional workgroup reviews each request. The workgroup will determine if the current standardized wording is inaccurate or misleading. If the workgroup denies the request, CMS will notify the PDP and the PDP must adhere to the standardized language. If the workgroup permits a

change, CMS will notify the PDP with the approved language. Note that the approved language will be decided by CMS and will be considered “standardized.” CMS will also notify the CMS Designee responsible for PDP marketing review of the approved language. If the request is based on a preferred wording, the request will not be approved.

Post-Enrollment Materials

Required Information

Language Requirements

Hours of Operation

Part D Plans must list the hours of operation for customer service anywhere that these phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the organization lists the 1-800-MEDICARE number (24 hours a day/7 days a week).

TTY/TDD Numbers

TTY/TDD numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. The TTY/TDD number must also include the hours of operation, if they are for customer service. Part D Plans can use either their own or State relay services, as long as the number included is accessible from TTY/TDD equipment.

Availability of Alternative Formats (EOC only)

To ensure that beneficiaries have access to beneficiary education materials in alternative formats (e.g., Braille, foreign languages, audio tapes, large print), Part D Plans must provide a disclosure on the EOC indicating the document is available in alternative formats.

Claim Forms and Paperwork

If a material addresses claim forms or paperwork, Plans are allowed to say:

- Virtually no paperwork
- Hardly any paperwork

Plans cannot say:

- No paperwork
- No claims or paperwork / complicated paperwork
- No claim forms

Contract Number on PDP Marketing Materials

In order to facilitate processing of beneficiary inquiries and complaints to CMS and its contractors, all organizations must print their CMS contract number on marketing materials and their identification card. At a minimum, the CMS contract number (i.e., S number) will need to be printed on the front page of the Summary of Benefits, Evidence of Coverage, and the identification card.

Reference to Studies or Statistical Data

Part D Plans may refer to the results of studies or statistical data in relation to customer satisfaction, quality, cost, etc., as long as specific study details are given. At a minimum, study details that need to be included are the source and dates. Upon submitting material to CMS for review, unless the study that is referenced is a CMS study, the Plan must provide the study sample size and number of Plans surveyed for review purposes.

Plans are prohibited from using study or statistical data to directly compare their Plan to another Part D Plan.

If a Part D Plan uses study data that includes aggregate marketplace information on several other Part D Plans, they will not be required to submit data on all of the organizations included in the study. However, the study details, such as the number of Plans included, must be disclosed.

Qualified superlatives (i.e., “one of the best,” “among the highest rank,” etc.) may be used. Absolute superlatives (i.e., “the best,” “highest ranked,” “rated number one,” etc.) may only be used if they are substantiated with supporting data.

Product Endorsements/Testimonials

Product endorsements and testimonials must adhere to the following guidelines:

- Content of product endorsements and testimonials, including statements by Plan members, must comply with CMS marketing guidelines.
- Speaker must identify the Part D Plan by name.
- If an individual is paid to promote a Part D Plan, this must be clearly stated (i.e., “paid endorsement”).
- If an individual is paid to portray a real or fictitious situation, the ad must clearly state it is a “Paid Actor Portrayal.” However, non-members cannot say they belong to the Plan. This requirement only applies to product endorsements / testimonials.
- If a Medicare beneficiary offers endorsement, the individual must be a current Plan enrollee offering the endorsement in their capacity as a Medicare beneficiary, as opposed to an actor paid to portray a fictitious situation or a celebrity paid for his or her endorsement who also happens to be a Medicare beneficiary.

Product endorsements and testimonials cannot:

- Use negative testimonials about other Plans
- Use quotes by physicians and other health care providers
- Use anonymous or fictitious quotes by Medicare beneficiaries

Formatting Requirements

Font Size Rule for Member Materials

Readability of written materials is crucial to informed choice for Medicare beneficiaries. All member materials must be printed with a 12-point font size or larger. CMS is cognizant of the fact that, when actually measured, 12-point font size may vary among different fonts with the result that some font

types may be smaller than others. Therefore, if Plans choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12-point.

Font Size Rule for Internet Materials

Any post-enrollment materials that a Plan places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor organization has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the organization codes the font for the Web page, not how it actually appears on the user's screen.

Font Size Rule for Footnotes and Subscripts

The 12-point font size or larger rule also applies to any footnotes or subscript annotations in post-enrollment notices.

Footnote Placement

Part D Plans must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. For example, the organization cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

Submission and Review Requirements

Other Requirements

Logos/Tag Lines

CMS recognizes the difference of purpose and intent between company logos/product tag lines and other advertising or marketing materials. The guidelines regarding the use of unsubstantiated statements that apply to advertising materials do not apply to logos/tag lines. Part D Plans may use unsubstantiated statements in their logos and in their product tag lines (e.g., "Your health is our major concern," "Quality care is our pledge to you," "XYZ Plan means quality care,"

etc.). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. Notwithstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., “XYZ Plan means the first in quality care” or “XYZ Plus means the best in managed care”).

Media Type

With respect to the Summary of Benefits (SB), the Evidence of Coverage (EOC), and the Pharmacy Directory, Part D Plans have the option of contacting members to determine in what format they would like to receive the materials (e.g., hardcopy, CD ROM, Part D Plans that choose this option must contact members in writing (e.g., by letter, postcard, newsletter article, etc.) to determine whether they would like to receive the SB, EOC, and/or the Pharmacy Directory in another format. If the Plan does not receive a response from the member, then the Plan must assume that the member wants to receive the information in hardcopy.

If the Plan sends one pharmacy directory to an address where up to four members reside, then it may send one written notice regarding choice of media type to that address (if it is notifying members by letter), rather than one notice to each individual member at that address. A reply from one member at that address constitutes a reply for the entire address.

Regardless of media type the following would apply:

- The member must receive all materials in the required time frames, regardless of the format.
- For the EOC and the SB, the Plan must provide marketing materials via an Internet Web page, as well as hard copy, and must establish a process to inform members when that Web page has been updated. For example, the Plan could notify members by newsletter article, by e-mail, by postcard, etc. Often any change in the EOC or SB is communicated to all members by newsletter and notification that the change has been made on the Web

page could be made at the same time. This requirement does not apply to pharmacy directories, since pharmacy directory updates can occur far more frequently than updates to the EOC or SB.

- The non-hardcopy format must match the approved hardcopy format, and if it does, it will not require additional CMS approval. If anything is added or deleted, the non-hardcopy format must receive separate CMS approval.

***NOTE:** Some organizations use a database/search function for their provider directory on the Internet. As long as the information that appears for a specific provider is the same information as what is contained in the hardcopy format, then the Internet provider directory would be considered to be the same as the hardcopy format and would not need additional CMS approval.*

Specific Guidance

Evidence of Coverage

***NOTE:** This section is applicable only to PDPs. MA-PD Plans should refer to Chapter 3 of the Medicare Managed Care Manual.*

All organizations are required to provide an Evidence of Coverage (EOC) to all enrollees (including employer group enrollees) annually.

At a minimum, the EOC must include the following information:

- Describe the Plan’s service area.
- Include the statement: “You must continue to pay your Medicare Part B premium if not otherwise paid for under Medicaid or by another third-party,” even if the Part D premium is \$0.
- Include the statement: “If you have a Medicare Supplement (Medigap) policy that includes prescription drug coverage, you must contact your Medigap Issuer to let them know that you have joined a Medicare Prescription Drug Plan. If you decide to keep your current Medigap supplement policy, your

Medigap Issuer will remove the prescription drug coverage portion of your policy and adjust your premium. Under certain circumstances, you can also buy a different Medigap policy without prescription drug coverage sold by your Medigap Issuer. Your Medigap Issuer cannot charge you more based on any past or present health problems. Call your Medigap Issuer for details.”

- When specifying benefits, specify the annual deductible amount; initial coverage limit; cost-sharing under the initial coverage limit; and cost-sharing between the initial coverage limit and the annual out-of-pocket threshold.
- Clearly state major exclusions and limitations. For example, utilization management programs applied to drugs on the formulary.
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary’s access to drugs or services.
- Describe quality assurance policies and procedures, including drug utilization management and medication therapy management programs.
- State that the Part D Plan’s contract with CMS is renewed annually, that the availability of coverage beyond the end of the current contract year is not guaranteed, and that the Plan may reduce its service area and would no longer offer prescription drug coverage in that area.
- The EOC must:
 - Define ‘formulary;’
 - Describe how the formulary functions (including any tiered formulary structures and utilization management procedures);
 - State that the drugs on the formulary may change during the contract year;
 - Explain how to obtain an exception to the formulary or tiered cost-sharing structure); and
 - Describe how to obtain additional information about the drugs included on the Part D Plan’s formulary.
- Explain how to access their Part D Plan benefits. In particular, they must describe how to fill a prescription at a retail network pharmacy and through the Plan’s mail-order

service (if applicable), explain how to access covered Part D drugs at out-of-network pharmacies, and describe how to submit a claim for a covered Part D drug.

- Explain the extra help that is available to people with limited incomes.
- Describe the grievance, coverage determinations, exceptions process, and appeals rights and procedures.
- Describe disenrollment rights, responsibilities, and procedures.

Explanation of Benefits

A Part D Plan must send an Explanation of Benefits (EOB) to Plan enrollees during months in which enrollees utilize their prescription drug benefits. The EOB must:

1. List the item(s) or service(s) for which payment was made and the amount of the payment for each item or service.
2. Include a notice of the enrollee's right to request an itemized statement, appeal/grievance rights, and exceptions process.
3. Include the cumulative, year-to-date total amount of benefits provided, in relation to:
 - a. The deductible for the current year.
 - b. The initial coverage limit for the current year.
 - c. The annual out-of-pocket threshold for the current year.
4. Include the cumulative, year-to-date total of incurred costs to the extent practicable.
5. Include any applicable formulary changes that the Plan is required to provide notice.

Low-Income Subsidy for Part D

NOTE: MA-PDs should refer to Chapter 3 of the Medicare Managed Care Manual for guidance regarding low-income subsidy marketing.

The low-income subsidy is extra help with prescription drug costs for Medicare-eligible individuals whose income and resources are limited. This help takes the form of payments to the Prescription Drug Plan that the individual joins. Persons eligible for Medicaid, Supplemental Security Income (SSI), or a Medicare Saving Program qualify for the extra help automatically and do not need to apply. All others may apply beginning July 1, 2005, with Social Security (SSA) by mail, by telephone, on the Internet at

<http://www.socialsecurity.gov> or in person at a community event or an SSA office. Applications may also be filed at the local Medicaid office. Further information will be available in forthcoming PDP Enrollment and Disenrollment Guidance. Please continue to check the CMS Web site at <http://www.cms.hhs.gov/>.

PDPs must communicate to their entire membership in pre-enrollment marketing materials that low-income subsidies are available to Part D eligible individuals. In order to ensure that Part D Plans effectively assist Part D eligible individuals while protecting them from undue pressures or privacy violations, Plans must adhere to the following guidance.

PDPs must:

Provide information in marketing materials regarding the availability of the low-income subsidy for Part D eligible individuals. The following marketing materials targeted to this population must include eligibility requirements for Medicare Part D subsidies:

- Member Letters
- Direct Mail
- Telephone Scripts
- Pre-Enrollment Packet
- Web Sites

Part D Plans May:

- Conduct outreach to all or a portion of its Plan membership. Selection of the focus population may be based upon demographic data and/or may focus on a specific geographic area. However, the Plan must provide outreach to all individuals within those pre-identified population segments. Additionally, if the Plan receives an inquiry from a Plan member not previously identified in the targeted group, it must provide assistance to the member as if he or she had been included on the outreach list.
- Follow-up with members who do not respond to the initial member letter. This follow-up may be in the form of second and/or third letter or telephone calls. If the member does not respond to the third effort, the Plan will refrain from contacting the member for at least six months following the last outreach attempt.
- Subcontract all outreach efforts to another entity or entities. In such cases, which the Plan retains all responsibilities for meeting CMS requirements, it must still submit all documentation to CMS for

approval including contracts held by the subcontractor with all entities related to the program. The Plan must also coordinate changes and revisions between the subcontractor and CMS.

- Provide training to staff conducting the outreach. If the Plan subcontracts this effort to another entity, it must ensure the subcontractor's staff is adequately trained.
- Include alternate sources of information in marketing materials. Member letters and/or brochures that contain Plan telephone numbers must also include the telephone number for the State Health Insurance Assistance Program (SHIP). Outreach materials may also include the telephone number for the Medicare Service Center (1-800-MEDICARE).

Part D Plans Shall Not:

- Conduct door-to-door solicitation or marketing prior to receiving an invitation from the member to provide assistance in his or her home.
- Store or share any member information, financial or otherwise, specific to the low-income subsidy, with any entity not directly involved in the outreach process.
- Contact any member who has refused outreach assistance or who has not responded to the telephone call or follow-up letter until at least six months following the last outreach attempt.
- Infer in any written materials or other contact with the member that the Plan has the authority to determine the member's eligibility for low-income subsidy programs.

Specific Guidance Regarding Eligibility and Enrollment for Low-Income Subsidy

For more information on the eligibility and enrollment requirements for the low-income subsidy, please access the following websites:

<http://www.cms.hhs.gov/medicarereform/lir.asp>

<http://www.socialsecurity.gov/prescriptionhelp/>

For preferred terminology:

<http://www.cms.hhs.gov/partnerships/tools/materials/preferredterms.pdf>

Low-Income Subsidy Premium Disclaimer

In all marketing materials where PDP monthly premium and other member costs are described, the PDP sponsor must include the following language with any such discussion:

“If you have qualified for additional assistance for your Medicare Prescription Drug Plan costs, the amount of your premium and cost at the pharmacy will be less. Once you have enrolled in [name of PDP], Medicare will tell us how much assistance you are receiving, and we will send you information on the amount you will pay. If you are not receiving this additional assistance, you should contact 1-800-MEDICARE (TTY/TDD users call 877-486- 2048), your State Medicaid Office, or local Social Security Administration Office to see if you might qualify.”

7. REQUIRED MARKETING MATERIALS

Materials Required for Part D Program Start-up

Part D Plans may begin marketing on October 1, 2005. At a minimum, the following materials must be reviewed and approved and/or appropriately submitted to CMS under File and Use Certification in accordance with the Marketing Guidelines prior to October 1, 2005:

- Web site content
- Summary of Benefits
- Initial Enrollment Form (see Enrollment Guidance)
- Initial Enrollment Letters (see Enrollment Guidance)
- Member identification card
- Evidence of Coverage (EOC)
- Pharmacy directory
- Comprehensive Formulary

All other marketing materials (e.g., advertising, sales presentations, telemarketing scripts, etc.) must be reviewed and approved and/or appropriately submitted to CMS under File and Use Certification in accordance with the Marketing Guidelines prior to their use.

9. MARKETING REVIEW PROCESS

PDP File & Use Eligibility

NOTE: MA-PDs must follow the File & Use requirements for the Medicare Advantage program found at: <http://www.cms.hhs.gov/healthplan/marketing>.

The File & Use Eligibility program is designed to streamline the marketing review process. Under this process, PDPs that can demonstrate to CMS that they can continually meet a set standard of performance will be able to print and distribute certain marketing materials without prior CMS approval.

The File & Use Eligible status can be used by qualifying Plans that:

- Do not use models without modification under the File & Use Certification Program, and/or
- Develop other materials that are not eligible for File & Use Certification

NOTE: Plans that have chosen to waive the File & Use Certification status can qualify for the File & Use Eligibility Program.

Materials that are not eligible for the File & Use Eligibility program are materials that pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These are post-enrollment materials (beneficiary notification materials) that describe benefits and/or cost sharing and/or Plan rules and enrollment and disenrollment forms. These include materials such as the Evidence of Coverage, Summary of Benefits and Annual Notice of Change.

Qualifying for the File & Use Eligibility Program

A Plan may qualify for File & Use Eligibility after being in the Medicare PDP Program for a specified timeframe and meeting the marketing material requirements as defined by CMS. The “eligibility” status permits a Plan to submit certain marketing materials under File & Use Eligibility. This status is granted on a calendar quarter (i.e., January 1, April 1, July 1, and October 1).

To qualify for File and Use Eligibility status:

- Plans must have submitted at least eighteen months of reviewable marketing materials.
- Ninety percent of the materials submitted with the past six months are found to be acceptable.
- Within ten calendar days of the next calendar quarter, Plans must submit a written request to CMS requesting that it be considered for File & Use Eligibility status.

For a Plan to be considered under File & Use Eligibility, CMS will select a random sample of the Plan’s materials that were submitted for a 45/10-day review over the previous six-month period. In cases where zero material is found during the prior six months, CMS will expand the time period three additional months to review the materials.

CMS will inform organizations that have successfully met the qualifying criteria for the File & Use Eligibility Program no later than 30 days prior to the calendar quarter. An organization must submit a written request to CMS that it be considered for File & Use Eligibility no later than 10 days after notification by CMS.

Defining “Acceptable” Materials

An “acceptable” marketing material under the File & Use Eligibility Program:

- Is not materially inaccurate or misleading
- Does not make a material misrepresentation
- Does not need to be changed to avoid adverse impact on a beneficiary’s decision to elect the Plan or to disenroll and/or to avoid leading a member to believe that he/she could not get coverage for a covered service
- Follows the Medicare Prescription Drug Benefit Program Marketing Materials Guidelines

Examples of changes that would result in a material being unacceptable include failing to include a disclaimer that a particular benefit is not available to everyone or providing inaccurate premium or benefit information.

How to Maintain File & Use Eligibility Status

CMS will conduct semi-annual evaluations based on a random sample of materials filed by organizations under the File & Use Eligibility Program. At least 90% of the materials evaluated must be considered “acceptable” based on criteria established by CMS. In markets where foreign language marketing materials are used, CMS may select such pieces in the sample to be reviewed.

File & Use Eligibility Policies and Procedures

Either the contracting entity or the parent company of multiple contracting entities may request that CMS grant File & Use Eligibility status. File & Use Eligibility status is awarded to a single contracting entity (i.e., single contract number). All Plans under a single contract number will be part of the File & Use Eligibility program once the single contract number is awarded File & Use Eligibility status.

Some organizations may use many non-English marketing materials. Once a contracting entity is granted File & Use Eligibility status, both the English and the non-English materials are included within the File & Use Eligibility Program.

The organization must provide CMS with copies of all “final” materials at least five calendar days prior to their distribution. The “final” materials are the copies that will be sent to the printer or the comparable copies that are provided for reproduction.

All organizations must specify the expected date of initial distribution or publication when filing materials with CMS.

Organizations that have File and Use Eligibility privileges may still submit marketing materials using the standard marketing review process. However, pieces submitted through this process will be subject to a full 45/10-day review. Approvals and Disapprovals for these pieces will not count towards determining organizations’ File and Use Eligibility status.

If the organization submits materials under the File & Use Eligibility Program, but decides it does not want to distribute the materials, it must notify CMS in writing that it no longer intends to print and

distribute the materials. This is to ensure that CMS does not review those materials as part of the random sample reviewed during the quarterly review.

Loss of File & Use Eligibility Status

An organization may lose File & Use Eligibility status if it uses materials that do not meet the definition of “acceptable” and/or fails to file two or more materials at least five calendar days prior to distribution or publication.

CMS will notify the organization in writing if it is in danger of losing File & Use Eligibility status. This notice will indicate that the organization has been placed on a probationary review period and will determine the length of the probationary period. The length of the probationary period will be determined by CMS on a case-by-case basis, depending on the type and impact of errors identified in marketing materials.

During the probationary period, the Plan must submit materials to CMS 30 days in advance of their use as opposed to the usual five days. CMS will evaluate marketing materials used under the File & Use Eligibility process. In the middle of the probationary period, CMS will provide written notice to the organization indicating whether improvement has been demonstrated, or if the Plan is still in danger of losing File & Use Eligibility status. At the end of the probationary period, CMS will notify the Plan in writing regarding whether or not the Plan may continue with File & Use Eligibility status. If the determination is to terminate File & Use Eligibility status, this notice will provide the Plan with 10-day advance notice of the termination.

The termination of File & Use Eligibility status does not mean that a Plan may never again obtain File & Use Eligibility status. If CMS terminates a Plan’s File & Use Eligibility status, the Plan may request to get back on File & Use Eligibility once two calendar quarters have passed since its status was terminated. If a Plan loses File & Use Eligibility status twice, it may not request to get back on File & Use Eligibility status for at least one year after the status was terminated the second time.

Submission Methods and Acceptable Formats

If, due to a unique situation, a PDP cannot submit materials through HPMS, mailed submissions must include a Marketing Material Transmittal Sheet. The submissions must be mailed using overnight or priority mail to:

Mailing address:
MPDB Marketing Review
1676 International Drive
McLean, VA 22102

Or materials may be submitted via e-mail (address forthcoming)

10. SPECIAL GUIDELINES

Specific Guidance about Value-Added Items and Services

NOTE: MA-PDs must follow the Value-Added Items & Services requirements for the Medicare Advantage program found at: <http://www.cms.hhs.gov/healthplan/marketing>.

Value-Added Items and Services (VAIS) are items and services provided to Part D Plan enrollees by a Plan that do not meet the definition of “benefits” under the Part D program, and may not be funded by Medicare program dollars. Nonetheless, VAIS may be of value to some beneficiaries, and we do not wish to deny Medicare enrollees access to items and services commonly available to commercial enrollees.

A Plan sponsor must comply with all applicable HIPAA laws, including obtaining an authorization before using or disclosing protected health information for the purpose of “marketing” as defined under the HIPAA Privacy Rule. An exception to obtaining an authorization occurs when the Plan sponsor’s communication is merely to describe a health-related product or service (or payment for its product or service) that is provided by, or included in, the Plan’s benefits. Included in the *health-related products or services* exception are communications relating to a product or service that is available only to a Plan enrollee that adds value to, but is not a part of, a Plan’s benefits (VAIS). Therefore an authorization would not be required in this instance. In order to qualify as a Value Added Item and Service (VAIS) under HIPAA, the benefit must be health related and must demonstrably add value to the Plan’s membership. The value cannot merely be a pass-through of a discount or item available to the general public. For additional information regarding HIPAA, go to <http://www.hhs.gov/ocr/hipaa/>.

Examples of non health-related VAIS may include, but are not limited to discounts in restaurants, stores, entertainment, travel, and general financial services.

Examples of health-related VAIS may include discounts on eyeglasses, and health club memberships.

CMS permits VAIS to be offered to Plan enrollees under the following rules.

The VAIS are partly defined by what they are not - they are not benefits under the Prescription Drug Benefit program. Part D benefits are defined using a three-prong test:

1. Health care items or services that are intended to maintain or improve the health status of enrollees;
2. Plans must incur a cost or liability related to the item or service and not just an administrative cost; and
3. The item or service is submitted and approved through the BID process. All three parts of the definition must be met for an item or service to be considered a benefit. If an item or service fails to meet one or more of these parts, it is not a benefit. However, it may be offered to Plan enrollees as a VAIS, subject to the restrictions that follow.

Restrictions on Value-Added Items and Services

Plans may make VAIS available to Medicare enrollees in accordance with the following guidelines:

- VAIS must be offered uniformly to all Plan enrollees and potential enrollees.
- Plans may not describe VAIS as benefits.
- Plans may not engage in activities that could mislead or confuse Medicare beneficiaries.
- Plans may not claim or imply that the VAIS are recommended by or endorsed by CMS or Medicare.
- Plans must maintain privacy and confidentiality of enrollee records in accordance with all applicable statutes and regulations.
- To the extent required under the HIPAA Privacy Rule, Plans must not use or disclose a beneficiary's protected health information for the purpose of distributing non health-related VAIS without prior written authorization from the enrolled Part D beneficiary.

Relationship of Value-Added Items and Services (VAIS) to Benefits and Other Operational Considerations

Plans can market, either through oral presentations or written materials, Value-Added Items and Services (VAIS). Plans can also mention VAIS in their newsletters. VAIS may not appear in the PBP, the Standardized SB, the ANOC or the EOC.

Any description of VAIS must be preceded by the following prominently displayed language:

“The products and services described below are neither offered nor guaranteed under our contract with the Medicare program. In addition, they are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the [Name of Plan] grievance process.”

Plans may include VAIS along with their ANOC, SB, and/or EOC in one bound brochure as long as the value-added services are clearly distinct from the ANOC, SB, or EOC (such as on a different color piece of paper), and the information on value-added services includes all the disclaimers required in this chapter.

Because VAIS does not meet the definition of a Part D benefit, neither “benefit” nor associated administrative costs may appear in the Plan’s BID. However any costs associated with true pass-through discount programs may be absorbed within the administrative component of the bid (because they are minimum), but the subsidizing of any of these items and services must be excluded from the Part D bid. Furthermore, because they are not contained within the contracted health benefits package, these services are not subject to the Medicare appeals process.

CMS will not require prior approval of materials describing VAIS, since VAIS are not benefits as described within CMS regulations and therefore are not technically within CMS purview. However, CMS will review these materials on monitoring visits to ensure compliance with these requirements.

CMS may initiate a monitoring visit if it becomes aware that materials have been distributed describing VAIS without the

appropriate disclaimers or in violation of the requirements stated herein. CMS will also investigate complaints by beneficiaries regarding VAIS, just as it would other possible violations of CMS requirements. Plans are reminded that arrangements involving VAIS offered or provided to beneficiaries must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries.

Value Added Items and Services Provided to Employer Groups

Value-added items and services may be offered to employer groups. Value-added items and services are offered outside the core benefit package, thus they are outside of CMS's purview.

Marketing of Multiple Lines of Business

NOTE: MA-PDs must follow the instructions for the Marketing of Multiple Lines of Business requirements for the Medicare Advantage program found at: <http://www.cms.hhs.gov/healthplan/marketing>.

PDPs may market other lines of business (both health related and non health related) in accordance with the following:

Direct mail: Any PDP direct mail marketing materials sent to current members describing other health related lines of business must contain instructions describing how individuals may opt out of receiving such communications. PDPs must make every effort to ensure that all individuals (including non-members) who ask to opt out of receiving future marketing communications are not sent such communications.

NOTE: PDPs must obtain prior written authorization from the enrollee before sending non health-related direct mail marketing materials. Plans must also obtain prior written authorization from the enrollee before sending marketing materials containing both health-related and non health-related products.

PDPs that advertise multiple lines of business within the same direct mail marketing document must keep the PDP lines of business clearly and understandably distinct from the other products. PDPs must make this distinction by utilizing different formatting styles that delineate the two products. For example, the document might highlight the name of

the PDP product in bold and underlined font, then include a paragraph to describe the product in “regular” font, next go on to highlight the name of a non-PDP product in bold and underlined font, and then include a paragraph describing the non-Plan product in “regular” font. Also, if a Plan advertises non-PDP products with Plan material, it must pro-rate any costs so that costs of marketing non-PDP materials are not included as “Plan-related” costs in the organization’s bid to CMS.

Direct Mail Exception

While PDPs may mention non-Plan lines of business at the time they send a Plan non-renewal notice, they may only do so using separate enclosures within the same envelope. PDPs must not mention the non-Plan lines of business within the actual non-renewal notice. The purpose of this exception is to ensure that the non-renewal notice gives beneficiaries focused information only about the Plan non-renewal.

Plans must not include enrollment applications for non-PDP lines of business in any package marketing its Plan products, as beneficiaries might mistakenly enroll in the other option thinking they are enrolling in a Part D benefit. If information regarding Part D products and non-Plan lines of business are included in the same package, postage costs must be pro-rated so that costs of marketing non-Part D materials are not included as “Plan-related” costs in its bids.

Plans can combine information and enrollment application for non-competing lines of business (e.g., PDP and Medigap). However Plans are not allowed to include enrollment applications within combined mailings that include competing product lines (e.g., MA-PD and Medigap).

Television

PDPs may market other lines of business concurrently with Plan products on television advertisements. However, they must ensure that non-Plan products are separate and distinct from the Plan products.

Internet

PDPs may market other lines of business concurrently with Plan products on the Internet, though to avoid beneficiary confusion, PDPs must continue to maintain a separate and distinct section of their Web sites for Plan information only. CMS will review PDPs' Web pages to ensure that Plans are maintaining the separation between Part D information and information on other lines of business.

HIPAA Privacy Rule and the Marketing of Multiple Lines of Business

Generally, PDPs are not required to obtain authorization from enrollees to use or disclose an enrollee's protected health information to make a communication about replacements of, or enhancements to, the plan of benefits of the PDP and the PDP's own health-related, value-added products and services. These categories are exceptions to the definition of marketing in the HIPAA Privacy Rule. In compliance with these exceptions, PDPs may use and disclose protected health information to make communications to enrollees about other lines of business provided by the PDP covered entity.

However, a Plan must obtain authorization from an enrollee, prior to using or disclosing the enrollee's protected health information for any marketing that does not fall within the exceptions to the definition of marketing under the HIPAA Privacy Rule. For example, authorization is needed if the product is a pass-through of a discount available to the public at large, an accident only policy, a life insurance policy, or an item or service that is not health-related.

Third Party Marketing Materials

From time to time, a third party may prepare marketing materials for a Part D Plan's membership and/or supply those materials to the membership. These materials are known as "third party marketing materials" and may be prepared both by benefit/service providing and non-benefit/service providing third parties. Marketing review of these materials is dependent upon the type of third party, as outlined in the remainder of this section.

Benefit Providing Third Party Marketing Materials

A benefit/service-providing third party is an entity that administers, covers, or provides the prescription benefits to the Part D Plan's Medicare membership (e.g., employer groups, nursing homes).

Other than Part D Plan employer group marketing materials, CMS reviews all marketing materials prepared by benefit/service-providing third party entities and used by the Part D Plan for its membership. Marketing materials must be submitted to CMS via the Part D Plan using the materials and are expected to follow all appropriate marketing guidelines. Marketing materials may not be submitted directly by the third party to CMS.

When the third party would like to use material previously approved by CMS, it must inform the Part D Plan. Also, the Part D Plan and the third party must work together to determine whether the material will be used for the Plan's membership or whether new material will need to be developed. If a Plan decides to have the third party provide the pre-approved material to its membership, the Plan must e-mail the CMS Designee a copy of that material.

Non-Benefit/Service Providing Third Party Marketing Materials

A non-benefit/service providing third party entity is an organization that neither administers the prescription drug benefit nor provides Part D drugs to Medicare beneficiaries. For the purpose of marketing review, non-benefit/service providing third party entities are organizations or individuals that supply information to a Plan's membership, which is paid for by the Plan or the non-benefit/service providing third party entity. An example of a non-benefit/service providing third party could be a research firm that provides comparative data relating to Part D Plans.

CMS does not review marketing materials originated by non-benefit/service providing third party entities.

Therefore, if a non-benefit/service providing third party wishes to market to Part D Plan members, they must submit their materials to the Plan, which in turn, may distribute the materials to their

membership. It is the responsibility of the Part D Plans to ensure that these marketing materials contain the disclaimer:

“Medicare has neither reviewed, nor endorses this information.”

This disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size and style as the commercial message.

Marketing Material Requirements for Non-English Speaking Populations or Populations with Special Needs

Part D Plans should make marketing materials available in any language that is the primary language of more than ten percent of a Part D Plan’s geographic service area. Additionally, call centers must be able to accommodate non-English speaking/reading beneficiaries. Part D Plans should have appropriate individuals and translation services available to call center personnel to answer questions non-English speaking beneficiaries may have concerning aspects of the prescription drug benefit.

In addition, basic enrollee information should be made available to the visually impaired. Part D Plans must make sure information about their benefits is accessible and appropriate to persons eligible for Medicare because of disability.

Review of Marketing Material in Non-English Language or Braille

Part D Plans that submit marketing materials containing non-English or Braille information (in whole or in part) must submit an English version (translation) of the piece and a letter of attestation. The Plan should submit an English version for approval first, and then submit the non-English or Braille version along with the letter of attestation. This way, any changes or revisions that are made to the English version will be accurately reflected in non-English materials when sent for review.

The letter of attestation must be signed and certified by an authorized official employed by the organization, and must attest that the translation conveys the same information and level of detail as the

corresponding English version. See model attestation letter at the end of this section.

Part D Plans will be subject to verification monitoring review and penalties for violation of CMS policy. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing review of non-English materials on an “as needed” basis. If materials are found inaccurate or do not convey the same information as the English version, Part D Plans may not distribute materials until revised materials have been approved. If multi-region organizations have submitted materials in English to CMS and the materials have been approved, the same materials in other languages or Braille may be used in other regions.

Model Attestation

ATTESTATION OF TRANSLATED NON-ENGLISH MATERIALS OR BRAILLE FOR PART D PLANS

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and [insert Plan name], hereafter referred to as the Part D Plan, governing the operations of the following Plan: [insert Plan and contract number], the Plan hereby attests that the non-English or Braille version(s) submitted in the attached, convey the same information and level of detail as the corresponding English version.

The Part D Plan acknowledges that the information concerning the translation(s) described below is for the use of and correspondence to the beneficiary and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The Part D Plan is submitting to CMS the attestation with the following materials: (INSERT MATERIAL IDENTIFICATION NUMBERS).

Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in these documents are accurate, complete, and truthful.

(NAME & TITLE [CEO, CFO, or delegate])

On behalf of

(NAME OF PART D PLAN)

DATE

Employer/Retiree Groups

CMS has waived the Part D Plan material marketing review requirements for all Employer Group Part D Plans. Therefore, Employer Group Part D Plans do not need CMS approval of marketing materials designed for members of the employer groups.

CMS will assume that Employer Group Part D Plans have chosen to use this waiver authority unless the Plan contacts CMS in writing. All Employer Group Part D Plans will be required to send informational copies of employer group-specific marketing materials to CMS within 14 days of their release/use (CMS will not be reviewing these materials; instead, they will keep them on file in the event any inquiries are received about them.)

The Part D Plan assumes responsibility for the accuracy of the employer group marketing materials, including making any corrections to those materials when necessary. The Part D Plan is expected to continue to follow the guidelines within this chapter when preparing its marketing materials. In the unusual circumstance of an organization knowingly releasing/distributing incorrect or false marketing materials, sanctions and/or fines may be imposed on that organization.

Anti-Discrimination

Part D Plans may not discriminate based on race, ethnicity, religion, gender, sexual orientation, health status, or geographic location within the service area. All items and services of a Part D Plan must be available to all eligible beneficiaries in the service area with the following exceptions:

- There may be additional eligibility standards for enrollment in the low-income subsidy.
- Certain products and services may be made available to enrollees with certain diagnoses, e.g., medication therapy management program for individuals with chronic illnesses or medically necessary coverage provisions.

Part D Plans may not engage in discriminatory practices such as targeting marketing to beneficiaries from higher income areas or implying that Plans are available only to seniors rather than to all Medicare beneficiaries.

See also Section 6 for Prohibited Terminology/Statements.

11. GUIDELINES FOR PROMOTIONAL ACTIVITIES

General Guidance about Promotional Activities

NOTE: MA-PDs should refer to Chapter 3 of the Medicare Managed Care Manual for guidance regarding Promotional Activities.

Promotional activities (including provider promotional activities) must comply with all relevant Federal and state laws, including, when applicable, the anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. A PDP may be subject to sanctions if it offers or gives something of value to a Medicare beneficiary that the PDP knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare. Additionally, PDPs are prohibited from offering rebates or other cash inducements of any sort to beneficiaries.

Furthermore, Plans are prohibited from offering or giving remuneration to induce the referral of a Medicare beneficiary, or to induce a person to purchase, or arrange for, or recommend the purchase or ordering of an item or service paid in whole or in part by the Medicare program.

PDPs may not offer post-enrollment promotional items that in any way compensate beneficiaries based on their utilization of services. Any promotional activities or items offered by PDPs, including those that will be used to encourage retention of members, must be:

- Of nominal value;
- Offered to all eligible members without discrimination; and
- Not in the form of cash or other monetary rebates.

NOTE: The same rules that apply to post-enrollment promotional activities also apply to pre-enrollment promotional activities.

Nominal Gifts

PDPs can offer gifts to potential enrollees if they attend a marketing presentation, as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the PDP. Nominal value is defined as an item worth \$15 or less, based on the retail purchase price of the item. Local Medicare fee-for-service fiscal intermediary and/or

carrier charge listings can be used to determine the value of medical services, examinations, laboratory tests, etc. associated with nominal value determinations in marketing scenarios. Cash gifts are prohibited, including charitable contributions made on behalf of people attending a marketing presentation, and including gift certificates that can be readily converted to cash, regardless of dollar amount. The dollar amount associated with the definition will be periodically reassessed by CMS.

An organization may offer a prize of over \$15 to the general public (for example, a \$1,000 sweepstakes on its corporate Web site) as long as the prize is offered to the general public and not just to Medicare beneficiaries and is not routinely or frequently awarded.

Drawings/Prizes/Giveaways

PDPs are prohibited from using free gifts and prizes as an inducement for enrollment. Any gratuity must be made available to all participants in the Plan’s marketing presentation regardless of enrollment. The value of any gift must be less than the nominal amount of \$15. Statements made concerning drawings, prizes or any promise of a free gift must include a disclaimer there is no obligation to enroll in the Plan. For example:

“Eligible for a free drawing and prizes with no obligation.”

“Free drawing without obligation.”

Any incentive that might have the effect of inducing enrollees to use a particular provider, practitioner, or supplier should be carefully reviewed by the Plan for compliance with section 1128A(a)(5) of the Social Security Act and the corresponding regulations at 42 C.F.R. § 1003.102(b)(13). In addition, incentives provided by Plans are subject to the Federal anti-kickback statute, section 1128B(b) of the Social Security Act.

Hold Time Messages

Hold time messages (recorded information played to caller while waiting on hold) within telephone scripts must only discuss health-related features.

Referral Programs

The following general guidelines apply to referral programs under which PDPs solicit leads from members for new enrollees. These include gifts that would be used to thank members for devoting time to encouraging enrollment. Gifts for referrals must be available to all members and cannot be conditioned on actual enrollment of the person being referred.

- PDPs may not use cash promotions as part of a referral program
- PDPs may offer thank you gifts of less than \$15 nominal value (e.g., thank you note, calendar, pen, key chain) when an enrollee responds to a Plan solicitation for referrals. These thank you gifts are limited to one gift per member, per year.
- A letter sent from the PDPs to members soliciting leads cannot announce that a gift will be offered for a referral.
- An organization can ask for referrals from active members, including names and addresses, but cannot request phone numbers. PDPs can then use this information for soliciting by mail.

Health Fairs and Health Promotional Events

PDPs may participate in health fairs and health promotional events as either a sole sponsor or co-sponsor of an event hosted by multiple organizations. CMS health fair and health promotional event policies for PDPs sponsoring health fairs and health promotional events are divided into three sections:

- **Sole-Sponsor**, referring to a single-sponsor for an event;
- **Multiple-Sponsor**, indicating more than one sponsor for an event; and
- **Both**, where the policy applies to both single and multiple-sponsor events.

NOTE: If an audience is comprised of the general public as well as Medicare beneficiaries, the following policies apply to the entire audience.

Sole Sponsor Policies:

- If offered, door prizes/raffles cannot exceed the \$15 limit each.

Multi-Sponsor Policies:

- Door prizes/raffles can exceed the \$15 limit if a PDP contributes to a pool of cash for prizes or contributes to a pool of prizes such that the prize(s) is not individually identified with the PDP, but is identified with a list of contributors. A jointly sponsored event may consist of the PDP and one or more sponsor participants who are not contracting providers with the PDP. A PDP may also contribute cash toward prize money to a foundation or another entity sponsoring the event. For example: A radio station, along with many sponsors, organizes a senior health fair. Anyone who attends may register for the door prize: a get-away weekend. The PDP may participate in the fair, contribute to the door prize, and permit attendees to register for the prize at its booth (as well as other sponsor booths). However, the PDP cannot claim to be the sole donor of the prize. It must be clear that the prize is attached to the seniors fair. No sales presentation may be made at the event.

Both (Sole-Sponsor & Multi-Sponsor) Policies:

- Such events should be social and should not include a sales presentation.
- Response by a PDP representative to questions asked at the event will not be considered a sales presentation as long as no enrollment form is accepted at the event.
- Advertisements for the event may be distributed to either enrollees, non-enrollees or both.
- The value of any give-away or free items (e.g., food, entertainment, speaker) cannot exceed \$15 per attending person. For planning purposes, event budgets can be based on projected attendance. The cost of overhead for the event (e.g., room rental) is not included in the \$15 limit.
- Pre-enrollment advertising materials (including enrollment forms) can be made available as long as enrollments are not accepted at the event.

Employer Group Health Fairs

PDP enrollment restrictions (i.e., no sales presentations can be made or enrollment applications accepted at the meeting) do not apply to health fairs or other promotional events sponsored by an employer group or labor organization as long as the following requirements are met:

- The meeting must be held solely for retirees and any active employees (and their spouses/interested decision makers) from the employer/labor organization. No one from the “general public” may be solicited or invited to attend the meeting; and
- The meeting may not be announced via “public media” communication outlets. Potential employer group/labor organization retirees must be notified of the meeting by individual notification or by company/labor organization sponsored media such as a newsletter or similar targeted mailing/vehicle.

CMS-Sponsored Health Information Fairs

CMS is required to conduct a nationally coordinated education and information campaign to inform Part D eligible individuals about Part D benefits and the election process provided under the law for enrolling in Part D. One of the coordinated education and information campaign activities is CMS sponsorship of Part D Plan Health Information Fairs. While most CMS-sponsored Part D Plan Health Fairs will be conducted immediately before and during the month of November each year (the Annual Election Period), occasionally CMS will sponsor Health Fairs as early as September and other times of the year. The following rules and procedures apply to CMS-sponsored Health Fairs, whenever they occur.

CMS will invite the Part D Plans to participate in the planning of local Health Fairs. PDP participation is optional, but it is important to include contractors in the planning process. CMS retains the right to modify the following guidelines:

PDPs may do the following:

- Assist in the planning of local Health Fairs;
- Distribute health plan brochures and application forms, while at the Health Fair. They may also include in their handouts a reply card, which may be given to interested beneficiaries for return to the organization via mail;
- Have a booth at the Health Fair;

- Distribute items with a total retail value of no more than \$15. These items MUST be offered to everyone, (e.g., organizations can not give gifts to only those individuals who show interest);
- Have any personnel present (i.e., marketing personnel, customer service personnel) as long as they adhere to these guidelines;
- Contribute funding for any Health Fair costs (i.e., purchasing of food; drawings, raffles, or door prizes for attendees which exceed the \$15 nominal value requirement) as long as the recognition of the donation is to a number of entities (not just one particular PDP); and
- Market multiple lines of business.

PDPs may not do the following:

- Conduct sales presentations;
- Collect enrollment applications. (Although application forms may be distributed, they may not be collected during Health Fairs);
- Collect names/addresses of potential enrollees. However, as noted above, they may distribute application forms and reply cards;
- Compare their benefits against other health plans. However, they may use comparative information, which has been created by CMS (such as information from CMS’s Web site) or information/materials that have been approved by CMS (i.e., the standardized Summary of Benefits);
- Use materials provided by a third party, unless they have been approved by CMS in advance; and
- Provided individual gifts with a retail value of more than \$15.00.

Specific Guidance about Provider Activities

The following definitions are relevant to describing provider activities:

- Marketing: Activities that steer an undecided potential enrollee towards a Plan, or limited number of Plans, and for which the individual performing marketing activities expects compensation or other consideration based upon the enrollment.
- Assisting in Enrollment: Assisting a potential enrollee with the completion of an application or discussing characteristics of different Plans to assist a beneficiary with appraising the merits of individual Plans, provided the individual performing these activities does not steer a potential enrollee towards a specific Plan or limited number of Plans.

- **Education:** Activities that inform a potential enrollee about Plans and Plan characteristics, generally or specifically, but do not steer a potential enrollee towards a specific Plan or a limited number of Plans by presenting only selective information.

PDPs are permitted to use contracted providers to assist in enrollment and education. As used in this guidance, the term “provider” refers to all providers contracted with the PDP, including but not limited to: physicians, hospitals, pharmacists, pharmacies, long-term care facilities, and social workers.

In general, providers must only provide assistance in enrollment and education in their capacity as a member of the PDP’s network and only in coordination with the PDP. All marketing materials describing a PDP must adhere to CMS Marketing Guidelines.

CMS requires PDPs that want network pharmacies to provide marketing materials to prospective enrollees to stipulate in their provider contracts that pharmacies will inform Part D eligible individuals where they can obtain information on all Part D options available within the service area.

CMS is concerned with provider activities for the following reasons:

- Providers are usually not fully aware of all Part D Plan benefits and costs; and
- A provider may confuse the beneficiary if the provider is perceived as acting as an agent of the Part D Plan vs. acting as the beneficiary’s provider.

Providers may face conflicting incentives when acting as a PDP representative since they know their patients’ health status. Desires to either reduce out-of-pocket costs for their sickest patients, or to gain financially by enrolling their healthy patients may result in recommendations that do not address all of the concerns or needs of a potential PDP enrollee.

Following are requirements associated with provider activities:

1. **Provider Activities and Materials in the Health Care Setting** – When patients seek information or advice from their own provider regarding their Medicare options, providers may engage in this discussion. Beneficiaries often look to their health care professionals to provide them with complete information regarding their health

care choices. Providers should inform prospective enrollees where they may obtain information on the full range of Plan options available to them under Part D. Because providers are usually not fully aware of all Medicare Plan benefits and costs, they are advised to additionally refer their patients to other sources of information, such as the State Health Insurance Assistance Programs, Part D Plan marketing representatives, their State Medicaid Office, local Social Security Administration Office, CMS’s Web site at <http://www.medicare.gov/>, or by calling 1-800-MEDICARE. Providers are permitted to print out and share information with patients from CMS’s Web site.

Providers are permitted to make available and/or distribute PDP marketing brochures (including enrollment applications) and display posters announcing PDP contract relationships. However, providers cannot accept enrollment applications or offer inducements to persuade beneficiaries to join PDPs or to steer beneficiaries to a specific PDP. In addition, providers cannot offer anything of value to induce PDP enrollees to select them as their provider.

2. **PDP Activities and Materials in the Health Care Setting** – While providers are prohibited from accepting enrollment applications in the health care setting, PDPs may conduct sales presentations and distribute and accept enrollment applications in health care settings as long as the activity takes place in the common areas of the setting and patients are not misled or pressured into participating in such activities. Common areas, where marketing activities are allowed, include areas such as hospital or nursing home cafeterias, community or recreational rooms, and conference rooms. If a pharmacy counter is located within a retail store, common areas would include the space outside of where patients wait for or interact with pharmacy providers and obtain medications.

PDPs are prohibited from conducting sales presentations and distributing and accepting enrollment applications in areas where patients primarily intend to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, and pharmacy counter areas (where patients wait for or interact with pharmacy providers and obtain medications).

NOTE: Upon request by the beneficiary, PDPs are permitted to schedule appointments with beneficiaries residing in long-term care facilities just as with other individuals.

- 3. Provider Affiliation Information** – Providers can announce a new affiliation with a PDP to their patients. An announcement to patients of a new affiliation which names only one PDP may occur only once. Additional communications from providers to their patients regarding affiliation must include all PDPs with which the provider contracts. This includes, for example, annual affiliation announcements and the display of PDP brochures and/or posters. If these communications describe PDPs in any way, the materials must be approved by CMS (materials that only list PDPs do not require CMS approval).

NOTE: This information may be particularly helpful to communicate to beneficiaries residing in a long-term care facility.

- 4. Comparative and Descriptive PDP Information** – Providers may distribute printed information to their patients comparing the benefits of different PDPs with which they contract. Materials may not be rank ordered or highlight specific PDPs and may only include benefit descriptions that are available in the Plans' Summary of Benefits. Such materials must have the concurrence of all PDPs involved and must be approved by CMS prior to distribution (i.e., these items are not be subject to File and Use Certification). The PDPs must determine a lead Plan to coordinate submission of these materials. CMS continues to hold the PDPs responsible for any comparative/descriptive material developed and distributed on their behalf by their contracting providers. Providers may not health screen when distributing information to their patients, as health screening is a prohibited marketing activity.

NOTE: PDPs may not use providers to distribute printed information comparing the benefits of different PDPs unless providers accept and display materials from all PDPs in the service area.

- 5. Providers/Provider Group Web Sites** – Providers may provide links to PDP enrollment applications and/or provide downloadable enrollment applications. The site must provide the

links/downloadable formats to enrollment applications for all PDPs with which the provider participates. Alternatively, providers may include a link to the CMS Online Enrollment Center.

6. **Health Fairs** – Providers can distribute Part D Plan brochures including enrollment applications at health fairs. Providers cannot compare benefits among Part D Plans in this setting, because they may not be fully aware of all benefits and costs of the various Part D Plans. In addition, providers are not permitted to accept enrollment applications or health screen.
7. **Leads from Providers** – Part D Plans and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to Part D sponsors for marketing purposes. This obligation includes compliance with the provisions of the HIPAA privacy rule and its specific rules regarding uses and disclosures of beneficiary information. In addition, Part D Plans are subject to sanction for engaging in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services (i.e., health screening or “cherry picking”).

The “*Medicare and You*” *Handbook* or “*Medicare Compare Information*” (from <http://www.medicare.gov>), may be distributed by providers without additional approvals. There may be other documents that provide comparative and descriptive material about Part D Plans, of a broad nature, that are written by CMS or have been previously approved by CMS. These materials may be distributed by Part D Plans and providers without further CMS approval. Please advise your Part D Plan providers of the provisions of these rules.

NOTES:

All payments that PDPs make to providers for patient education or other outreach services must be fair market value, consistent with an arm’s length transaction, for bona fide and necessary services, and otherwise comply with all relevant laws and regulations, including the Federal and any state anti-kickback statute.

For enrollment and disenrollment issues related to beneficiaries residing in long-term care facilities (e.g., enrollment period for beneficiaries residing in long-term care facilities and use of personal representatives

in completing an enrollment application), please continue to check the CMS Web site at <http://cms.hhs.gov> for forthcoming PDP Enrollment and Disenrollment Guidance.

Questions and Answers

Q: Can PDPs provide marketing materials to providers such as brochures, banners, and other materials?

A: Yes. PDPs may supply Plan marketing materials to providers that will be distributed in the health care setting. However, if this Plan information contains comparative PDP information, the provider is required to accept and display materials from all PDPs serving that region. Furthermore, providers must inform Part D eligible individuals where they can obtain information on all Part D options available in their service area.

Q: Can Providers speak with prospective Part D enrollees about Part D options available to them?

A: Yes. Providers can supply beneficiaries with information about Part D options available to them that they may not have received through other sources. Beneficiaries often look to their health care professionals to provide them with complete information regarding their health care choices. Providers must inform prospective enrollees where they can obtain information on the full range of options available to them under Part D.

Q: Can providers steer beneficiaries to a preferred PDP?

A: No. Although beneficiaries often look to their providers to give them information regarding their health care choices, most providers will not be fully aware of benefits and cost for all Part D Plans. Providers may communicate with their patients regarding the PDPs with which the provider contracts.

Q: With permission, can marketing representatives for a PDP setup informational tables and/or educational seminars inside or outside of a general store that has a pharmacy counter area?

A: Yes. PDP representatives may conduct sales presentations and distribute and accept enrollment applications within the common areas of a general store that has a pharmacy counter area. However,

marketing representatives are not allowed near the pharmacy counters (where patients wait for or interact with pharmacy providers and obtain medications).

Q: Can providers distribute enrollment forms for PDPs in the health care setting?

A: *Yes. Providers may distribute enrollment forms for PDPs in the health care setting. However, providers are prohibited from accepting enrollment forms.*

Specific Guidance Regarding the Use of Brokers and Independent Insurance Agents

CMS is aware that health plans often use independent agents to market their product offerings, and that many Part D Plans intend to use them in 2006 and beyond. CMS is also aware that insurance plans sometimes use performance-based compensation, tying independent insurance agents' compensation to the volume or value of their sales. Given such compensation arrangements, agents may face financial incentives to steer enrollees towards the Plan offering the most compensation. Ensuring that beneficiaries select the Plan most appropriate to their needs, as opposed to the financial interests of their insurance agents, is particularly important in the Part D program as variability between plans is expected and benefit designs may incorporate significant cost sharing for beneficiaries. Marketing by an independent insurance agent contracted by a Plan is considered marketing by the Part D Plan. Set forth below is guidance for those Part D and Medicare Advantage organizations interested in using insurance agents to market their plans.¹

Independent insurance agents may be in a unique position to enroll healthier beneficiaries into specific health plans (or “cherry pick”), given their often-longstanding relationships with clients. “Cherry picking” healthier patients is problematic because it distorts the market and can be viewed as discriminatory. This is especially true in the Part D program, where focusing enrollment mainly on beneficiaries with particular expected drug spending patterns may impact benefit designs and could be used to inflate CMS and beneficiary expenditures. Therefore, Part D Plans must stipulate in their contracts with independent insurance agents that any coordinated marketing to be carried out by the broker or

¹ Part D Plans are responsible for ensuring that all their activities comply with the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the “Act”) (codified at 42 U.S.C. § 1320a-7b(b)).

independent agent must be done in accordance with all applicable CMS marketing guidelines and all Federal health care laws (including civil monetary penalty laws).

Specifically, Part D Plans may utilize brokers and independent agents if the Plan:

- Complies with all CMS marketing guidelines (and any other applicable State insurance or other requirements) to ensure that beneficiaries receive truthful and accurate information.
- Establishes clear provisions within the broker agreement that the Plan is responsible for ensuring that the agent abides by the Part D marketing guidelines.
- Conducts monitoring activities to ensure compliance with the provisions of the broker agreement.
- Uses state licensed brokers and independent agents. A Part D Plan sponsor may only employ or contract with a marketing representative for the purpose of marketing a Part D Plan, if the marketing representative meets state licensure, certification or registration requirements, if a state has such a requirement.
- Discloses to potential enrollees that brokers are paid a commission upon beneficiary enrollment, if that is the compensation arrangement.

Part D Plan broker and independent agent compensation structures must:

- Avoid incentives to mislead beneficiaries, cherry pick certain beneficiaries, or churn beneficiaries between Plans.
- Provide reasonable compensation in line with industry standards. Fees should reasonably relate to the value of the services provided.
- Establish compensation schedules through the written broker agreement. The commission rate (i.e., the percentage per enrollment) should not vary based on the value of the business generated for the Plan paying the commission (e.g., profitability of the book of business). Commissions should be paid for all beneficiaries who qualify for enrollment in Part D Plans, regardless of the beneficiary's risk profile.
- Not include payments outside of the compensation schedule set forth in the written broker agreement.
- Not include payments by brokers or independent agents to beneficiaries.

- Withhold or withdraw payment if an enrollee disenrolls within an unreasonably short time frame (i.e., rapid disenrollment).

Door-To-Door Solicitation

PDPs are prohibited from soliciting Medicare beneficiaries door-to-door for health-related or non health-related services and/or benefits prior to receiving an invitation from the beneficiary to provide assistance in the beneficiary's residence.

Unsolicited E-mail Policy

A PDP may not send e-mails to a beneficiary, unless the Medicare beneficiary agrees to receive e-mails from the PDP and the beneficiary has provided his/her e-mail address to the PDP. Furthermore:

- PDPs are prohibited from renting e-mail lists to distribute information about the Part D benefit.
- PDPs may not acquire e-mail addresses through any type of directory.

***NOTE:** Since the Medicare beneficiary is conducting business with the PDP, permission to send e-mail must be received by the PDP. Only then may the PDP e-mail that beneficiary.*

Answers to Frequently Asked Questions About Promotional Activities

Q: We purchased books on health maintenance that we plan to give away to anyone attending one of our marketing presentations, regardless of whether or not they enroll in our PDP. Because we purchased a large number of these books, we were able to buy them at a cost of \$14.99 per book. However, on the inside jacket, the retail price is shown as \$19.99. May we give these books away at our marketing presentation?

A: *No. The retail purchase price of the book is \$19.99, which exceeds CMS's definition of nominal value.*

Q: We are participating in a health fair during which we will have marketing staff present. During the fair, we will offer a number of free health screening tests to people who attend. The value of these tests, if purchased, would be considerably more than \$15. Is this permissible?

A: No. You may not offer these tests for free because their value exceeds CMS's definition of nominal value.

Q: We would like to offer gifts of nominal value to people who call for more information about our PDP. We would then like to offer additional gifts if they come to marketing events. Each of the gifts meets CMS's definition of nominal value, but taken together, the gifts are more than nominal value. Is this permissible?

A: Yes.

Q: Listed below are some possible promotional items to encourage people to attend marketing presentations. Are these types of promotions permissible?

- Meals
- Day trips
- Magazine subscriptions
- Event tickets
- Coupon book (total value of discounts is less than \$15)

A: Yes. All these promotional items are permissible as long as they are offered to everyone who attends the event, regardless of whether or not they enroll and as long as the gifts are valued at \$15 or less. Cash gifts are prohibited, including charitable contributions made on behalf of people attending a marketing presentation and including gift certificates that can be readily converted to cash, regardless of dollar amount.

Q: Can a PDP advertise eligibility for a raffle or door prize of more than nominal value for those who attend a marketing presentation if the total value of the item is less than \$15 per person attending?

A: No. You cannot have a door prize of more than nominal value. Such gifts or prizes are prohibited by CMS. However, the raffle or door prize can exceed the \$15 limit if the organization is jointly sponsoring the prize with other PDPs at a health fair. See discussion of Rules Pertaining to Health Fairs.

Q: What about post-enrollment promotional activities? Are there any rules prohibiting such items or activities as coupon books, discounts, event tickets, day trips, or free meals to retain enrollees?

A: Currently, PDPs may not offer post-enrollment promotional items that in any way compensate beneficiaries based on their utilization of services. Any promotional activities or items offered by PDPs, including those that will be used to encourage retention of members, must be of nominal value, must be offered to all eligible members without discrimination, and must not be in the form of cash or other monetary rebates. The same rules that apply to pre-enrollment promotional activities apply to post-enrollment promotional activities.

Q: Can PDPs provide incentives to current members to receive preventive care and comply with disease management protocols?

A: Yes, as long as the incentives are:

- *Offered to current members only;*
- *Not used in advertising, marketing, or promotion of the PDP;*
- *Provided to promote the delivery of preventive care;*
- *Not structured to steer enrollees to particular providers, practitioners, or suppliers; and*
- *Are not cash or monetary rebates.*

NOTE: *If these products are in the CMS approved contracted Part D Plan benefit package (Bid and PBP) under “Preventive Services,” the provision of such incentives are within the purview of the medical management philosophy of the PDP and do not require additional review by CMS for marketing accuracy/compliance. Thus, the nominal value rule **would not** apply.*

Q: Can a PDP offer reductions in premiums or enhanced benefits based on the length of a Medicare beneficiary’s membership in the PDP?

A: No. Longevity of enrollment is not a basis for reductions in premium or enhanced benefits.²

² This “no” statement also applies to “zero” premium plans that might want to award a nominal value gift as a reward for longevity of enrollment.

Q: Can a PDP provide discounts to beneficiaries who prepay premiums for periods in excess of 1 month?

A: No. PDPs cannot provide any discounts to Medicare beneficiaries for prepayment of premiums in excess of 1 month.

Q: Can a PDP take people to a casino or sponsor a bingo night at which the member’s earnings may exceed the \$15 nominal value fee?

A: No. The total value of the winnings may not exceed \$15 and the winnings cannot be in cash or an item that may be readily converted to cash.

Q: Can PDPs send a \$1 lottery ticket as a gift to prospective members who request more information?

A: Offering a \$1 lottery ticket to prospective members violates the “no cash or equivalent” rule discussed above, whether or not the person actually wins since, generally, the “unscratched” ticket has a cash value of \$1.

Q: Can a PDP pay beneficiaries that sign up to be “ambassadors” a flat fee for transportation?

A: The PDP may reimburse the beneficiary for any actual, reasonable transportation costs but must not pay the beneficiary a flat fee for transportation. If the PDP employs a beneficiary to be an “ambassador”, and travel reimbursement is part of a bona fide employment arrangement, then CMS has no oversight of this issue.

Q: Can PDPs that own nursing homes conduct health fairs and distribute enrollment forms to nursing home residents?

A: Yes, organizations that own nursing homes may conduct health fairs and distribute enrollment forms if the sales presentations are confined to a common area (i.e., community or recreational rooms) or if a member volunteered for an individual presentation. Promotional activities and sales presentations cannot be made in individual resident rooms without a prior appointment for a “home” visit. Such activities would be considered door-to-door solicitation and are prohibited. The organization is required to meet all health fair/sales presentation and enrollment requirements as currently outlined in this chapter and regulations.

12. USE OF MEDICARE MARK

Use of Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act, 42 U.S.C. §1320b-10, prohibits the use of the Department's name and logo, the agency's name and marks, 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), Office of External Affairs (OEA).

Summary

This notice provides information and instructions to all Medicare Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans on the use of the Medicare Prescription Drug Benefit program mark.

EFFECTIVE DATE: June 2005

Authorized Users

The Medicare Prescription Drug Benefit program authorizes Medicare PDPs and MA-PDs to use the Medicare Prescription Drug Benefit program mark only after written notification of approval into the program. PDP and MA-PD entities may use the mark after submission of marketing materials consistent with marketing guidelines.

Use of Medicare Prescription Drug Benefit Program Mark on Items for Sale or Distribution

Medicare PDP and MA-PD entities may use the Medicare Prescription Drug Benefit program mark on items they distribute, provided the item follows guidelines for nominal gifts, as stated elsewhere in the marketing guidelines. Items with the Medicare name and/or the Medicare Prescription Drug Benefit program mark cannot be sold for profit.

Approval

Requests to distribute other items bearing the Medicare Prescription Drug Benefit program mark 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 program and only for those items for which such written approval was granted. Requests for approval should be sent to: CMS External Affairs Office/Visual & Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03.

Restrictions on Use of Medicare Prescription Drug Benefit Program Mark

Unless otherwise approved, all unauthorized individuals, organizations, and/or commercial firms may not distribute materials bearing the Medicare Prescription Drug Benefit program mark.

Unauthorized use of the Medicare name or the Medicare Prescription Drug Benefit program mark should be reported immediately so that appropriate legal action can be taken. Reports of unauthorized use should be referred to CMS's External Affairs Office at 7500 Security Blvd., C1-16-03, Baltimore, MD 21244-1850, or by telephone to 410.786.7214.

Prohibitions

42 U.S.C. §1320b-10 prohibits the misuse of the Medicare name and marks. In general, it authorizes the Inspector General of the Department of Health and Human Services (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 the 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.

Mark Guidelines

Positive Program Mark

The Medicare Prescription Drug Benefit program mark is a logotype comprised of the words Medicare Rx with the words Prescription Drug Coverage directly beneath.



Always use reproducible art available electronically. Do not attempt to recreate the program mark or combine it with other elements to make a new graphic. Artwork will be supplied in .EPS, .TIFF or .JPG format after notification of approval into the program. Other file formats are available from CMS's Office of External Affairs upon request.

Negative Program Mark

The Medicare Prescription Drug Benefit program mark may be reversed out in white. The entire mark must be legible.



Approved Colors

The 2-color mark is the preferred version. It uses PMS 704 (burgundy) and 65% process black. It is recommended that if the CMS mark is used in conjunction with the brand mark, that the black versions of those logos be used.



The 1-color version in grayscale is acceptable. The mark elements are 100% black except for the word “Medicare” which is 55% black.



The 1-color version in 100% black also is acceptable.



Languages

The Spanish version of the Medicare Prescription Drug Benefit program mark may be used in place of the English language version on materials produced entirely in Spanish. The 2-color version is preferred, but the grayscale, black and negative versions may be used.



Size

To maintain clear legibility of the program mark, never reproduce it at a size less than 1" wide. The entire mark must be legible.



Clear Space Allocation

The clear space around the Medicare Prescription Drug Benefit program mark prevents any nearby text, image or illustration from interfering with the legibility and impact of the mark. The measurement "x" can be defined as the height of the letter "x" in "Rx" in the program mark. Any type or graphic elements must be at least "x" distance from the mark as shown by the illustration.



Bleed Edge Indicator

The program mark may not bleed off any edge of the item. The mark should sit at least 1/8" inside any edges of the item.

Incorrect Use

- Do not alter the position of the mark elements.
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark as provided.
- Do not rotate the mark or any of its elements.
- Do not alter or change the typeface of the mark.
- Do not alter the color of any of the mark elements.

- Do not position the mark near other items or images. Maintain the clear space allocation.
- Do not position the mark to bleed off any edge. Maintain 1/8" safety from any edge.
- Do not use any of the mark elements to create a new mark or graphic.
- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

Card Design

Usage of the Medicare Prescription Drug Benefit program mark on any item must follow the guidelines.

On the card, the mark must be positioned within the bottom third of the card.

Included on the card must be the words: "Prescription Drug Plan." 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.

Part D Plan Sponsor Name/Logo		sponsor logo place- holder
RxBin	999999	
RxPCN	ABC1234567	
RxGrp	ABC123456789	
Issuer	(80840)	
ID	12345678901	
Name	JOHN Q PUBLIC	
	CMS - 85555 XXX	