MEDICARE MARKETING GUIDELINES FOR:

- MEDICARE ADVANTAGE PLANS (MA)
- MEDICARE ADVANTAGE PRESCRIPTION DRUG PLANS (MA-PDS)
- PRESCRIPTION DRUG PLANS (PDPS)
- 1876 COST PLAN

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

PREFACE

These Marketing Guidelines reflect CMS's current interpretation of the marketing requirements and related provisions of the Medicare Advantage and Medicare Prescription Drug Benefit rules (chapter 42 of the Code of Federal Regulations, Parts 422 and 423). These guidelines were developed after careful evaluation by CMS of current industry marketing practices, recent advancements in communication technology, and how best to protect the interests of Medicare beneficiaries. The marketing guidance set forth in this document may be subject to change as communication technology and industry marketing practices continue to evolve, and as CMS gains more experience administering the Medicare Prescription Drug Benefit and Medicare Advantage programs.

These Marketing Guidelines are for use by Medicare Advantage Plans (MAs), Medicare Advantage Prescription Drug Plans (MA-PDs), Prescription Drug Plans (PDPs) and 1876 Cost Plans. To assist readers in finding elements that pertain to their type of organization, each section of these Guidelines is coded according to the below convention:

(A) = All organizations
(B) = MA-PD and PDP
(C) = PDP only
(D) = MA-PD only
(E) = MA only
(F) = 1876 Cost Plans only

***NOTE**: 1876 Cost Plans that do not offer or do not mention Part D as an optional supplemental benefit should follow MA specific guidance. Cost Plans that mention Part D as an optional supplemental benefit in their marketing materials should follow MA-PD guidance.*

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1. INTRODUCTION: MMA AND PART D

On January 28, 2005 the Centers for Medicare & Medicaid Services (CMS) issued the final rule for the Medicare Prescription Drug Benefit. The new voluntary prescription drug benefit program, known as Part D, was enacted into law in Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the Prescription Drug Benefit will become available to beneficiaries beginning on January 1, 2006, with enrollment beginning on November 15, 2005. The drug benefit will be offered to Medicare beneficiaries through Medicare Advantage Prescription Drug Plans (MA-PDs), Private Prescription Drug Plans (PDPs), Program of All Inclusive Care for the Elderly (PACE), and 1876 Cost Plans.

Purpose of Marketing Guidelines (A)

These guidelines represent CMS's current, official position on marketing policy and operational instructions. Throughout this document, the term "Organization" is used to identify the following primary CMS contracting entities: Medicare Prescription drug coverage under coverage under a MA-PD, PDP, or 1876 Cost Plan. Marketing by PACE plans is governed by separate guidance specific to PACE plans.

- Part D Plan includes: PDPs and MA-PDs, including 1876 Cost Plans
- Health Plans includes: MA Plans and 1876 Cost Plans.
- When used individually, the terms "MA", "PDP" and "MA-PD", "1876 Cost Plans", "RPPO" and "SNP" will denote that the marketing guidance that follows is specific to that type of organization.

In particular, the guidelines are intended to meet several objectives:

- Expedite the process for CMS's review of marketing materials;
- Conserve Organization resources by avoiding multiple submissions/reviews of marketing materials prior to final approval;
- Ensure consistent marketing review throughout the program;
- Enable Organizations to develop accurate, consumer-friendly marketing materials that will assist beneficiaries in making informed health care choices; and
- Establish consistent review standards for all Organizations, unless the marketing material is specific to a plan type.

***NOTE**: 1876 Cost Plans that do not offer or do not mention Part D as an optional supplemental benefit should follow MA specific guidance. Cost Plans that mention Part D as an optional supplemental benefit in their marketing materials should follow MA-PD guidance.*

Implementation Schedule (A)

Organizations may not distribute any marketing materials until they receive notification from CMS.

Organizations may not distribute or make available any marketing materials until they have contracted with CMS and are able to initiate enrollment and operate as a Medicare Organization in accordance with Title 42 of the Code of Federal Regulations.

Organizations that meet the above requirements and comply with CMS Marketing Review Guidelines may begin releasing their 2006 marketing materials on October 1, 2005.

Acceptable Plan Names (A)

Following are the requirements regarding the naming of an Organization's sponsored plan:

- Beneficiaries with disabilities must be considered part of the audience for any marketing material used within the marketplace. Organizations may not use Plan names that suggest that a Plan is available only to Medicare beneficiaries age 65 or over, rather than to all beneficiaries. This prohibition generally bars Plan names involving terms such as "seniors," "65+", etc. CMS will allow the "grand fathering" of MA and MA-PD Plan names (not PDP names) that were established by Medicare Advantage organizations before June 29, 2000. Organizations may not use a Plan name that suggests a Plan is available only to beneficiaries with disabilities.
- Organizations are permitted to use ethnic and religious affiliations in their Plan names only if the legal entity offering the Plan has a similar proper name/affiliation. For instance, if a Plan were affiliated with the Swedish Hospital System of Minnesota, it would be permissible for the Plan to use the tag line, "Swedish Plan, offered by Swedish Hospital System of Minnesota".
- Organizations may not use "Medicare Endorsed" as part of their Plan name or anything similar suggesting the Medicare endorsement.
- Organizations may use the term "Medicare" in their names. If an Organization chooses to utilize the term "Medicare" it must insert the Plan name before "Medicare" (i.e., Acme Medicare Plan).

NOTE: *MA organizations may use the term "Medicare" or the term "Advantage" in their plan names. Furthermore, all plans in existence as of January 1, 2004, who had the name "MA organization" may continue to use that name indefinitely. However, new plans are not allowed to do business under the name "Medicare Advantage." If an organization chooses to retain the Medicare Advantage plan name it must insert the company name before "Medicare Advantage" (e.g., Acme Medicare Advantage plan).*

Joint Enterprise for PDPs (C) and Regional Preferred Provider Organizations (RPPOs)

Part D Plans that are licensed by a State as a risk-bearing entity can jointly enter into a single contract with CMS to offer a Regional Preferred Provider Organization (RPPO) 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 RPPO 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 in a state where one or more of the contracted health plans creating the single entity is licensed by that State as a risk-bearing entity or qualifies for a wavier under 42 C.F.R. § 423.410 or §422.372.

All marketing materials must be submitted under the Joint Enterprise's contract number and must follow the appropriate Marketing Guidelines.

Multi-Contract Groups for PDPs (C)

PDPs 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 Section 5, Template Materials, for further information.

Multi-Region Organizations for MA and MA-PD (D, E)

For organizations that operate in more than one of CMS's Regional Offices (RO), the marketing review approach (e.g., lead region, local regions, etc.) is determined by the agreement each organization makes with CMS Multi-Region Team management.

The Multi-Region MA organization must ensure that materials submitted are consistent with the requirements in this section.

In addition, the Multi-Region MA organization must distribute final copies of its national marketing materials, within a time frame to be determined by its CMS Multi-Region team, to the lead and local ROs with a dated cover letter, which identifies the recipients.

NOTE: *Although the local ROs may no longer play a part in approval of the national marketing piece, the health plan/MA organization must send a final copy of the approved material to the local ROs for their records.*

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

General Information (B, E)

General operational guidance will be posted at http://www.cms.hhs.gov/discountdrugs/ in the document "End of Program and Transition Guidance for Drug Discount Card Sponsors." Questions not answered by this document should be submitted to the MMA Q&A database at http://mmaissuesform.cms.hhs.gov/, and select "drug card" as the topic to ensure that the question is routed to the appropriate CMS subject matter expert.

CMS intends to issue a final rule on the drug card program entitled "CMS-4063-F Medicare Prescription Drug Discount Card; Flexibility of Marketing Rules." Additional information about the final rule will be made available upon the rule being made available to the public.

3. HIPAA PROVISIONS (A)

On April 14, 2003, new Federal rules governing the use and disclosure of certain individually identifiable health information by health Plans, health care clearinghouses, certain health care providers ("covered entities"), became enforceable. Medicare Prescription Discount Drug Card Sponsors were added as covered entities by the Medicare Prescription Drug Improvement and Modernization Act of 2003. The regulatory text of the final rule "Standards for Privacy of Individually Identifiable Health Information" (the "HIPAA Privacy Rule"), as modified, can be found at 45 CFR Parts 160 and 164, Subparts A and E. Part D Plans may use or disclose their members' protected health information as permitted by these regulations and any other applicable privacy laws (for example, more stringent state laws governing the use and disclosure of health information). The HIPAA Privacy Rule generally allows covered entities to use or disclose this information without beneficiary authorization for treatment, payment, or health care operations (as those terms are defined by the rule) and for a number of public interest or benefit purposes, such as public health activities and research subject to certain requirements. Organizations are not required to obtain authorizations prior to using their Medicare beneficiary members' data to provide information to such members regarding their benefit packages. For additional information regarding the HIPAA Privacy Rule, go to the following Department of Health and Human Services, Office for Civil Rights Web Site address: http://www.hhs.gov/ocr/hipaa/.

4. PDP STATE LICENSURE (C)

Title I of the MMA requires all PDPs to be either licensed as a risk bearing entity or approved for a waiver of the state licensure requirement under 42 CFR Part 423, Subpart I in each state or territory in which it operates.

Plans with State license(s) may not in their marketing materials or other communications characterize Plans with waivers of state licensure as being subject to less stringent requirements or otherwise less protective of beneficiaries.

5. OVERVIEW

Definitions (A)

The following definitions are for the purposes of these guidelines only.

Assisting In Enrollment (A)

Assisting a potential enrollee with the completion of an application and/or objectively discussing characteristics of different Plans to assist a potential enrollee with appraising the relative merits of all available individual Plans, based solely on the potential enrollee's needs. The individual performing these activities must not receive compensation directly or indirectly from the Plan for such assistance in enrollment.

Marketing (A)

Steering, or attempting to steer, an undecided potential enrollee towards a Plan, or limited number of Plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the Plan for such marketing activities. "Assisting in enrollment" and "education" do not constitute marketing.

Education (A)

Informing a potential enrollee about Medicare Advantage or other Medicare Programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific Plan or limited number of Plans.

Provider Promotional Activities (A)

Activities that a provider may perform to educate potential enrollees or to assist potential enrollees in enrollment. Provider Promotional Activities are discussed in Section 11 of these Marketing Guidelines, "Guidelines for Promotional Activities."

Marketing Materials (A)

Marketing materials include any informational materials that perform one or more of the following actions:

- Promote an Organization.
- Provide enrollment information for an Organization.
- Explain the benefits of enrollment in an Organization.
- Describe the rules that apply to enrollees in an Organization.

- Explain how Medicare services are covered under an Organization, including conditions that apply to such coverage.
- Communicate with the individual on various membership operational policies, rules, and procedures.

The definition of marketing materials extends beyond the public's general concept of advertising materials to include notification forms and letters used to enroll, disenroll, and communicate with the member regarding many different membership scenarios. The Internet is considered another vehicle for the distribution of marketing information. Therefore, all regulatory rules and requirements associated with all other marketing conveyances (e.g., newspaper, radio, TV, brochures, etc.) are applicable to Medicare Organization marketing activity on the Internet. CMS marketing review authority extends to all marketing activity (i.e., advertising, pre-enrollment, and post-enrollment activity) the Medicare Organization pursues via the Internet. The specific requirements that apply depend on the type of material.

Press releases are not considered marketing materials and do not need to be submitted for review, even if such materials contain marketing information (i.e., a description of Plan benefits or cost sharing).

Health education materials are generally not under the purview of CMS marketing review; however, materials that perform the actions of marketing materials as defined above must be approved by CMS before use.

Explanatory Materials (A)

Explanatory materials are a subset of marketing materials primarily intended to explain the benefits, operational procedures, cost sharing, and/or other features of an organization to current members or to those considering enrollment. Explanatory materials are further subdivided into Pre-Enrollment materials and Post-Enrollment materials, both of which are defined below.

Examples of Explanatory Materials:

- Evidence of Coverage
- Summary of Benefits
- Enrollment and disenrollment forms
- Enrollment and disenrollment letters
- Pharmacy Directory
- Formulary
- Member ID card

- Appeals and grievance letters
- Exceptions process letters
- Sales scripts/sales presentations

Pre-Enrollment Marketing Materials (A)

Pre-enrollment materials (e.g., sales scripts, direct mail that includes an enrollment form, sales presentations, etc.) provide more detail on the Organization than what is provided in an advertisement and are generally used by prospective enrollees to decide whether or not to enroll in an Organization. Organization rules and Organization benefits are among the information included in pre-enrollment materials.

Post-Enrollment Marketing Materials (A)

Post-enrollment materials are those materials used by an Organization to convey benefits or operational information to enrolled Plan members. Post-enrollment marketing materials include all notification forms and letters and sections of newsletters that are used to communicate with the individual on various membership operational policies, rules, and procedures. Post-enrollment marketing materials include, but are not limited to, the Evidence of Coverage, the Summary of Benefits, and the Pharmacy Directory. These materials are also called beneficiary notification materials and are subject to additional CMS requirements.

Advertising (A)

Advertising materials are primarily intended to attract or appeal to a potential Organization 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:

- Television Ads
- Radio Ads
- Outdoor Advertising (billboards, signs attached to transportation vehicles, etc.)
- Banner/Banner-like Ads
- Print Ads (newspaper, magazine, flyers, brochures, posters, church bulletins, etc.)

- Direct Mail that does not include enrollment forms (postcards, self mailers, home delivery coupons, and reply cards)
- Post Stands and Free Standing Inserts (newspapers, magazines, etc.)
- Event Signage
- Internet Advertising
- Pharmacists' promotional buttons
- Window Stickers
- Counter Tents

The purpose of advertising materials is to allow recipients the opportunity to request additional information that will assist them in making an informed enrollment decision.

Value Added Items and Services (VAIS) (A)

Value-Added Items and Services (VAIS) are items and services offered to Plan members by a Plan that do not meet the definition of benefits under the Medicare program and involve only administrative or minimal cost. VAIS may not be funded by Medicare program dollars. If VAIS services are discontinued, Plans should notify enrollees in a timely manner.

Health-Related VAIS (A)

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

Non Health-Related VAIS (C)

Non health-related VAIS are not intended to improve or maintain the health status of enrollees, and the cost incurred by the Organization is usually only administrative and is not included within the Organization's bid to CMS. Furthermore, to the extent required under the HIPAA Privacy Rule, Organizations must receive prior written authorization from Medicare beneficiaries before contacting them regarding non health-related VAIS items and services.

Types of Plans Based on Service Areas (A)

The MMA requires a number of changes to the Medicare program. In order to implement the new Medicare Prescription Drug Benefit and changes to the Medicare Advantage program, CMS defined appropriate regions for PDPs and regional MA Plans as required under the MMA. On December 6, 2004, CMS announced the establishment of 26 MA regions and 39 PDP regions (CMS PDP Regions, including the 5 territories).

Furthermore, in order to remain consistent with the Medicare Advantage and Medicare Prescription Drug Benefit final rules, all marketing materials submitted by Medicare Advantage Drug Plans (Regional and Local) are reviewed by CMS Regional Offices. All marketing materials submitted by PDPs are reviewed by CMS Designee.

National Plans

- **PDPs:** A PDP can market itself as a "national Plan" if, at a minimum, it covers the 34 CMS PDP regions that include the 50 states and the District of Columbia. PDPs that cover more than the minimum 34 PDP regions (i.e., those that include the 50 states, the District of Columbia, and one or more territories) are also considered national Plans. PDPs sponsored by more than one organization, a Joint Enterprise, can also use the term "national" if the Joint Enterprise covers, at a minimum, the 34 CMS PDP regions that include the 50 states and the District of Columbia. (Refer to Federal Register Vol. 70 FR 13398).
- **MAs/MA-PDs:** An MA/MA-PD can market itself as a "national Plan" if, at a minimum, it covers the 26 CMS MA regions that include the 50 states and the District of Columbia. MAs/MA-PDs that cover more than the minimum 26 regions (i.e., those that include the 50 states, District of Columbia, and one or more territories) are also considered national Plans.

Regional Plans

- **PDPs:** A "regional PDP" is a Plan that serves one or more entire PDP region(s), but not all 34 PDP regions that include the 50 states and the District of Columbia.
- **MAs/MA-PDs:** A "regional MA/MA-PD" is a coordinated care Plan structured as a Preferred Provider Organization (PPO) that serves one or more entire MA region(s) but not all 26 CMS MA regions that include the 50 States and the District of Columbia.
- All regional Plans must have a network of contracting providers that have agreed to a specific reimbursement for the Plan's covered services. Regional Plans must provide uniform benefits within their service area.

- **Local Plans** (MA, MA-PDs, 1876 Cost Plans)**:** A "local" Plan is offered by a legal entity that is not a regional Plan. Local Plans may choose the counties in which they operate. Local Plans may also vary benefits and premiums at the county level. The uniform benefit requirement applies to local Plans at the service area or segment level.

Limitations on Distribution of Marketing Materials (A)

An Organization is prohibited from advertising outside of its defined service area unless such advertising is unavoidable. For situations in which this cannot be avoided (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area, such as an MSA (Metro Statistical Area) that covers two regions), Organizations are required to disclose clearly their service area. Marketing activities outside of an Organization's defined service area are the basis for corrective action.

Co-Branding Requirements (A)

Co-branding is defined as a relationship between two or more separate legal entities, one of which is a sponsoring Organization. The sponsoring Organization displays the name(s) or brand(s) of the co-branding entity or entities on its marketing materials to signify a business arrangement. Co-branding arrangements allow an Organization and its co-branding partner(s) to promote enrollment into the Plan. Co-branding relationships are entered into independently from the contract that the Organization has with CMS. Organizations are allowed to enter into co-branding arrangements as long as the following requirements are met:

- The Organization must inform CMS of any co-branding relationships at the time that the Organization begins inputting their Plan benefit information (Plan Benefit Package - PBP) into the Health Plan Management System (HPMS). The HPMS PBP module will allow Organizations to indicate whether the Organization is co-branding.
- If there are any changes in the co-branding relationship within the contracting year, including the addition of new co-branded entities, Organizations must inform their CMS Plan Manager, who will then notify appropriate CMS staff. The PDP must remove any reference to the former co-branding partner from its marketing materials.
- The approved Organization must adhere to all contractual stipulations based upon its contract with CMS. It is the Organization's responsibility to ensure that its co-branding partner(s) also adhere(s) to all applicable CMS policies and procedures.

- The Organization must attest that its co-branding partners were provided with these Marketing Guidelines and that the co-branding partners agreed to follow these guidelines with respect to all marketing materials related to the PDP.

Neither the Organization nor its co-branding partners, whether through marketing materials or other communications, may imply that the co-branding partner is endorsed by CMS, or that its products or services are Medicare-approved. Co-branded marketing materials must be compliant with the Marketing Guidelines and must be submitted by the sponsoring Organization to CMS or its Designee for review. Organizations may elect to submit co-branded materials as template materials. Guidance for submitting template materials is provided below.

Template Materials (A)

Submission of Template Materials (A)

A "template material" is any marketing material that includes placeholders to be populated by variable elements. Variable elements can be specific to one 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.

An Organization may not change and/or add benefit or premium 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 placeholders populated by date or location, phone numbers, addresses, and other non-benefit or non-premium information are not required to be submitted as new material. Likewise, co-branding information added to previously approved template materials is not subject to re-review, as long as the changes are limited to populating existing variable fields (e.g., organization name, logos, or contact information).

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

Use of Data from Medigap Issuers (B)

If a Medigap issuer chooses to sponsor a MA-PD or PDP, it will be allowed to use its existing enrollment information from its Medigap plans to market its Part D Plan to its Medigap enrollees, to the extent permitted by the HIPAA Privacy Rule and other applicable Federal or State privacy laws. However in doing so, it must market to all of its members not just a subset.

Organization Responsibilities (A)

PDP Plans are required to use the Health Plan Management System (HPMS) when submitting materials for review. Detailed instructions on entering materials using this system are provided in the HPMS User's Guide.

MA and MA-PD Plans may use HPMS, but may also submit marketing materials for review to the appropriate CMS Regional Office via email, facsimile or the US Postal Service.

Upon submission of materials, Organizations have the following responsibilities:

- Ensure that materials are consistent with the Marketing Materials Guidelines.
- Submit copies of its proposed national and/or regional marketing materials with all necessary accompanying information (such as required substantiation, attestation, etc).
- Examine all comments by reviewers and ensure that appropriate corrections have been made before submitting a revised version of a disapproved material.

CMS or its Designee reviews marketing materials to ensure that they are consistent with the Marketing Material Guidelines and are not materially inaccurate or misleading or otherwise make material misrepresentations. Generally, CMS does not review marketing materials for typographical or grammatical errors, unless such errors render the marketing materials inaccurate or misleading.

All material should be clearly stated and in no way deceptive to the reader.

Prohibited Terminology/Statements (A)

To ensure accurate and fair marketing by all Organizations, CMS prohibits the distribution of marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations. Additionally, Organizations may not misrepresent themselves or the benefits and services they provide.

An Organization may not claim within its marketing materials that it is recommended or endorsed by CMS, Medicare, or the Department of Health and Human Services. However, it may explain that the Organization is approved for participation in Medicare programs and/or that it is contracted to administer Medicare benefits.

Organizations may use the term "Medicare-approved" to describe their benefits and services within their marketing materials.

Model and Standardized Materials (A)

Standardized Language (A)

Marketing materials containing standardized language drafted by CMS, which is mandatory for use by Organizations.

Model Language (A)

For certain pre- and post-enrollment documents, CMS has drafted model language, which when utilized without modification entitles the Organization to a ten-day marketing review period. The use of CMS model language is optional. However, if the Organization chooses not to use model language, it must include all elements of the model language and required disclaimers as outlined in the appropriate sections of Section 6 (Marketing Material Development).

Part D Model Documents (B)

Below is a partial list of model materials that CMS will be developing. For a full list of all model materials, please refer to the HPMS Marketing Module.

- Model Pharmacy Directory
- Model Explanation of Benefits (EOB)
- Model Comprehensive Formulary
- Model Abridged Formulary

6. MARKETING MATERIAL DEVELOPMENT

Advertising (A)

Guidelines for Advertising Materials (A)

Organizations 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 be 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.

Advertising Material Language Requirements (A)

Disclosures (A)

1. For all advertising materials except banner ads, banner-like ads and ODA, (i.e., television and radio ads, direct mail, print ads and internet advertising), organizations must include the statement that the Organization contracts with the Federal government. For banner ads, banner-like ads, and ODA, Organizations are not required to include **any** disclaimers or disclosures on the ads.

2. In addition to the disclaimer required in # 1 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 (A)

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

- Virtually no paperwork
- Hardly any paperwork.

Organizations cannot say:

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

Hours of Operation (A)

An Organization must list the hours of operation for its customer service department in all places where phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the 1-800-MEDICARE number is listed (i.e., 24 hours a day/7 days a week). This requirement does not apply to any phone numbers included on advertising materials for persons to call for more information.

TTY/TDD Numbers (A)

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. The TTY/TDD number must also include the hours of operation if they

are for customer service. Organizations can either use 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.
- 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, Organizations 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 for the other phone numbers).
- TTY/TDD numbers are not required in radio ads.

Reference to Studies or Statistical Data (A)

Organizations 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 date. Upon submitting material to CMS for review, unless the study that is referenced is a CMS study, the Organization must provide the study sample size and number of Plans surveyed.

Organizations are prohibited from using study or statistical data to directly compare their Plan to another Plan.

If an Organization uses study data that includes aggregate marketplace information on several other 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 (e.g., “one of the best,” “among the highest rank,” etc.) may be used. Absolute superlatives (e.g., “the best,” ‘highest ranked,” “rated number one,” etc.) may only be used if they are substantiated with supporting data.

Pharmacies (B)

If the number of participating pharmacies is used in an ad, the ad must include only those pharmacies available to Part D Plan enrollees. (For more information regarding multi-region service areas, refer to Section 5, Limitations on Distribution of Marketing Materials).

When applicable, Part D Plans that display a total number of pharmacies in an ad or direct mail material must delineate between preferred and non-preferred pharmacies.

NOTE: *When Plans reference their "preferred" pharmacies within their advertising materials, they must explain to the beneficiary what a preferred pharmacy is, what it means for them to be a preferred pharmacy and what benefits the enrollee may enjoy when they use a Plan preferred pharmacy (e.g. you will pay an even lower co-payment for your generic drugs, if applicable).*

If the Part D Plan uses the name and/or picture of a pharmacist and/or pharmacy to market the Part D Plan, the information may **only** be used within the context of informing beneficiaries of pharmacies that are associated with the Part D Plan's network pharmacy.

Formatting Requirements (A)

Font Size Rule (A)

With the exception listed below, for all written advertising materials footnotes must be the same size font as the majority of the text in the advertisement. The text size is left to the discretion of the Organization 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 to Font Size Rule (A)

Information contained in brochures and direct mail pieces must be no smaller than Times New Roman 12-point or equivalent font. If an Organization publishes a notice to close enrollment (as required in the Enrollment and Disenrollment guidance) in the Public Notices section of a newspaper, the Organization need not use 12-point font and can instead use the font normally used by the newspaper for its Public Notices section.

Font Size Rule for Internet Advertising (A)

Any advertising materials that an Organization 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 Organization codes the font for the Web page, not how it actually appears on the user's screen.

Other Requirements (A)

Logos/Tag Lines (A)

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. Organizations 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").

For organizations with an existing investment in a company logo/product tag line, CMS will permit "grand fathering" of company logos/product tag lines established before the final rule of the Medicare Prescription Drug Benefit, took effect (i.e., before January 28, 2005).

Product Endorsements/Testimonials (A)

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 Organization's product by name.
- If an individual is paid to promote a specific product, 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 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 anonymous or fictitious quotes by physicians, health care providers, and/or Medicare beneficiaries.
- Use negative testimonials about other Plans.

Drawings/Prizes/Giveaways (A)

Organizations are prohibited from using free gifts and prizes as an inducement to enroll. Any gratuity must be made available to all participants regardless of enrollment. The value of any gift must be less than the nominal amount of $15. In accordance with this guideline, organizations offering drawings, prizes, or giveaways must state one of the following phrases in at least 12-point font:

- "Eligible for a free drawing and prizes with no obligation"
- "Free drawing without obligation"

Organizations cannot state "Eligible for free drawing and prizes."

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.

Any incentive that might have the effect of inducing enrollees to use particular providers, practitioners, or suppliers should be carefully reviewed by the Organization for compliance with section 1128A(a) (5) of the Social Security Act and the corresponding regulations at 1003.102(b) (13) (See 65 FR 24400, 24407 (April 26, 2000)). In addition, incentives provided by Organizations are subject to the Federal anti-kickback statute, section 1128B (b) of the Social Security Act.

Radio and TV Spots (A)

Radio advertisements placed by Organizations must include the Organization's toll-free number. However, they do not need to include the TTY/TDD number. They also do not have to mention the date on which CMS approved the script for the radio advertisement. If disclaimers are required, Organizations can use language that allows them to work disclaimers into the script or they can note them at the end of the spot.

As with radio advertisements, television advertisements placed by Organizations must include the Organization's toll-free number. This information must be displayed on the crawl or banner. Television advertisements do not have to mention the date on which CMS approved the advertisement's script or include Medicare contact information. If disclaimers are required, they must be worked into the script (e.g., actor portrayal) and/or shown on the screen.

In contrast to radio advertisements, television advertisements must include the TTY/TDD number for the Organization's toll-free number. The TTY/TDD number can be a different size or font so it is clearly differentiated from the Organization's toll-free number.

Final scripts for both television and radio advertisements must be submitted to CMS under File & Use certification.

Contracting Statement (A)

All advertising materials (other than banner ads, banner-like ads, and ODA) must include a statement either in the text of the material or as a footnote that the Organization contracts with the Federal government.

Pre-Enrollment Materials (A)

Guidance for Pre-Enrollment Materials (A)

Required Disclaimers (A)

Language Requirements (A)

The below requirements must be included on all pre-enrollment materials, unless noted otherwise or if model language is available. If model language is available and not used, Plans must include all elements of the model language and all required disclaimers.

Lock-In Statement/Access Information (D, E):

The Lock-In statement when used by MA HMO plans means that the beneficiary is locked into a provider network and if the beneficiary obtains routine care from out-of-plan providers, neither Medicare nor the plan will be responsible for the cost of care. "Limits" applies when the beneficiary makes an enrollment health care choice. Therefore, when appropriate for the plan, the concept of "lock-in" must be clearly explained in all pre-enrollment materials. For marketing pieces that tend to be of short duration we suggest: "You must receive all routine care from plan providers" or "You must use plan providers except in emergent or urgent care situations or for out-of-area

renal dialysis." However, in all written materials used to make a sale, a more expanded version is suggested: "If you obtain routine care from out-of-plan providers neither Medicare nor [name of MA organization] will be responsible for the costs."

For PPOs, POS plans, private fee-for-service plans and, if appropriate, Visitors Programs for any plan type, explain that use of non-plan or non-preferred providers is allowed, but may cost more to the beneficiary.

For Medicare 1876 cost plans (F), enrollees must be informed that after enrollment is effective, in order for them to receive the full coverage offered, services other than emergency and urgently-needed services must be obtained through the HMO or CMP. In the case of cost enrollees, however, they may receive services that are not provided or arranged by their HMO or CMP, but they would be responsible for payment of all Medicare deductibles and coinsurance as well as any additional charges as prescribed by the Medicare program. They also would be liable for any charges not covered by the Medicare program.

Networks and Sub-networks (D, E)

All pre-enrollment marketing materials must clearly explain the concept of networks and sub-networks and the process for obtaining services, including referral requirements.

Marketing plans to beneficiaries of non-renewing Medicare plans (D, E)

MA organizations may market plans directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the marketing does not begin until after the date the beneficiary has received the plan termination letter. In addition to the targeted message, any pre-enrollment marketing pieces must contain a statement indicating that the Medicare health plan is open to all Medicare beneficiaries eligible by age or disability in the plan's service area.

Preferred Provider Organizations (D, E)

Cost Savings Described in Marketing Materials

If a PPO states in marketing materials that prospective enrollees may save money if they join the plan, it must also acknowledge the added cost of accessing services out-of-network and/or that using services in-network can cost less than using services out-of-network.

Preferred and Non-Preferred Benefits

If a PPO offers benefits for which the coinsurance is the same percentage both in and out of network, the PPO must make it clear in all pre-enrollment material that member responsibility may be greater out-of-network since the coinsurance is based on the Medicare allowed amount and not on the potentially lower contracted amount.

Also, explain in pre-enrollment materials that with the exception of emergency or urgent care, it may cost more to get care from non-plan or non-preferred providers.

Mandatory Supplemental Benefits (E)

PPOs must clearly state in marketing materials that the plan provides reimbursement for all covered benefits regardless of whether they are received in-network.

Benefit and Plan Premium Information (D, E)

Pre-enrollment materials that describe benefit and plan premium information must (D, E)

- Include the statement: "You must continue to pay your Medicare Part B premium" with premium information, even if the premium is $0.
- When specifying benefits, specify annual limits, annual benefit payout, and applicable co-payments (e.g., $5 co-payment for a doctor visit).
- Clearly state major exclusions and limitations.
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary's access to services.
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits and whether any unused portion of that benefit can be carried over from one calendar quarter to the next.
- Include a closing statement such as: "For full information on [organization name] (e.g., routine physical exam, eyeglasses, dental, etc.) benefits, call our Customer Service Department at [phone number]. Our office hours are [insert hours]."
- Cost contractors must describe their premiums and cost sharing for services received through the cost plan, and any optional supplemental benefit packages they offer. They must also indicate that premiums, cost sharing, and optional supplemental benefits may

change each year and include information on when such benefit options may be selected or discontinued.

- Make the statement that the Medicare health plan's contract with CMS is renewed annually and that the availability of coverage beyond the end of the current contract year is not guaranteed.

Enrollment Limitations (A)

Organizations must include a statement indicating that members may enroll in a Plan only during specific times of the year. Organizations 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 Organization's customer service to obtain more information.

Network Limitations (C)

PDPs must include a statement that indicates that eligible beneficiaries must use network pharmacies to access their prescription drug benefit, except under non-routine circumstances when they cannot reasonably use network pharmacies. If the Plan requires members who utilize pharmacies outside of the network to pay any differential in the non-network pharmacy's charge and the plan's allowable charge.

Hours of Operation (A)

Organizations 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 (A)

Where Organizations may submit multiple separate and distinct bids and Plan Benefit Packages (PBPs) to cover the same region/service area, there is no requirement that all Medicare Plans of the sponsoring organization 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 (A)

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. Organizations can either use state relay services or their own, as long as the number is accessible from TTY/TDD equipment.

Availability of Alternative Formats (A)

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

Claim Forms and Paperwork (A)

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

- Virtually no paperwork
- Hardly any Paperwork

Organizations cannot say:

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

Reference to Studies or Statistical Data (A)

Organizations 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 Organization must provide the study sample size and number of Plans surveyed.

Organizations are prohibited from using study or statistical data to directly compare their Plan to another Plan.

If an Organization uses study data that includes aggregate marketplace information on several other 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 (A)

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 Plan by name.
- If an individual is paid to promote a 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 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 anonymous or fictitious quotes by physicians and other health care providers and/or Medicare beneficiaries

Formatting Requirements (A)

Font Size Rule for Member Materials (A)

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 Organizations 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 (A)

Any pre-enrollment materials that an Organization places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor the 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 (A)

The 12-point font size or larger rule described above also applies to any footnotes or subscript annotations in notices. Footnotes are not required to be the same font size as the text in the body of the marketing material.

Footnote Placement (A)

Organizations 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 must also appear at the bottom of page 8.

Submission and Review Requirements (A)

Sales Scripts (A)

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

Eligibility Requirements (B)

Both PDPs and MA-PDs must clearly state in their pre-enrollment materials that an individual is eligible to enroll in the plan if the individual:

- Is entitled to Medicare benefits under Part A or enrolled in Part B; and
- Resides in the service area of the Part D Plan.

NOTE: *Part D Payment Demonstration Plans (B) must include the following statement: "You cannot enroll in this plan if your current or former employer help pays for your drugs."*

PDPs must also state that Medicare beneficiaries (C):

- May be enrolled in only one Part D Plan at a time.
- Enrolled in an MA Plan may not enroll in a PDP, unless they are a member of a Private Fee-for-Service MA Plan (PFFS) that does not provide Medicare prescription drug coverage, a Medical Savings Account MA Plan (MSA), or a 1876 Cost Plan.

MA-PDs must also state that (D):

- Their Medicare Prescription Drug Benefit is only available to members of the MA-PD Plan.
- If a beneficiary is already enrolled in a MA-PD Plan, the enrollee must receive their Medicare Prescription Drug Benefit through that Plan.

1876 Cost Plans must state that (F):
Medicare beneficiaries may be enrolled in only one Part D Plan at a time. These plans must also indicate that all Medicare beneficiaries may apply to enroll in the 1876 Cost Plan.

Other Requirements (A)

Prescription Drug Services (A)

If benefits are mentioned in pre-enrollment materials, Organizations must inform eligible individuals of the types of pharmacies included in their network (e.g., retail, mail order, LTC, I/T/U, and Home Infusion). If Mail Order Prescription Drug Service is available, Organizations must provide ways for the potential beneficiary to obtain additional information regarding this feature. Likewise, Organizations must also note that generally benefits are only available at the contracted network pharmacies (under emergency circumstances, benefits may be obtained out-of-network). Organizations must also provide contact information for obtaining additional network pharmacy information. Contact information must include a toll-free number, a TTY/TDD number (if applicable), and a mailing address.

Contracting Statement (A)

Organization materials must include a statement either in the text of the material or as a footnote that the Organization contracts with the Federal government.

The SB, EOC, Member Handbook and all pre-enrollment materials must include the above disclaimer.

Special Requirements for MAs or MA-PDs (D, E)

The following language must be used by MA or MA-PD plans in the contracting statement. This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.

- "A/An [insert plan type: HMO, PPO, POS plan, PSO, etc.] with a Medicare contract"
- "An MA organization with a Medicare contract"
- "A Health Plan with a Medicare contract"
- "A Federally Qualified HMO with a Medicare contract"
- "A Federally Qualified Medicare contracting HMO"
- "Medicare approved [insert plan type: HMO, PPO, POS plan, PSO etc.]"
- "A Coordinated Care Plan with an Medicare Advantage contract"

Program Description (A)

The following program description information must be included in pre-enrollment materials:

- Plan service area; and
- Plan Statement that enrollees must use network providers to receive Plan benefits except under emergency circumstances.

Premiums (B, E)

The following statement must be included in all pre-enrollment materials, even if the premium is $0:
"You must continue to pay your Medicare Part B premium if not otherwise paid for under Medicaid or by another third-party."

NOTE: *1876 Cost Plans (F) that mention Part D as an optional supplemental benefit must include, at a minimum, the additional premium amount for the Part D benefit.*

Logos/Tag Lines (A)

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. Organizations 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").

For Organizations with an existing investment in a company logo/product tag line, CMS will permit "grand fathering" of company logos/product tag lines established before the final rule of the Medicare Prescription Drug Benefit took effect (i.e., before January 28, 2005.)

Pharmacy Network Information (A)

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

Online Enrollment Center (B)

NOTE: *Because the Part D benefit that an 1876 Cost Plan may offer is an optional supplemental benefit to the cost plan itself, to obtain Medicare prescription drug coverage through a Cost Plan, one must enroll in the Cost Plan. Cost Plans cannot accept enrollment in formats other than paper enrollment forms.*

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

Part D 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>."

In addition, Plans meeting CMS requirements will also be permitted to conduct online enrollment through their Organization's Web site. (See Part D Enrollment Disenrollment Guidance)

Availability of Medicare Subsidy Information (B)

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 TTY/TDD and hours of operation>, 1-800-MEDICARE (TTY/TDD users call 877-486-2048, 24 hours a day/7days a week), their State Medicaid Office, or the Social Security Administration at 1-800-772-1213 or on the toll-free TTY/TDD number, 1-800-325-0778, between 7 a.m. and 7 p.m., Monday through Friday."

Limited Income Subsidy Premium Disclaimer (C)

In all pre-enrollment marketing materials where PDP monthly premiums 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 should call 877-486-2048), your State Medicaid Office, or the Social Security Administration at 1-800-772-1213 or on the toll-free TTY/TDD number, 1-800-325-0778, between 7 a.m. and 7 p.m., Monday through Friday, to see if you might qualify."

Specific Guidance for Summary of Benefits (B, E)

The Summary of Benefits (SB) is the primary pre-enrollment document to inform prospective as well as existing enrollees of the benefits offered by the Organization's plan. The information within the SB is standardized language to allow beneficiaries to more easily compare the benefits offered by different Organizations.

The SB is a stand-alone marketing document that includes the following sections:

- **Section (1):** The introduction and the beneficiary information section, which informs prospective members of important aspects of enrolling in the Organization's plans.
- **Section (2):** The benefit comparison matrix, which is an output report of the Organization's Plan Benefit Package (PBP); and
- **Section (3):** An optional free-form text area, which is limited to six pages. This section can be used by Plans to further describe special features of the program.

The SB is a summary document and, therefore, is not intended to include benefit information in the same detail as the Evidence of Coverage.

All organizations, except 1876 Cost Plans, are required to use the standardized SB. 1876 Cost Plans that intend to have a plan appear in the Medicare Personal Plan Finder should refer to the Summary of Benefits for Cost Plans appearing later in this section.

General Instructions (B, E)

General requirements and guidance for SB are provided below.

1. Organizations must adhere to the language and format of the standardized SB and are permitted to make changes only if approved by CMS. Changes in the language and format of the SB template will result in the disapproval or delayed approval of the SB.

2. The title "Summary of Benefits" must appear on the cover page of the document.

3. The entire SB must be provided together as one document (i.e., all three sections OR sections one and two if section three is not being utilized).

4. The entire SB must be submitted for review as one document. If Plans opt to utilize Section 3, the entire SB will receive 45-day review.

5. Front and back cover pages are acceptable.

6. Font size of 12-point or larger must be used for the SB (including footnotes). Organizations may use bold or capitalized text to aid in readability, provided that these changes do not steer beneficiaries to, or away from, particular benefit items or interfere with the legibility of the document.

NOTE: *Since Sections 1 and 2 of the SB will not be generated from the PBP in 12 – point font, the MA organization should change the font to ensure that the font size is 12 point.*

7. Colors and shading techniques are permitted, but must not direct a beneficiary to or away from particular benefit items and must not interfere with the legibility of the document.

8. The SB may be printed in either portrait or landscape page format.

9. Organizations offering more than one Plan may describe several Plans in the same document by displaying the benefits for different Plans in separate columns within the benefit comparison matrix (i.e., MA vs. MA-PD) (Section 2). However since the PBP will only print sections 1 and 2 of the SB report for one plan, the MA organizations will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. Since information in section 1 will conflict between MA and MA-PD plans, organizations will need to submit a hard copy change for section 1 in order to reflect accurate information.

10. Organizations offering Plans with identical benefits within one contract (e.g., one contract S/H/R number), may display the information for these Plans in the same column within the benefit comparison matrix (Section 2). In addition, PDPs may display identical benefits in different regions. The benefits for the Plans must be the same; only the service areas may differ (e.g., more than one S number).

11. If the SB describes only one of several Plans offered by the Organization, the availability of other Plans must be noted in the Annual Notice of Change (ANOC).

12. If the SB describes more than one Plan, the Organization must identify the specific Plan in which the member is currently enrolled within the cover letter included with the SB.

13. Organizations may include additional information about covered benefits within a separate flyer or other material and may provide this with the SB.

14. The SB header containing such information as the company name, customer service telephone number, etc., only displays on the first page of the SB section 2. It is acceptable for organizations to display SB header on each page or on each section of the SB.

15. If an organization chooses to submit an SB for CMS review, without section 3 and no hard copy changes, it will be treated as a model without modification and will be reviewed within the 10-day time frame.

16. Organizations that offer plans exclusively to individuals through an employer-sponsored group are not currently included in the mandated use of the standardized SB for either annual notification or initial marketing purposes.

The following applies to MA/MA-PD plans only:

17. If an MA organization wants to include mandatory supplemental benefits beyond those benefits found in the benefit comparison matrix, the MA organization must place the information in section 3 of the SB. The MA organization must include a brief description of the benefits and any co-pay requirements.

Instructions for Section 1 – Beneficiary Information (B, E)

This section, which applies to all Organizations, must be incorporated into the SB exactly as it is written within the standardized document, unless otherwise noted.

NOTE: *The last sentence in Section 1 states, "If you have special needs, this document may be available in other formats." Organizations contracting with CMS are obligated to follow the regulatory requirements of the Americans with Disabilities Act and the Civil Rights Act of 1964. Compliance with these requirements satisfies the intent of the above referenced SB sentence. No additional requirements are imposed by the above referenced SB sentence.*

NOTE for PDPs: *PDPs must not use the section 1 that is generated by the PBP. Plans will receive instructions for a mandatory global hard copy change for section 1 in August 2005*.

The following four paragraphs apply to MA and MA-PD plans:

1. Section 1, as generated by the PBP, will include the applicable H number and plan number at the top of the document. MA organizations must delete this information.

2. The fourth paragraph (How can I compare my options?) contains a sentence "We also offer additional benefits, which may change from year to year." If this is not applicable to your plan, you must remove this sentence.

3. The second question and answer in section 1 includes the plan's service area; the PBP will generate a list of counties, with an * indicating those counties that are partial counties. The MA organization may list the zip codes of these counties in this section or provide a cross-reference in section 3 and list the

zip codes here. The MA organization must also explain in section 1 that the * indicates a partial county.

4. The second question and answer in section 1 lists the plan's service area, but does not indicate that the information listed represents counties. Therefore, the MA organization must amend the SB so that the answer reads, "The service area for this plan includes the following counties: <list of counties automatically generated by the PBP>."

Instructions for Section 2 – Benefit Comparison Matrix

The SB benefit comparison matrix will be generated by the PBP in chart format with the required language. Therefore, the information included in the PBP must first be correct in order for the SB comparison matrix to be correct. The order and content of information presented in the benefit comparison matrix must be the same as the information presented in the PBP, with the exception of the permitted and/or necessary changes discussed below.

Instructions for Section 3 – Plan-Specific Features

Section 3 is used by Organizations to describe special features of a program or to provide additional information about benefits described within Sections 1 and 2. Section 3 is optional and is not standardized with regard to format or content. It may contain text, graphics, pictures, maps, etc.

This section is limited to a maximum of six pages of text and graphics. The page limit is defined as six single-sided pages or three double-sided pages. However, there is one exception to this limit: Organizations translating the SB to another language may add pages as necessary to ensure the translation conveys the same information as the English language version.

Organizations may provide additional information in Section 3 about covered benefits described within the benefit comparison matrix. The information in Section 3 must include a reference to the information in the benefit comparison matrix using the following sentence: "See <page #> for additional information about <benefit category>." The benefit category field must be populated exactly as it appears in the benefit comparison matrix.

Footnotes for MA and MA-PD (D, E)

The comparison matrix generated by the PBP will contain the required footnotes in the benefit column for Original Medicare (OM). Therefore, the MAs and MA-PDs must include the following footnotes provided below if they apply to the benefit. Please note that the footnote number must appear in the text of the column and the footnote must appear at the bottom of each page.

> ***NOTE:*** *For review purposes, the MA and MA-PD can list all of the footnotes at the end of section 2, but the final proof copy must include the footnotes at the appropriate points in the text. If the MA and MA-PD chooses this option, the MA and MA-PD must notify the CMS Regional Office conducting the review and must indicate in the SB where the footnotes will actually appear in the final printed version.*

1. <Year>, you pay a total of one $(current) deductible

   This footnote must be referenced after every statement in the Original Medicare column that describes the required Medicare coinsurance, e.g., "You pay 20% of Medicare approved amounts." The only exception where footnote (1) does not need to be referenced is mammograms, pap smears/pelvic exams and prostate cancer screening exams. If the footnote is applicable to the plan it must also be referenced in the Plan column. This footnote must also appear at the bottom of each page.

   NOTE: *The Medicare Part B deductible may change each year.*

2. If a doctor or supplier chooses not to accept assignment, their costs are often higher, which means you pay more.

   This footnote must be referenced after every statement in the OM column that describes the following benefits and after footnote (1), where applicable. The text of this footnote must appear at the bottom of each page.

3. A benefit period begins the day you go to the hospital or skilled nursing facility. The benefit period ends when you have not received hospital or skilled nursing care for 60 days in a row. If you go into the hospital after one benefit period has ended, a new benefit period begins. You must pay the inpatient hospital deductible for each benefit period. There is no limit to the number of benefit periods you can have.

   This footnote must be referenced after the words "benefit period" in the OM column describing Inpatient Hospital Care and Skilled Nursing Facility and the

text of this footnote must appear at the bottom of the page on which these benefits are described. Additionally, if the footnote is applicable to the plan it must also be referenced in the Plan column.

4. Lifetime reserve days can only be used once. This footnote must be referenced after the statement, "Days 91-150: $ (The Medicare amount may change each year) each lifetime reserve days" in the OM column describing Inpatient Hospital Care. Additionally, if the footnote is applicable to the plan it must also be referenced in the Plan column. The text of this footnote must appear at the bottom of the page on which these benefits are described.

Permitted Changes to Summary of Benefits Language and Format (A)

Organizations 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 immediately below for further detail.

Requests to Change Hard Copy Summary of Benefits (A)

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? (A)

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. Another example would be if an MA does not have a physician network, a change may be permitted to remove a sentence referring to the requirement that members see doctors within the plan's network.

What types of Changes will NOT be Permitted? (A)

Requests for changes in which the existing sentences are accurate will not be permitted. Organizations will NOT be permitted to add additional sentences in Section 2 of the Summary of Benefits in order to further explain their benefits. PDPs 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 (PDPs only) (C)

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 to Request a Change (D, E)

To request a change to the hard copy SB, MA or MA-PD 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, MA or MA-PD should provide:

- The H number and Plan ID – each H number and Plan ID should be in a separate e-mail;
- If the request for change applies to multiple H numbers and Plan IDs, the Plan may include all applicable H numbers and Plan IDs in one e-mail;
- The Regional Office and Contact who review the MAO marketing material;
- 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)

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 Organization and the Organization must adhere to the standardized language. If the workgroup permits a change, CMS will notify the Organization 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 marketing review of the approved language. If the request is based on a preferred wording, the request will not be approved.

Summary of Benefits for 1876 Cost Plans (F)

1876 Cost Plans are not required to use the standardized Summary of Benefits; however, they are required to provide members with an SB. If an 1876 Cost Plan intends to have the plan appear in Medicare Health Plan Compare and Medicare Personal Plan Finder, it will need to complete the Plan Benefit Package (PBP) to create a standardized SB. 1876 Cost Plans that create a standardized SB should follow all instructions below.

1876 Cost Plans should follow all instructions previously outlined for the Summary of Benefits. In addition, the following instructions are specific to 1876 Cost Plans.

General Instructions (F)

The benefit description column and Original Medicare column must remain unchanged.

All sentences in the plan column of the matrix must be completed with applicable co-pays or coinsurance amounts.

Additional instructions provided in italicized text and in parentheses should be removed from the Summary of Benefits prior to submitting the document to CMS for review.

Unless otherwise indicated, 1876 Cost Plans should choose all of the applicable sentences in each category to describe their benefits.

Instructions for Section 1- Beneficiary Information Section (F)

For Cost Plans that are "closed" to new enrollment, the pre-enrollment language in section 1 will not apply. Therefore, these Cost Plans should include the following disclaimer in their ANOC. Any additional information regarding the contractor's "closed status" should also be included in the cover letter.

The CMS requires the Summary of Benefits (SB) to be used in both pre-enrollment and annual notice of change (ANOC) functions. Plan member receiving the SB should disregard all pre-enrollment language.

Instructions for Section 2 - Benefit Comparison Matrix (F)

1876 Cost Plans may include the following footnote on each page of the benefit comparison matrix. The text of the footnote should appear at the bottom of every page.

"If you go to a provider outside of <insert name of plan> who accepts Medicare patients, your coverage would be the same as Original Medicare. Original Medicare deductibles and coinsurance apply."

Specific Guidance for Drug Utilization Management and Medication Therapy Management Programs (MTMPs) (B)

Part D Plans can choose to provide information regarding Medication Therapy Management Programs (MTMPs) in pre-enrollment materials. The Plan can include the following information as part of their explanation:

- Number of drugs included in program
- Number and name of disease states included in program

Post-Enrollment Materials (A)

Guidelines for Post-Enrollment Materials (A)

Required Disclaimers

Language Requirements (A)

The below requirements must be included on all pre-enrollment materials, unless noted otherwise or if model language is available. If model language is available and not used, Plans must include all elements of the model language and all required disclaimers.

Lock-In Statement (D, E)

The concept of "lock-in" must be clearly explained in the SB, the EOC, and Member Handbooks.

For Medicare cost plans, all pre-enrollment materials must clearly explain that members may use plan and non-plan providers, and also explain the benefit/cost sharing differentials between use of plan and non-plan providers.

Networks and Sub-networks (D, E)

The SB, the EOC, Provider Directories and Member Handbooks must clearly explain the concept of networks and sub-networks and the process for obtaining services including referral requirements.

Preferred Provider Organizations Only

Mandatory Supplemental Benefits: PPO must clearly state in marketing materials that all covered benefits are available from in-network and out-of-network.

Prior Notification/Authorization Requirements: Some PPOs may require or request that members notify them prior to receiving certain services. In these cases, the organization must clearly define the benefit of voluntary member compliance in marketing materials. It must also include the information in the PBP Notes section so that the appropriate language regarding the reward that would accrue to members that voluntarily comply may be used in marketing materials.

Post-Stabilization (PPO Demonstrations Only): In the EOC and the SB (Section 3), PPO Demonstrations must specify all cost-sharing requirements with regard to emergency hospital admissions, including whether the in-network or out-of-network cost-sharing is required for enrollees who are stabilized and receive post-stabilization care in a non-preferred (out-of-network) hospital following an emergency situation. If the Demo includes a cap on enrollee out-of-pocket costs for such services, state the out-of pocket maximum amount. In the EOC, clearly state any other requirements associated with an out-of-network emergency hospital admission, e.g., enrollee notification upon stabilization, policies with regard to transfers to network hospitals, etc.

Marketing plans to beneficiaries of non-renewing Medicare plans (D, E)

MA organizations may market plans directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the marketing does not begin until after the date the beneficiary has received the plan termination letter. In addition to the targeted message, any pre-enrollment marketing pieces must contain a statement indicating that the Medicare health plan is open to all Medicare beneficiaries eligible by age or disability in the plan's service area.

Cost Savings Described in Marketing Materials (D, E)

If a PPO states in marketing materials that prospective enrollees may save money if they join the plan, it must also acknowledge the added cost of accessing services out-of-network and/or that using services in-network can cost less than using services out-of-network.

Preferred and Non-Preferred Benefits (D, E)

If a PPO offers benefits for which the coinsurance is the same percentage both in and out of network, the PPO must make it clear in all pre-enrollment material that member responsibility may be greater out-of-network since the coinsurance is based on the Medicare allowed amount and not on the potentially lower contracted amount.

Also, explain in pre-enrollment materials that with the exception of emergency or urgent care, it may cost more to get care from non-plan or non-preferred providers.

Mandatory Supplemental Benefits (D, E)

PPO must clearly state in marketing materials that all covered benefits are available from in-network and out-of-network providers.

Hours of Operation (A)

Organizations 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 (A)

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. Organizations 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) (A)

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

Claim Forms and Paperwork (A)

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

- Virtually no paperwork
- Hardly any paperwork

Organizations cannot say:

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

Contract Number on Marketing Materials (A)

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 or H 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 (A)

Organizations 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 Organization must provide the study sample size and number of Organizations surveyed for review purposes.

Organizations are prohibited from using study or statistical data to directly compare their Plan to another Organization's Plan.

If an Organization uses study data that includes aggregate marketplace information on several other Organizations, they will not be required to submit data on all of the Organizations or Plans included in the study. However, the study details, such as the number of Organizations 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.

Contracting Statement (A)

The Summary of Benefits, Member Handbook, and Evidence of Coverage must include a statement either in the text of the material or as a footnote that the Organization contracts with the Federal government.

Product Endorsements/Testimonials (A)

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 Plan by name.
- If an individual is paid to promote a 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 (A)

Font Size Rule for Member Materials (A)

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 (A)

Any post-enrollment materials that a Plan places on its Web site needs to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor an 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 (A)

The 12-point font size or larger rule also applies to any footnotes or subscript annotations in post-enrollment notices. Footnotes are not required to be the same font size as the text in the body of the marketing material.

Footnote Placement (A)

Organizations 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 must also appear at the bottom of page 8.

Other Requirements (A)

Logos/Tag Lines (A)

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. Organizations 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").

For Organizations with an existing investment in a company logo/product tag line, CMS will permit "grand fathering" of company logos/product tag lines established before the final rule of the Medicare Prescription Drug Benefit, took effect (i.e., before January 28, 2005).

Media Type (A)

With respect to the Summary of Benefits (SB), the Evidence of Coverage (EOC), and the Provider/Pharmacy Directory, Organizations have the option of contacting members to determine in what format they would like to receive the materials (e.g., hard copy, CD ROM), Organizations 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 Provider/Pharmacy Directory in another format. If the Organization does not receive a response from the member, then the Organization must assume that the member wants to receive the information in hard copy.

If the Organization sends one Provider/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 Organization 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 materially updated rather than routinely updated. Examples of material updates could include changes that affect fundamental enrollee due process rights (e.g., appeals, grievances) or plan coverage and rules (e.g., access to and scope of benefits). Organizations may 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 Provider/

Pharmacy Directories, since Provider/Pharmacy Directory updates can occur far more frequently than updates to the EOC or SB.

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

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

Specific Guidance (A)

Materials Required at the Time of Enrollment and Annually (A)

Organizations must provide the following information at the time of enrollment and on an annual basis:

- Annual Notice of Change (**Annually Only**): All Organizations are required to give members notice of program changes taking place on January 1 of the upcoming year, by October 31 of the current year. This requirement applies to all Organization enrollees. "Give notice" means that members must have **received** the notice by the required date. This notice is known as the "Annual Notice of Change," or "ANOC." The ANOC must be member-specific and have the member's own name either on the envelope addressed to the member or on the ANOC itself. A model ANOC is forthcoming.
- Summary of Benefits
- Evidence of Coverage
- Abridged Formulary including information on how the beneficiary can obtain a complete formulary (MA-PD, PDP only)
- ID Card (At time of enrollment and as required by Organization)
- Provider Directory (at time of enrollment only)

ID Card Requirements (B)

Part D Plans must provide a member identification card to each enrollee, based on the National Council for Prescription Drug Program's (NCPDP's) "Pharmacy ID Card Standard." This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled Identification Card – Health Care Identification Cards. Further guidance on the technical specifications of the NCPDP

Data Elements follows below. For additional information on NCPDP requirements, refer to the NCPDP Healthcare Identification Card Pharmacy ID Card Implementation Guide (Version 1, Release 8 April 2004).

The following supplemental information is provided to Plans in following NCPDP requirements:

- Plans offering medical benefits and Part D benefits may merge their existing ID card with the Part D benefit, adding additional elements that would identify the Part D benefit, or create a separate ID card for the Part D benefit. If a Part D specific ID card is to be developed, it must conform to the layout specifications defined by the NCPDP Pharmacy ID Card Implementation Guide.
- For combination cards (medical and Part D benefits), the RxBIN, RxPCN, and RxGrp must be on the front of the card, grouped together, and in the order specified in the NCPDP Pharmacy ID Card Implementation Guide.
- If a machine-readable ID card is issued, the physical characteristics of the ID card are defined by the INCITS 284 standard. If a non-machine-readable ID card is issued, the physical characteristics of the ID card are at the discretion of the card issuer, provided that the card is not smaller than 3-1/8" by 2"and not larger than 3-1/8" by 2-3/8". Please refer to Addendum 1 for more information on machine-readable ID cards.
- All mandatory data elements required to be on the front of the ID card must be on the front of the ID card; however, Plans issuing combination ID cards may vary the location of these elements.
- All mandatory data elements required to be on the back of the ID card must be on the back of the ID; however, Plans issuing combination ID cards may vary the location of these elements.
- At their option, Plans can add co-pay information to the ID card, provided that co-pays are appropriately labeled.

The Part D Member ID cards contain both NCPDP mandatory elements and several CMS-required elements. Requirements are provided below.

Front of Card:

1. The font size for the front of the ID card must be 8-point or larger for mandatory elements.
2. The name or logo of the benefit administrator and/or processor issuing the identification card (including co-branding symbols & logos).
3. Card Issuer's ID. This should default to 80840 until a HIPAA authorized number has been enumerated, e.g., National Payer ID.

4. The Cardholder's (beneficiary's) identification number, which cannot be the SSN or Healthcare Insurance Claim Number (HICN). The Plan or the claim administrator generates the cardholder's ID number.
5. Cardholder's first name, middle initial (if available), and last name.
6. Complete electronic transaction routing information, including the International Identification Number (RxBIN). The Processor Control (RxPCN) and Group Numbers (RxGrp) are mandatory when required by the benefit administrator to electronically route a prescription claim.
7. CMS Part D Contract and Plan Benefit Package numbers. This information must be right justified.
8. Medicare Symbol (Refer to Section 12 for more information)

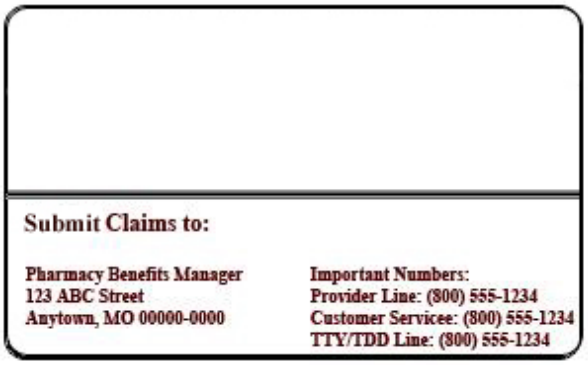
NOTE: *Please refer to Table 6.1 in Addendum 1 for mandatory NCPDP element placement.*

Figure 6.1 Front of card

Back of Card:

1. The font size on the back of the ID card must be 8-point or larger for mandatory elements.
2. Claims submission name(s) and address(es).
3. Provider Line, Customer Service Numbers, and Customer Service TTY/TDD number.
4. Bar coding, when required by state law.
5. Optional Elements:
    a. Medicare Contact Information (1-800- Medicare and 1-800-486-2048 TTY/TDD).
    b. P.O. Box/Address to return lost cards.
    c. Benefit Administrator Web site information.

Figure 6.2 Back of card.



NOTE: *Optional elements are not included on the figures above.*

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CMS recommends that all Medicare health plans, especially PPOs and PFFS Plans, include the phrase "Medicare limiting charges apply" on Member ID cards. However, use of this phrase is optional. CMS believes that use of this phrase on a card that most providers will see is a reliable method of informing providers of the billing rules for the plan, and thus could reduce the chance for incorrect or inappropriate balance billing.

The CMS also recommends that PPOs and PFFS Plans include the statement that the provider should bill the PPO or PFFS organization and not Original Medicare. The CMS believes this statement will help prevent claim processing errors. However, use of this statement is optional.

The member ID number cannot be the Social Security Number or Health Care Insurance Claim Number (HICN).

Pharmacy Directories (B)

Part D Plans and 1876 Cost Plans offering Medicare prescription drug coverage must include information regarding their participating network pharmacies within their marketing materials and provide it upon beneficiary request. A network pharmacy is a pharmacy where beneficiaries can make use of the prescription drug benefits.

Required Pharmacy Information (B)

Information required in the Pharmacy Directory for non-chain pharmacies includes pharmacy name, address, phone number, and type of pharmacy (e.g., retail, mail order, institutional, etc.). In lieu of providing the addresses for all locations, chains may provide a toll-free customer service number and a TTY/TDD number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest their home. Organizations may also include chain pharmacy locators or search engines on their Web sites.

- Organizations may have pharmacy directories for each of the geographic areas they serve (e.g., metropolitan areas, surrounding county areas, etc.) provided that all directories together cover the entire PDP service area. If a directory is a subset of a service area, Organizations must include the following disclaimer:

  "All network pharmacies may not be listed in this directory. Please contact Organization at xxx-xxx-xxxx for additional information."
- Organizations may provide an optional disclaimer that states the directory is current as of a particular date and that the pharmacy's listing in the directory does not guarantee the pharmacy is still in the network.
- MA-PDs may combine physician and pharmacy directories in one document (Applicable to MA-PD's only).
- Organizations may list both preferred and non-preferred pharmacies. However, the Organization must identify each category and describe any restrictions imposed on members that use non-preferred pharmacies.

If Organizations use a search engine on their Web sites in lieu of posting the Pharmacy Directory, the search engine must include all of the information listed above.

Out-of-Network Pharmacy Access (B)

Organizations must include information within their marketing materials that informs individuals that they will have adequate access to covered Part D drugs dispensed on a non-routine basis by out-of-network pharmacies when the enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy.

Mail-Order Prescription Drug Services (B)

Organizations must include a description of any mail order services that are offered. The description must:

- State that enrollees are not required to use mail-order prescription drug services to obtain their extended supplies of maintenance medications;
- State that enrollees have the option of using a preferred or non-preferred retail pharmacy in the network to obtain a maintenance supply of medications;
- State that if a retail pharmacy does agree to accept the mail-order reimbursement rate for an extended supply of medications, the enrollee should have no out-of-pocket payment differences;
- State that if a retail pharmacy does not agree to accept the mail-order reimbursement rate but has accepted an alternative retail/mail-order pharmacy rate for an extended supply of medications, the enrollee will be liable for any difference in charge (see Q&A --search on ID 4379 at: http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php).
- State the maximum expected turnaround time for the processing and shipment of all mail orders;
- Describe the process for enrollees to obtain a prescription if a mail order is delayed; and
- Include a toll-free telephone number and TTY/TDD to call if there are questions.

Provider Directories (D, E)

MA organizations/Medicare Health Plans are required to disclose the following information to each enrollee in clear, accurate, and standardized form at the time of enrollment and at least annually thereafter. MA organizations/Medicare Health Plans usually include this information in their Provider Directory. The directory is then given to new members upon enrollment and existing members on an annual basis. Also, Medicare cost plans are required to send a Provider Directory to members at the time of enrollment and annually.

The directory must include:

1. The number, mix, and distribution, including addresses of providers from whom enrollees may obtain services, as well as any out-of-network coverage or point-of-service option.

In addition, provider directories should also contain the following:

1. Names, complete addresses, and phone numbers of the primary care physicians;

2. Names and addresses (city or town) of specialists, skilled nursing facilities, hospitals, outpatient mental health providers, and pharmacies, where outpatient prescription drugs are offered by the MA plan;

3. General information regarding network lock-in, including the role of the primary care physician (PCP) as well as the process for selecting a new PCP and any specific requirements for referrals to specialists and ancillary providers;

4. A description of the plan's service area, including a list of cities and towns;

5. Telephone numbers for customer service or appropriate contact information (including the hours of service) for members who have questions or require assistance in selecting a PCP;

6. Instructions to enrollees that, in cases where non-contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any;

7. Information regarding out-of-area coverage and emergency coverage, including the process and procedures for obtaining emergency services, and the location where emergency care can be obtained, as well as other locations where contracting physicians and hospitals provide emergency services, and post-stabilization care included in the MA plan;

8. Prior authorization rules and other review requirements that must be met in order to ensure payment for the services; and

9. A general disclaimer that indicates that the directory is current as of a particular date and that a provider's listing in the directory does not guarantee that the provider is still in the network or accepting new members.

PCP and Specialty Directories (D, E)

Medicare health plans may publish separate PCP and Specialty directories provided that both directories must be given to enrollees at the time of enrollment and at least annually thereafter. Organizations that use sub-networks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate sub-network) and describe any restrictions imposed on members that use these sub-networks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. Organizations must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

Medicare health plans may print a separate directory for each sub-network and disseminate this information to members in a particular sub-network. This practice is permissible, provided that the directory clearly states that a directory that lists providers for other networks is available and provides this information to members upon request.

Mailing the Provider/Pharmacy Directory to Addresses with Multiple Members (A)

With respect to the annual mailing of the directory, Medicare health plans have the option to either mail one directory to every member, or to mail one directory to every address where **up to four members** reside. (Keep in mind that individuals in, for example, apartment buildings, are only considered to be at the "same address" if the apartment number is the same.) Please note that every member must still receive his or her own directory at the time of enrollment.

If you choose to mail the directory to every address where up to four members reside, you must keep the following in mind:

- If a member at that address subsequently requests that you mail another copy of the directory, you must mail them a directory.
- When mailing a directory to one address, you should include the name of at least one of those individuals in the mailing address (however, we prefer that you include the names of all individuals, to prevent any members mistakenly believing that you failed to mail them a directory).

Changes to Provider Network (D, E)

MA organizations/Medicare Health Plans must make a good faith effort to provide notice of termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified

Provider/Pharmacy Directory Change Pages (A)

Organizations/Medicare Health Plans that have a web site or that provide Plan information through the Internet must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an Internet Web site. (Exception: Employer Group plans can direct members to their employer for information on the EOC and SB.) With respect to those members who choose to receive a hard copy directory as opposed to an electronic copy, Organizations have the option of mailing a complete directory to members, or to instead mail only change pages to members. (***NOTE:*** *CMS still requires that every member receive a complete directory at the time of enrollment.*) In addition, if at any time a member requests a complete directory, the Organization must comply with the request.

If an Organization chooses to send change pages to members, the following will also apply:

- In instances where significant changes to the provider/pharmacy network occur, the Organization must send a special mailing of change pages immediately. In general, the Organization can define "significant changes" when determining whether a special mailing is necessary. However, the CMS may also determine a mailing is needed and may direct the Organization to conduct such a mailing.
- A new, complete Provider/Pharmacy Directory must be mailed to all members at least every three years.
- Change pages may consist of the actual page being changed or a list of changes with referenced pages. Change pages must be dated.
- Organization may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in provider's addresses and phone numbers. However, in accordance with 42 CFR 422.111(c).
- When sending out change pages, the Organization must include a cover letter that explains that the member can receive a complete directory upon

request. The Organization should also include information on how to obtain provider/pharmacy network information on the Internet and/or by telephone. In addition, the first time the Organization sends change pages the cover letter should explain that the Organization will now be sending change pages to members, as opposed to a complete directory.

Post-Enrollment Formulary Requirements (B)

Abridged Formulary

Section 423.128 of the Final Rule requires Part D Plans to provide a list of drugs included on the Part D Plans formulary to enrollees upon enrollment and at least annually thereafter. The final rule does not specify whether this list should be an abridged or comprehensive list of covered drugs. However, because concerns that a comprehensive formulary would be costly for Organizations to print and distribute and confusing for enrollees to use, CMS has elected to allow Organizations to provide an abridged version of their formulary.

CMS will make available a model abridged formulary that Organizations may choose to follow. The model document provides more detailed guidance regarding the requirements for the abridged formulary, but, at a minimum, the document must include the following information:

- The definition of a formulary.
- An explanation of how to use the Part D Plan's formulary document.
- The following statement: "<Part D Plan Name> covers both brand-name drugs and generic drugs. Generic drugs have the same active-ingredient formula as a brand name drug. Generic drugs usually cost less than brand name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand name drugs."
- The following disclaimer: "This is not a complete list of drugs covered by the Part D Plan. For a complete listing, please call <Customer Service Phone Number> or log onto <Web site address>."
- Additional disclaimers as determined by CMS.
- A statement describing the Part D Plan's general utilization management procedures, as well as a statement that the formulary may change during the year (***NOTE:*** *Under 423.120(b)(6), an Part D Plan may not change its formulary from the beginning of the annual coordinated election period through 60 days after the beginning of the contract year.*)
- The document must also include the date the formulary was last updated and describe how to obtain updated formulary information.

- A chart (the approved CMS formulary) of covered drugs organized by therapeutic category that includes at least two covered drugs for each therapeutic class. Exceptions to this include when only one drug exists in the category or class or in the case where two drugs exist in the category or class, and one is clinically superior to the other. If a subset of the formulary is used, it must be consistent with the CMS approved Part D Plan formulary. (***NOTE:*** *While Part D Plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D Plans have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may be confusing for beneficiaries.*) The chart must include at least the three columns described below.
  - Drug Name: We suggest capitalizing brand name drugs (e.g., LIPITOR) and listing generic drugs in lowercase italics (e.g., penicillin). Part D Plans may include the generic name of a drug next to the brand name of the drug.
  - Tier Placement: Part D Plans that provide different levels of coverage for drugs depending on their tier should include a column indicating the drug's tier placement. For example, if a formulary includes Generic, Preferred Brand, and Other Brand Name tiers, the formulary should list which tier applies to the drug. Part D Plans may also choose to replace the tier placement column with a column providing the co-payment or co-insurance amount.
  - Utilization Management: Part D Plans should indicate any applicable utilization management procedures (e.g., preauthorization, step therapy, quantity limits, etc.) for the drug. A description of these utilization management procedures must be provided somewhere within the document (e.g., in footnotes). For example, a Part D Plan may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.
- Because many beneficiaries may only know the name of their prescription and not its therapeutic class, the abridged formulary must also include an index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug (i.e., name, tier placement, and utilization management strategy).
- An explanation of how to obtain an exception to the Part D Plan's formulary, utilization management tools or tiered cost sharing.
- Abridged formularies must be submitted to CMS or its Designee for review to ensure they comply with the Guidelines. Part D Plans are responsible for ensuring that their abridged formulary includes at least two covered drugs in each therapeutic class (unless only one drug exists in the category or class or

two drugs exist in the category or class but one is clinically superior to the other); reviewers will generally not verify that the document includes two covered drugs in each class. However, CMS or its Designee may elect to complete a retrospective review that includes a review of the specific drugs included on the abridged formulary. These reviews may be conducted on either a random or a for-cause basis.

- Updated formularies do not need to be submitted for re-review provided the only changes are to update the document date, add or delete specific drugs, or update tier placement or utilization management designations. The Part D Plan is required to submit to CMS or its Designee a final printed version of the item for possible retrospective review.

Comprehensive Formulary (Part D Plans) (B)

Section 423.128(c)(1)(v) of the Final Rule states that an Part D Plan upon the request of a Part D eligible individual, must provide "the Part D Plan's formulary." Section 423.4 defines "formulary" as "the entire list of Part D drugs covered by a Part D Plans." These provisions together require Part D Plans to provide a comprehensive written formulary to any potential or current enrollee upon his or her request.

NOTE: *If an individual contacts the Part D Plan to request a comprehensive formulary, the Part D Plan may offer to provide the individual with coverage information for specific drugs instead. That is, the customer service representative may offer to look up the individual's prescription(s) in order to provide information about coverage, tier placement, and utilization management procedures for his or her drugs. However, if the individual refuses the specific drug information or accepts it but indicates that they would still like to receive a complete written formulary, the Part D Plan must send a comprehensive formulary. Customer service representatives may also inform individuals that current and comprehensive formulary information is available on the Part D Plan's Web site. However, if the individual indicates that they do not have Internet access or that they would like to receive a complete written formulary, the Part D Plan must send a comprehensive formulary.*

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary would include the entire list of drugs covered by the Part D Plan and would exclude the disclaimer informing beneficiaries that they can obtain a comprehensive formulary by contacting the Part D Plan.

Formularies Provided on Plan Web Sites (B)

Section 423.128(d)(2)(ii) of the Final Rule requires Part D Plans to include their current formulary, updated at least once per month, on their Web site. Part D Plans may choose to meet this requirement in one of several ways:

- By providing an electronic copy of the comprehensive formulary document that individuals may view and/or print. As mentioned above, the information in this document must be updated at least once per month and it must be accessible by a drug name search. The document should be posted as a PDF file, but may be posted in other formats as well.
- CMS suggests that Part D Plans provide a search tool that allows individuals to search for their specific prescription drug. The search tool must include:
  - Definition of formulary. Part D Plans may either include this information or provide a link to this information in an introductory screen.
  - An explanation of how to use the search tool.
  - The following statement: "<Part D Plan Name> covers both brand name drugs and generic drugs. Generic drugs have the same active-ingredient formula as a brand name drug. Generic drugs usually cost less than brand name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand name drugs."
  - A statement that the formulary may change during the year.
  - Search results that indicate whether a drug is covered, its tier placement, and any applicable utilization management procedures.
  - An explanation of how to obtain an exception to the Part D Plan's formulary, utilization management tools or tiered cost sharing. This information or a link to this information must be included in both an introductory screen and when search results indicate a drug is not covered.

Formulary information available on a Web site is subject to review by CMS or its Designee. Review of these materials will follow the procedures for review of Web sites, which is described within Section 6 (Marketing Material Development Guidelines) of these Guidelines.

Other Formulary Documents (B)

Part D Plans may develop additional formulary documents providing that the comprehensive and abridged formulary documents are developed and distributed in compliance with the Guidelines described above. For example, Part D Plans may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them.

Provision of Notice Regarding Formulary Changes (B)

Part D Plans must provide at least 60 days notice to CMS, SPAPs, authorized prescribers, and network pharmacies before removing a Part D drug from the Part D Plan's formulary or making any changes in the preferred or tiered cost-sharing status of a covered Part D drug. Part D Plans can determine the most effective means by which to communicate formulary change information to these parties, including electronic means. Part D Plans must also notify enrollees in one of the following ways:

- Provide direct written notice to affected enrollees at least 60 days prior to the effective date of the change;
- At the time an affected enrollee requests a refill of the Part D drug, provide the enrollee with a 60-day supply of the Part D drug under the same terms as previously allowed and provide written notice of the formulary change.

NOTE: *Part D Plans may immediately remove from their Part D Plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting these requirements. Part D Plans must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists.*

The written notice must contain the following information:

- The name of the affected covered Part D drug;
- Information on whether the covered Part D drug is being removed from the formulary or changing its preferred or tiered cost-sharing status;
- The reason why the covered Part D drug is being removed from the formulary or changing its preferred or cost-sharing status;
- Alternative drugs in the same therapeutic category, class or cost-sharing tier, and the expected cost-sharing for those drugs; and
- The means by which enrollees may obtain an updated coverage determination or an exception to a coverage determination.

The above notice must also be posted on the Part D Plan's Web site.

Evidence of Coverage for PDPs (C)

PDPs are required to provide 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: "If you currently have a Medicare Supplement (Medigap) policy **that includes coverage for prescription drugs**, you must contact your Medigap issuer and tell them you have enrolled in <Plan Name>. If you decide to keep your current Medigap policy, your Medigap issuer will remove the prescription drug coverage portion of your policy and adjust your premium. In addition, under certain circumstances, you may be able to purchase a different Medigap policy from the same company". You should have received a letter in the fall of 2005 from your Medigap issuer explaining your options and how the removal of drug coverage from your Medigap policy will affect your premiums. If you do not receive this letter, please contact your Medigap issuer.
- 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.
- 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.

Evidence of Coverage for MA, MA-PD and 1876 Cost Plans (D, E)

All MA organizations/Medicare Health Plans are required to give an EOC to all members annually. They must also send new members an EOC no later than when they notify the member of acceptance (confirmation) of enrollment. These requirements apply to all plan members, including employer group members. CMS provides a model EOC for HMOs, PPOs, and Medicare cost plans under separate cover.

The following information must be contained in the EOC:

Lock-In Requirements/Selecting a Primary Care Physician - How to Access Care in the plan (D, E)

Medicare health plans must describe rules for receipt of primary care, specialty care, hospital care, and other medical services in their EOC. The EOC must:

- Disclose specific rules for referrals for follow-up specialty care.
- HMOs: Explain that when a beneficiary enrolls in a plan, he/she agrees to use the network of physicians, hospitals, and providers that are affiliated with the plan for all health care services, except emergencies, urgently needed care, or out-of-area renal dialysis services.
- Explain that use of non-plan or non-preferred providers is allowed, but may cost more to the beneficiary (this requirements applies to PPOs and POS plans and, if appropriate, Visitors Programs for any plan type).
- Explain the impact of using the Medicare card for out-of-plan utilization that is not an emergency or urgent care.
- Explain that a plan member selects a primary care physician (PCP) to coordinate all of the member's care. A PCP is usually a family practitioner, general practitioner, or internist. The PCP knows the plan's network and can guide the member to plan specialists when needed. The member always has the option to change to a different PCP. Changes in PCP will be effective according to the plan guidelines that, in some instances, could be the first or

the 15th day of the following month as opposed to immediately. (This requirement does not apply to PPOs or PFFS plans that do not use PCPs.)

- For HMOs, explain that neither the MA organization nor Medicare will pay for medical services that the member receives outside of the network unless it was authorized, nor it is an emergency, urgently needed care, or out-of-area dialysis service. The member may be responsible for paying the bill.
- For PPOs, explain that with the exception of emergency or urgent care, it may cost more to get care from non-plan or non-preferred providers.
- Explain prior authorization rules for any in or out-of-network services and describe other review requirements that must be met in order to ensure payment for the services
- For Medicare cost plans, enrollees must be informed that after enrollment is effective, in order for them to receive the full coverage offered, services other than emergency and urgently needed services must be obtained through the HMO or CMP. In the case of cost enrollees, however, they may receive services that are not provided or arranged by their HMO or CMP, but they would be responsible for payment of all Medicare deductibles and coinsurance as well as any additional charges as prescribed by the Medicare program. They also would be liable for any charges not covered by the Medicare program.

Emergency Care (D, E)

EOCs must describe rules for emergency care and post-stabilization care. In particular, they must:

- Explain that members are not required to go to health plan-affiliated hospitals and practitioners when they experience an emergency.
- MA organizations: Define the term "Emergency medical condition" (MA organizations can find this definition in Section 3 & 4 of the MA/Cost Model EOC.
- Define the term "Emergency services" (MA organizations can find this definition in Section 3 & 4 of the MA/Cost Model EOC).
- Describe rules and coverage for post-stabilization care. MA organizations can refer to Section 4 for more information on responsibility for emergency care and stabilization and post-stabilization requirements.
- Describe precisely where emergency coverage will be available under the organization (e.g., the United States and its Territories, worldwide, etc.).

Urgent Care (D, E)

EOCs must describe rules for urgent care. In particular, they must:

- Define "urgently needed services" (for MA organizations, this definition can be found in Section 3 & 4 of the MA/Cost Model EOC).
- Explain that urgently needed care provided by non-plan providers is covered when a member is in or out of the service area or MA continuation area under the unusual circumstance that the organization's provider network is temporarily unavailable or inaccessible. Normally, if a member needs urgent care and is in the organization's service area or MA continuation area, the member is expected to obtain care from the organization's providers.

Appeal Rights (D, E)

EOCs must describe the appeals process and rights to appeals. In particular, they must explain that members have a right to appeal any decision the organization makes regarding, but not limited to, a denial, termination, payment, or reduction of services. This includes denial of payment for a service after the service has been rendered (post-service) or denial of service prior to the service being rendered (pre-service). For more information on appeals, MA organizations can refer to Section 10 of the MA/Cost Model EOC.

Beginning 2006, 1876 Cost Plans must explain to their members that complaints about optional supplemental benefits are handled through the *appeal* process.

Benefits, Plan Premium and Billing Information (D, E)

EOCs must describe benefit and plan premium information. In particular, they must:

- Include the statement: "You must continue to pay your Medicare Part B premium" with premium information, even if the plan premium is $0."
- When specifying benefits, specify annual limits, annual benefit payout (e.g., $700 for eyeglasses every 2 years) and applicable co-payments (e.g., $5 co-payment for a doctor visit).
- Clearly state major exclusions and limitations. For example, restriction of pharmacy benefits to a specific formulary or a restricted set of pharmacies must be explained.
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary's access to drugs or services.
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits, and whether any unused portion of that benefit can be carried over from one calendar quarter to the next.

- Make the statement that the MA organization's contract with CMS is renewed annually, and that the availability of coverage beyond the end of the current contract year is not guaranteed.
- Provide instructions to enrollees that, in cases where non-contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.
- For PPOs clearly explain all benefits are available from both in-network and out-of-network providers.
- For PPOs clearly explain the non-preferred cost sharing level and if it differs from the in-network level.

For more information on benefits, premiums and cost sharing, refer to Sections 4 and 8 of the MA/Cost Model EOC.

Explanation of Benefits for PDPs (C)

A PDP 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. (If a Plan provides coverage between the initial coverage limit (ICL) and catastrophic coverage threshold (CCT), plans should give the amount the beneficiary must spend before reaching the CCT).
    c. Total Out-of-Pocket Expenditure (TrOOP).
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.

NOTE: *All year-to-date total amounts mentioned above in (b) and (c) should not include amounts paid by the member's current or former employer/union or another insurance plan or policy.*

Anti-Duplication Notices (A)

Since Organizations will provide all covered Medicare drug benefits directly to enrolled beneficiaries, Organizations will not have to provide anti-duplication notices to Medicare beneficiaries. However, if Organizations choose to market to their enrollees other health insurance products that are not part of their contract, these other products will have to include an anti-duplication notice as required by Section 17 of the NAIC model regulation.

Limited Income Subsidy for Part D Plans (C)

The limited income subsidy is extra help with prescription drug costs for Medicare-eligible individuals whose income and resources are limited. This help is in 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 a 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 limited 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 limited 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

PDPs 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 the Plan retains all responsibilities for meeting CMS requirements. The Plan 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).

PDPs 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 limited 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.
- Imply in any written materials or other contact with the member that the Plan has the authority to determine the member's eligibility for limited income subsidy programs.

Specific Guidance Regarding Eligibility and Enrollment for Limited Income Subsidy (C)

For more information on the eligibility and enrollment requirements for the limited income subsidy, please access the following Web sites:
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

Limited Income Subsidy Premium Disclaimer (C)

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 the Social Security Administration at 1-800-772-1213 or on the toll-free TTY/TDD number, 1-800-325-0778, between 7 a.m. and 7 p.m., Monday through Friday to see if you might qualify."

Specific Guidance on Marketing Activity for MA Special Needs Plan (SNP) (for MA and MA-PD only) (D, E)

The MMA (Medicare Modernization Act of 2003) allows MA organizations to offer plans that serve special needs individuals. The legislation designates two specific segments of the Medicare population as special needs individuals. These are institutionalized individuals and those entitled to Medical Assistance under a State Plan under Title XIX. Additionally, MMA allows the Secretary to designate other chronically ill or disabled beneficiaries as "special needs beneficiaries" to allow plans to enroll additional high-risk groups who would benefit from a specialized MA plan.

If SNP use contracted providers to identify eligible individuals, this then falls into "Provider marketing."

Dual Eligible SNP (D, E)

- Dual eligible SNP may work with their respective states to market exclusively to special needs individuals, so they can limit to whom they market, but within that group of special needs individuals, can't limit. As with any MA organization, the SNP must market to all eligible individuals.
- A Medicare Advantage Organization with multiple plans must ensure that the active dual eligible members in non-SNPs are not steered into joining the SNP.
- While SNPs are permitted to market to all eligible individuals, they are prohibited from engaging in any activities that could mislead or confuse Medicare beneficiaries.
- The marketing materials for the dual eligible SNP must be targeted only to the specific dual eligible individuals, and all materials must clearly identify the eligibility requirements for that plan.
- While CMS provides a model Evidence of Coverage (EOC) for HMOs, PPOs and Medicare cost plans, a SNP can develop a comprehensive EOC, based on its uniqueness, to include Medicaid benefits. If a SNP chooses to develop a comprehensive EOC, coordination must take place with the State Medicaid Agency for review of the description of Medicaid benefits. We encourage SNPs to coordinate their activities with the State, anytime SNP marketing materials mention Medicaid, or how its benefits interface with the State Medicaid program. The Regional Office is responsible only for review of marketing materials that specify Medicare benefits and information on Medicare program, and its approval of an EOC should not be deemed an approval of the provisions in the EOC pertaining to Medicaid.

Institutional SNP (D, E)

By definition, an institutional SNP will enroll a limited group of beneficiaries and may also have limited enrollment options (e.g., the plan may have only one contracted long term care facility in a county with a few open beds.). Given these conditions, CMS may not require such a SNP to broadly market its plan. However, all Medicare beneficiaries, including beneficiaries who meet the SNP eligibility requirements, must have reasonable access to information describing all MA plans, including an institutional SNP, that are available in their service area. Importantly, information on these plans must be made available on the CMS Web site so that interested beneficiaries (or their families) can identify institutional SNPs that are available in the service area.

SPAP Materials (B)

State Pharmaceutical Assistance Programs (SPAPs) are state-financed prescription drug programs that provide drug coverage to limited income or disease-specific populations. SPAPs also provide pharmaceutical assistance to limited income Medicare beneficiaries. Beginning January 1, 2006, many of the SPAP beneficiaries will become eligible for Part D and must enroll with a Plan in order to receive the Medicare Prescription Drug Benefit.

The SPAP beneficiaries are familiar with the SPAP benefits and may feel uncomfortable with switching to a Part D Plan. They may therefore require additional promotion during a Plan's marketing campaign. In order to enroll this population, we recommend that Plans meet with existing SPAPs in order to gather specific, de-identified information regarding the demographics of this population, as well as other pertinent Plan information that can be used in marketing to these individuals.

For example, the Plan may request information regarding the SPAP's current benefit package in order for the Plan to emphasize within its marketing materials that its benefits are as generous as those previously offered to the beneficiary through the SPAP. Plans may also want to include information on SPAP network pharmacies that will be part of the Plan's network. In addition, the Plan may want to know the SPAP's formulary or preferred drug list so that it can emphasize that its Plan benefits will accommodate the SPAP beneficiary's drug needs.

As of January 1, 2006, SPAPs may opt to provide wrap-around coverage to beneficiaries in addition to the benefits they receive from the Plan. Plans may provide information via a Web site or another medium explaining to all beneficiaries that they may qualify for SPAP wrap-around benefits in their state. Part D Plans can emphasize that they are required to coordinate benefits with the SPAP so that the beneficiary will realize a reduced cost sharing amount or no cost sharing at the pharmacy. Part D Plans can provide this information in other written marketing materials as well.

Co-branding with SPAPs (B)

A Part D Plan's logo may be used in connection with the coverage of benefits provided under a SPAP and may contain an emblem or symbol indicating such a connection. This decision to "co-brand" with SPAPs resides with the Part D Plan. There is nothing in the statute that requires the Plan to add the SPAP emblem to its card. Therefore, if an SPAP approaches a Plan to request that its emblem or symbol be placed on the cards (as well as other marketing materials), the Plan may decide not to co-brand. However, it would be prudent for the Plan to cooperate with the SPAP, as it will promote their products to the SPAP population.

States have asked if they can choose which Plans to co-brand with, or if they must offer to co-brand with all Plans. The SPAP must offer co-branding of materials, including the identification card, to all Plans covering the service area of the SPAP. Whether a Plan chooses to co-brand with the SPAP, or not, is completely up to the Plan. Also, if a Plan approaches the state to co-brand, the SPAP may do so as long as the SPAP agrees to co-brand with all Plans that approach them with similar standards. It should be noted that both the SPAP and the Part D Plan must notify CMS in advance of the co-brand arrangement and must agree to adhere to all applicable Marketing Guidelines.

States have also asked whether it would be discriminatory if the SPAP, during its education and outreach campaign, informed the beneficiary which Plans have agreed to co-brand. We do not believe that this would discriminate against other Plans, as long as all Plans have been offered the option to co-brand with the state and the standards for co-branding offered by the state do not vary materially from one Plan to another. In other words, as long as the SPAP gives all Part D Plans equal opportunity to co-brand with them and is providing the same benefits for all beneficiaries regardless of the co-branded Plans, the SPAP is not discriminating.

Co-branding relationships that involve remuneration between parties in a position to influence the referral of Medicare-payable business should be carefully scrutinized for compliance with the fraud and abuse laws, including the Federal anti-kickback statute.

Internet Marketing (B)

Part D Plans are required to have an Internet Web site that is compliant with Web-based technology and information standards for people with disabilities as specified in Section 508 of the Rehabilitation Act. For additional information, please go to the following Web site address: http://www.section508.gov.

Definitions (B)

- Corporate Web site – An organization's general Web page that may include information on the organization's mission, history, contact information, and products and services.
- Web page – A single element of a Web site, usually an HTML-based document exclusively dedicated to a specific product (e.g., MA-PD or PDP).
- Web address – An address that is typed into the Web browser. Also known as a URL (Universal Resource Locator).
- Web link – A shortcut within a Web site or Web page that connects the user to another location on the Internet.

URL Guidelines (B)

All organizations offering Medicare prescription drug coverage must have a Web site or Web page dedicated to the Prescription Drug Benefit. This site/page must include the name of the particular Part D Plan and clearly indicate that it is a Medicare contractor. All marketing materials must include a Web address that connects the beneficiary either to the corporate Web site or directly to the Plan's Part D Web page. Subsequently, Web pages that are specifically designed for the Part D Plans should be accessed either directly from the Plan's Web address or from the organization's corporate Web site

A Part D Plan may market its organization's other lines of business concurrently with its Part D Plan products on the Internet. However, to avoid beneficiary confusion, any links provided by the Part D Plan to health-related or non-health related products/services must be clearly labeled as such to allow the beneficiary to make an informed decision and understand that by clicking on those links, he/she will be leaving the Part D Plan-specific Web pages.

Any marketing materials that a Part D Plan places on its Web site must be in a minimum 12-point Times New Roman-equivalent font. However, CMS acknowledges that the Part D Plan does not have 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 Part D Plan codes the font for the Web page, not how it actually looks on the user's screen.

All Web sites must be submitted to the appropriate entity for review. Part D Plans may submit their Web sites, through HPMS, either as links to test sites or as screen shots

Part D Plan Web site Content Requirements (B)

The following information must be included on all Part D Plan Web sites. Plans may provide this information via links off of their Part D Plan Web pages; however, the navigational icons used to access these links must clearly describe the information contained on each informational link. Links can consist of numerous pages as long as the navigational icons used within the linked pages clearly describe the information being accessed.

- Part D Plan's toll-free customer service number, TTY/TDD number, physical or Post Office Box address, and hours of operation.
- Part D Plan Description:
  - Service area
  - Benefits:

  - Applicable conditions and limitations
  - Premiums
  - Cost sharing (e.g., co-payments, coinsurance and deductibles), including a description of a how an individual may obtain additional information on the plan's tiered or co-payment level applicable to each drug.
  - Any conditions associated with receipt or use of benefits
  - 60-day notice regarding removal or change in the preferred or tiered cost-sharing status of a Part D drug. This information is to be maintained on the Web site until the next annual mailing of the updated formulary.
- Pharmacy Access Information
  - Pharmacy addresses and type of pharmacy (e.g., retail, mail-order, home infusion)
  - Number of pharmacies in network
  - How the Plan meets access requirements (e.g., <Plan Name> has contracts with pharmacies that equals or exceeds CMS requirements for pharmacy access in your area.)
- Out-of-Network coverage
- Current formulary information (updated monthly) based on guidance provided in Section 6 (Formularies Provided on Plan Web sites)
- Grievance, coverage determinations, appeals procedures, and exceptions process
- Quality assurance policies and procedures, including medication therapy management, and drug and/or utilization management
- Potential for contract termination
- Beneficiaries' and plan's rights and responsibilities upon disenrollment
- How to obtain an aggregate number of the Plan's grievances, appeals, and exceptions

Required Links (B)

The following information must be accessible via a link:

- Summary of Benefits
- Enrollment Instructions and Forms
- Evidence of Coverage
- Privacy Notice

Prohibited Links (B)

Part D Plans may not provide links to foreign drug sales on their Web sites.

Internet Must Use Chart (B)

The following Must Use/Must Not Use Chart applies only to URL guidelines and Part D Plan Web site content requirements. Please refer to the applicable sections for specific marketing requirements pertaining to advertising, pre-enrollment, and post-enrollment marketing materials.

Subject		Must Use	Must Not Use	Reason
	URL Guidelines	All Part D Plans must maintain a Web page, or, if they choose, a Web site dedicated to the Part D program. All marketing materials must include a Web address that connects to either a corporate Web site or to the Plan's Part D Web page.	.	Beneficiaries should be able to find a Part D Plan's program information with a minimum of difficulty.
	Web site Links	All links on a Part D Plan's Web site must be clearly labeled with navigational icons that indicate the information contained in the link. Any links to health-related or non-health related products/services must be clearly labeled as such.	Links to foreign drug sales	It should be clear to beneficiary how to navigate the Web site.
	Required Information	Part D Plans must include a date/stamp on each Web page to inform the beneficiary that the information might not be current.		
	Contact Information	The Web site must contain the Part D Plan's toll-free customer service number, TTY /TDD number, and either a physical address or Post Office Box address. Plans must also include hours of operation.		It is important to make available to beneficiaries different methods to contact the Part D Plan.
	Font Size	Part D Plans must use a minimum 12-point Times New Roman or equivalent font for all Internet content.		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 font requirement refers to how the Part D Plan codes the font for the Web page, not how it actually looks on the user's screen.

Subject		Must Use	Must Not Use	Reason
	Service Area	Regions served by the Part D Plan must be listed. If the Part D Plan is a national Plan, then it must be identified as such.		
	Benefits	• Applicable conditions and limitations • Premiums • Cost-sharing (e.g., co-payments, coinsurance and deductibles) • Any conditions associated with receipt or use of benefits	Non-health related products or services may not be presented as benefits	
	Pharmacy List	• Addresses for all non-chain pharmacies. For chain pharmacies, a local or toll-free number and a TTY/TDD number must be provided to find the nearest chain pharmacy location. • Number of pharmacies in network • How the Plan meets access requirements (e.g., "<Plan Name> has contracts with pharmacies that equal or exceed CMS requirements for pharmacy access in your area.") If Organizations use a search engine on their Web sites in lieu of posting the Pharmacy Directory, the search engine must include all of the requirements in Section 6 (Marketing Material Development).		
	Current Formulary	All Plans must include a current formulary, updated at least monthly. For formulary requirements, please refer to Section 6 (Marketing Material Development)		

Subject		Must Use	Must Not Use	Reason
	Out -of - Network Coverage	All Plans must include provisions for non-routine access to covered Part D drugs at out-of-network pharmacies, including limits and financial responsibility for access to these drugs.		
	Grievance, Exceptions, Coverage Determinations and Appeals Procedures	All Plans must include a description of their grievance, exceptions, coverage determinations, and appeals procedures on their Web site.		
	Quality Assurance Policies and Procedures	All Plans must include a description of their quality assurance policies and procedures, including medication therapy management, and drug and or utilization management.		
	Potential for Contract Termination	All Plans must include a notice of possible contract termination or reduction in service area and the effect these actions may have on its members.		
	Required Links	The following documents must be accessible by links: • Summary of Benefits • Enrollment Instructions and Forms • Evidence of Coverage • Privacy Notice		These materials are required for beneficiaries to be able to make an informed choice and to enroll in a particular program.

Subject		Must Use	Must Not Use	Reason
	If applicable: **Notice of Formulary Change**	Plans must provide 60-day notice on their Web site regarding removal or change in the preferred or tiered cost sharing status of a Part D drug. The notice must contain the following: • The name of the affected covered Part D drug; • Information on whether the covered Part D drug is being removed from the formulary, or changing its preferred or tiered cost-sharing status; • The reason why the covered Part D drug is being removed from the formulary, or changing its preferred or cost-sharing status; • Alternative drugs in the same therapeutic category, class or cost-sharing tier, and the expected cost-sharing for those drugs; and • The means by which enrollees may obtain an updated coverage determination or an exception to a coverage determination.		

Outreach to Dual Eligible Memberships (E)

A number of MA plan members are, due to financial status, eligible for State financial assistance through State Medicaid Programs. This assistance provides them an array of financial savings ranging from partial payment of Medicare Part B premiums to full payment of Medicare premiums and other plan cost sharing. Historically, some of those eligible do not apply for these State savings programs because:

1. The individuals equate Medicaid with Welfare and associate a social stigma to the terms;

2. They are not aware of the savings that are available;

3. They do not understand the eligibility requirements; or

4. They find the process sometimes complex and difficult to understand.

Some MA organizations choose to conduct outreach to their MA members to educate them and to assist them in applying for these savings programs. This may be especially true because CMS capitates MA organizations at a higher rate for some dual eligible members. The CMS encourages but does not require MA organizations to assist their members with applying for State financial assistance because of the potential benefits to both the members and to the MA organizations.

This section instructs MA organizations in outreach program requirements and the process for submitting those programs and member materials (e.g. letters, call scripts, etc.) to CMS for approval. It also provides CMS staff with operating procedures for reviewing and approving the outreach programs.

General Guidance on Dual Eligibility (E)

There are several categories of dual eligibility, each having specific income requirements and providing different levels of financial assistance to those who qualify at that level. The categories are outlined in the following chart:

Additional information is available at http://www.cms.hhs.gov/medicaid/. Income requirements for Hawaii and Alaska specifically noted. Resource and Income Limits shown below may vary by state; contact the state for specific resource amounts. The below chart reflects FY 2003 information. It will be revised with up to date information.

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
QMB only Qualified Medicare Beneficiary without other Medicaid	$769 – individual $1,030 – couple Alaska: $955 –individual $1,282 – couple Hawaii: $881 – individual $1,182 – couple	Medicare premiums, deductibles, and coinsurance. No Medicaid services.	Medicare	QMB rates for Medicare deductibles and coinsurance
QMB Plus Qualified Medicare Beneficiary with Full Medicaid	$769 – individual $1,030 – couple Alaska: $944 – individual $1,282 – couple Hawaii: $881 – individual $1,182 – couple	Medicare premiums, deductibles, and coinsurance. Medicaid services.	Medicare Medicaid	QMB rates for Medicare deductibles and coinsurance Medicaid rates for Medicaid services only.
SLMB only Specified Limited Income Medicare Beneficiary without other Medicaid	$918 – individual $1,232 – couple Alaska: $1,141 – individual $1,534 – couple Hawaii: $1,053 – individual $1,414 – couple	Medicare Part B premiums. No Medicaid services.	Medicare	No liability for Medicare deductibles and coinsurance.

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
SLMB Plus Specified Limited Income Medicare Beneficiary with Full Medicaid	$918 – individual $1,232 – couple Alaska: $1,141 – individual $1,534 – couple Hawaii: $1,053 – individual $1,414 – couple	Medicare Part B premiums. Medicaid services.	Medicare Medicaid	No liability for Medicare deductibles and coinsurance. Difference between Medicare payment and Medicaid rates for Medicaid services.
QI-1 Qualifying Individuals – 1	$1,031 – individual $1,384 – couple Alaska: $1,282 – individual $1,725 – couple Hawaii: $1,183 – individual $1,589 – couple	Medicare Part B premium.	Medicare	No liability for Medicare deductibles and coinsurance.
QDWI Qualified Disabled and Working Individuals	$3,078 – individual $4,125 – couple Alaska: $3,822 – individual $5,132 – couple Hawaii: $3,528 – individual $4,732 – couple	Medicare Part A premium.	Medicare	No liability for Medicare deductibles and coinsurance.

Guidelines for Outreach Program (E)

In order to assure CMS that MA organizations' outreach programs effectively assist members while protecting them from undue pressures or privacy violations, MA organizations must adhere to the following guidance.

The Medicare Advantage Organizations MUST:

1. Provide outreach to all levels of dual eligibles, including those levels that do not provide MA organizations with additional capitation amounts from CMS. All outreach materials, telephone scripts must include eligibility information that includes QI-1 and QI-2 levels.
2. Clarify in outreach materials that the member may voluntarily offer information, including financial information, but that the member is not obligated to provide this information.

3. Clarify in outreach materials and discussions with members that the member's failure to provide information will in no way adversely affect the beneficiary's membership in his or her health plan.

4. Clarify in outreach materials, to include member letters, that the Medicare Savings Programs are part of either the "State Medicaid program" or "state medical assistance programs.

5. State in materials and discussions with members that the MA organization will not share the information with any other entity not directly associated with determining eligibility or under contract to participate in the outreach process.

6. Clarify in outreach materials that the MA organization is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination.

7. Provide guidance to a member on how to proceed with the application process even if the MA organization's screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs.

8. Provide adequate training to staff conducting the outreach. If the MA organization subcontracts this effort to another entity, it must ensure that the subcontractor's staff is adequately trained to provide outreach.

9. Include alternate sources of information in outreach materials. Member letters and/or brochures that contain outreach information telephone numbers must also include the telephone number for the State Health Insurance Assistance Program (SHIP) and the appropriate State Agency. Outreach materials may also include the telephone number for the Medicare Service Center (1-800-MEDICARE).

10. Include privacy guidelines in outreach materials, telephone scripts, and internal processes and/or contracts with entities performing outreach for the MA organization. Contractual privacy guidelines must clearly state that all financial information collected from members of the MA organization will not be used for any other purpose by the entity collecting the data. Privacy guidelines must also state that entities involved in the outreach will not share member information with anyone not involved in the outreach process.

11. Ensure that contracts with entities taking part in some aspect of outreach activities meet MA Administrative Contracting requirements listed in the Medicare Managed Care Manual, Chapter 11, §100.5.

12. Work closely with CMS's regional office staff during the outreach submission and review process so that CMS can work cooperatively with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach process initiation.

The Medicare Advantage Organizations MAY:

1. Conduct outreach for only 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 organizations must provide outreach to all individuals within those pre-identified population segments. Additionally, if the organization receives an inquiry from a Plan member not previously identified in the targeted group, it must provide assistance to that member as if he or she had been included on the outreach list.

2. Provide hands-on assistance to the member in completing all necessary applications for financial assistance including submitting the paperwork to the appropriate State office. This assistance can be in the member's home only if the member requests such a visit.

3. Use the "Authorization to Represent" limited to the specific purposes of completing and submitting paperwork on behalf of the member, discussing the member's case with case workers, representing the member in cases of appeal, and gather information from and on behalf of the Plan member. The "Authorization to Represent" form must specify that the authorization is limited to securing benefits under "the Medicare savings program" or "the Medicaid Program" and cannot extend to other programs unless agreed upon and noted by the member. "Authorization to Represent" shall not give the outreach specialist the authority to sign any documents on behalf of the member nor make any enrollment decisions for the member.

4. Follow-up with members who do not respond to the initial member letter. This follow-up may be in the form of a second and/or third letter or telephone calls. If the member does not respond to the third effort, the MA organization refrain from contacting the member for at least six months following the last outreach attempt.

5. Provide assistance to members reapplying for financial benefits if and when required to do so by the state agency.

6. Subcontract all outreach efforts to another entity or entities. In such cases, while the MA organization retains all responsibility for meeting CMS's 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 MA organization must also coordinate changes and revisions between the subcontractor and CMS.

The Medicare Advantage Organization Shall NOT:

1. Conduct door-to-door solicitation or outreach prior to receiving an invitation from the member to provide assistance in his or her home.

2. Share any member information, financial or otherwise, with any entity not directly involved in the outreach process.

3. Store or use member financial information for any purpose other than the initial screening eligibility, the submission and follow-up of an application for benefits, for recertification purposes, and as required by law.

4. 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.

5. Imply in any written materials or other contact with the member that the organization has the authority to determine the member's eligibility for state assistance programs.

Submission Requirements (E)

To facilitate CMS's review of outreach programs, an MA organization must submit one copy of the materials listed below to its Central Office Plan Manager, one copy to the Regional Office Plan Manager, one electronic copy to the Dual Eligibility Outreach Product Consistency Team (PCT), and the Regional Office Plan Manager.

1. Detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow chart showing the result of each action.)

2. Timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area (e.g., county) included in the activities. This is to allow CMS to more accurately coordinate outreach activities with its partners (e.g., SHIP, State Agencies).

3. Executed contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.

4. Supporting documentation from the appropriate State Agency providing specific state income requirements for each savings program level, and names and contacts within the appropriate State Agency/agencies.

5. Outreach letters and other materials (e.g., brochures, Authorization to Represent form) going to plan members.

6. Internal training programs the organization is using to educate staff involved in outreach.

7. Telephone scripts or other outreach assistance scripts that will guide representatives in answering members' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the member is not required to provide any information to the representative and that the information provided will in no way affect the beneficiary's membership in the plan.

8. Internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.

In some instances, an MA organization may chose to submit an outreach proposal that CMS has already approved for use by another MA organization. This is common when an MA organization is part of a national organization with multiple contracts, each of which is conducting its own outreach. This is also common when a subcontracting entity designs and conducts the outreach. These subcontractors often seek to contract with multiple MA organizations and conduct the same outreach programs for each of their clients.

If an MA organization submits an outreach proposal (a) That CMS previously approved on or after April 1, 2002; (b) That CMS approved within the twelve months prior to the submission; and (c) That does not contain substantive changes to qualify it as an "initial" proposal, the MA organization must submit the items listed above (1 - 8) in addition to the following:

> An attestation from either the MA organization or its contracted outreach vendor stating (a) That the proposal has been approved by CMS, (b) The date of that approval, and (c) That the new submission does not contain substantive changes to the approved program.

CMS Review/Approval of Outreach Process (E)

NOTE: *The CMS review process for new outreach proposals differs from the review process for previously approved outreach proposals. The processes for both submissions are stated below.*

Reviewing New Outreach Programs (E)

1. The MA organization is responsible for submitting the outreach proposal to CMS and working with CMS through the review and approval process even if a subcontractor developed the proposal. CMS will hold the MA organization fully responsible for all the provisions of the outreach program and for assuring the members of their rights and protections outlined in the MA program regulations.

2. In that CMS considers outreach materials to be a form of marketing, CMS will review outreach proposals according to current time frames for reviewing marketing material. The agency will conduct its initial review and provide comments to the MA organization within 45 days of receipt of a new (not previously approved) proposal.

3. MA organizations must submit one complete copy of the materials to the CMS Central Office Plan Manager, a second copy of the same materials to the CMS Regional Office Plan Manager, and an electronic copy of the materials to the Dual Eligibility Outreach PCT. If a proposal incorporates states in regions other than those represented above, the PCT ensures that the appropriate Regional Office Plan Manager receives a copy of the proposal for comment from the National Account Representative (NAR) for the state(s).

   The Dual Eligibility Outreach PCT will review all the enclosed documentation in conjunction with the Plan Managers and will provide comments to the Central and Regional Office Plan Managers. The Regional Office Plan Manager will relay CMS comments back to the MA organization will gather revisions (when necessary) and will finish the review and approval process based upon the MA organization's revisions.

4. The Regional Office Plan Manager will share outreach materials with the appropriate NARS and state representatives. The NARS and state representatives should, at a minimum, share the member letters with the State agency as a way to verify the accuracy of the information contained in the proposal and to receive input from state partners.

5. Upon final approval of the proposal and outreach materials, the Regional Office Plan Manager will send an approval letter to the MA organization.

6. The Regional Office will then contact its partners (SHIPs, State Medicaid Offices, etc.) to notify them of the outreach effort and possible increase in beneficiary inquiries. The

Regional office will share copies of outreach letters with the State Agencies to prepare them for incoming questions.

Reviewing Previously Approved Outreach Programs (E)

If an MA organization submits an outreach proposal that CMS has already approved and that does not contain substantive changes, then the CMS Regional Plan Manager, in conjunction with the appropriate NARs, will only review the targeted membership information (audience number and outreach dates), the contract(s) between the MA organization and its outreach subcontractor(s), the updates to benefit levels and income and resource criteria, and the attestation. CMS will respond to the MA organization within the 10-day time frame CMS has established for reviewing standardized marketing materials. CMS's Regional office will file the outreach proposal for future reference. CMS recognizes that the MA organization will have to make simple periodic changes to their outreach programs in order to update minimum income levels, etc. As stated previously CMS does not consider these updates to be "substantive changes" in that they do not prompt a full review of an outreach proposal. However, the MA organization is still responsible for submitting such changes to the appropriate CMS regional office for marketing review to ensure accuracy of such changes.

If the MA organization wishes to make substantive changes to the outreach process, it must submit those changes to the appropriate CMS Central Office and Regional Office Plan Managers for review through the PCT according to the review process above.

7. REQUIRED MARKETING MATERIALS

Materials Required for Program Start-up (A)

Organizations may use 2006 marketing materials beginning October 1, 2005. At a minimum, the following materials (if applicable) must be reviewed and approved and/or appropriately submitted to CMS under File & Use Certification, in accordance with the Marketing Guidelines by the following dates:

- Pre-Enrollment Web site content – Prior to October 1, 2005
- Summary of Benefits – Prior to October 1, 2005
- Pharmacy Directory – Prior to October 1, 2005
- Comprehensive Formulary – Prior to October 1, 2005
- Member Identification Card – Prior to November 1, 2005
- Evidence of Coverage (EOC) – Prior to November 1, 2005
- Initial Enrollment Form (see Enrollment Disenrollment Guidance)
- Initial Enrollment Letters (see Enrollment Disenrollment Guidance)

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 & Use Certification in accordance with the Marketing Guidelines prior to their use.

Required Pre-Enrollment Materials (A)

Required pre-enrollment materials provide additional details on the Organization (e.g., rules, benefits, etc.) compared to what is provided in advertising materials. Generally, prospective enrollees use the pre-enrollment package to assist them in making an informed decision among the available choices for health and Part D coverage.

Pre-enrollment materials must include the following:

- A cover letter that includes the Plan's toll-free customer service telephone number, a TTY/TDD telephone number, Web site URL, customer service hours of operation, and physical or post office address.
- The letter must also indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227) and TTY/TDD users should call 1-887-486-2048 for more information about Medicare benefits and services including general information regarding the health or Part D benefit.
- Enrollment instructions and forms.
- Summary of Benefits – Refer to Section 6 (Marketing Material Development) for additional guidance.

- Written explanation of the Plan's exceptions and grievance and appeals processes, including differences between the three and when it is appropriate to use each
- Written notice that the Plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Plan. In addition, the Plan may reduce its service area and no longer offer services in the area where the beneficiary resides.

Additionally, Plans have the option of including the following materials in pre-enrollment distribution or making them available to any Part D eligible individuals upon request:

- **Pharmacy Directory** – Refer to Section 6 (Marketing Material Development – Specific Guidance for Post Enrollment Materials) for content guidance.
- **Provider Directory**- Refer to Section 6 (Marketing Material Development – Specific Guidance for Post Enrollment Materials) for content guidance.
- **Formulary** – Refer to Section 6 (Marketing Material Development Guidelines – Specific Guidance Post-Enrollment Materials) for content guidance.

Required Post-Enrollment Materials (A)

Post-enrollment materials are those materials used by Organizations to convey benefit or Plan operational information to enrolled beneficiaries. Post-enrollment marketing materials include all notification forms and letters and sections of newsletters that are used to enroll, disenroll, and communicate with enrollees regarding membership issues.

The following materials must be distributed to a beneficiary at the time of enrollment:

- Evidence of Coverage (EOC) – Refer to Section 6 (Marketing Material Development) for additional information.
- Summary of Benefits (SB) – Refer to Section 6 (Marketing Material Development) for additional information.
- Formulary (Part D Plans only)– Refer to Section 6 (Marketing Material Development) for additional information.
- Pharmacy Directory (Part D Plans only) – Refer to Section 6 (Marketing Material Development) for additional information.
- Membership Identification Card

The following must be distributed to all enrollees annually:

- Annual Notice of Change (ANOC) – Refer to Section 6 (Marketing Material Development) for additional information.
- Summary of Benefits (SB) – Refer to Section 6 (Marketing Material Development) for additional information.
- Evidence of Coverage (EOC) – Refer to Section 6 (Marketing Material Development) for additional information.
- Abridged formulary including information on how the beneficiary can obtain a complete formulary – Refer to Section 6 (Marketing Material Development) for more information.

Furthermore, Part D Plans must provide their enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an Explanation of Benefits (EOB) which includes:

- Items or services for which payment was made;
- Notice of the enrollee's right to request an itemized statement;
- Year-to-date statement of total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds;
- Cumulative year-to-date total of incurred costs; and
- Applicable formulary.

NOTE: *A Model EOB will be forthcoming.*

Plans have the option of developing and distributing other post-enrollment materials as needed to ensure proper communication with members.

Availability of Alternative Formats (A)

To ensure that beneficiaries have access to beneficiary education materials in alternative formats (e.g., Braille, foreign languages, audio tapes, large print), Organizations must provide a disclosure on pre-enrollment and post-enrollment materials indicating the document is available in alternative formats. Organizations should make marketing materials available in any language that is the primary language of more than 10 percent of the geographic area. In addition, basic enrollee information should be made available to the visually impaired.

In general, for marketing with materials that contain non-English or Braille information (in whole or in part), the organization must submit the non-English or Braille version of the marketing piece, an English translation of the piece, and a letter of attestation. However, in an effort to reduce the burden on the organization and CMS, the organization may choose to

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.

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.)

All Organizations will be subject to verification monitoring review and associated 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 to be inaccurate or do not convey the same information as the English version, organizations may not continue to distribute materials until revised materials have been approved. If multi-region organizations have submitted materials in English to their lead RO and the materials have been approved, the same materials in other languages or Braille may be used in other regions.

The following applies to Organizations for File & Use (Certification and Eligibility) of non-English materials:

- When an Organization is on File & Use (Certification and/or Eligibility) it is on File & Use for both English and non-English materials. Therefore, continual violations in non-English materials could be grounds for placing an organization on probation.
- When an Organization is on File & Use (Certification and/or Eligibility) probation, the probation is for both English and non-English materials. If File & Use (Certification and/or Eligibility) status is revoked, it is revoked for both English and non-English materials.
- If an Organization is on File & Use (Certification and/or Eligibility), it must submit English and non-English versions of materials 5 calendar days prior to their use.

8. MATERIALS NOT SUBJECT TO REVIEW (A)

The following items are not reviewed by CMS or its Designee:

- Privacy notices
- Press releases
- Newsletters (unless sections are used to enroll, disenroll, and communicate with members on membership operational policies, rules, and/or procedures)
- Blank letterhead
- General health promotion materials that do not contain marketing materials
- Non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of the Medicare Prescription Drug Benefit (e.g., notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, invoices, etc.)
- Customer service correspondence that addresses issues that are unique to individual members
- CMS guidance regarding "Educating Beneficiaries about the 2006 Medicare Advantage Program and Prescription Drug Coverage" can be found at: http://www.cms.hhs.gov/healthplans/letters/beneeducpdp63005.pdf

9. MARKETING REVIEW PROCESS

Except where otherwise noted, all marketing materials must be reviewed prior to use by Organizations**.** The process by which CMS or its Designee will review marketing materials is explained in this section.

Material Submission Process (A)

All marketing materials must be submitted to CMS accordingly:

- MA organizations' marketing material will be submitted through the Health Plan Management System (HPMS) Marketing Module, mail, fax or e-mail to the Regional Office.
- PDP marketing materials will be submitted through the HPMS PDP marketing module.

The HPMS Marketing Module is an automated tool that an organization uses to enter, track, and maintain marketing materials submitted to CMS for review. HPMS has the capability to accept electronic copies of the actual marketing materials. The marketing review time period begins the date on which the initial marketing materials are entered into HPMS. The Marketing Module User's Guide provides extensive information on HPMS and is located at http://gateway.cms.hhs.gov.

Material Disposition Definitions (A)

For all marketing materials reviewed, the following dispositions shall be rendered:

Approval (A)

CMS or its Designee has determined that the material submission is compliant with the Marketing Guidelines. The material submission is approved for use in its current format and may be distributed by an organization.

Marketing materials, once approved, remain approved until either the material is altered by the organization or conditions change such that the material is no longer accurate. CMS may, at any time, require an organization to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time of approval.

NOTE: *Prior to an organization executing a contract with CMS, marketing material dispositions will be considered "conditionally" approved.*

Disapproval (A)

The CMS Regional Offices or the CMS Designee determines that the material submission is not compliant with the Marketing Guidelines and applicable regulations or law.

CMS or the CMS Designee shall provide a specific reason for disapproval and provide an explanation for the disapproval in the form of an e-mail to the Part D Plan's designated contact person. Whenever possible, the CMS Regional Office or the CMS Designee will provide specific citations to the requirement with which the material was found to be non-compliant.

Deemed (A)

If CMS or its Designee does not approve or disapprove marketing materials within the specified review periods, the following will apply:

- Materials subject to a 45-day review period will be given the status of "Deemed" approved on the 46th day.
- Materials subject to a 10-day review period will be given a status of "Deemed" approved on the 11th day.
- Organizations that do not have a final contract will receive a conditional deemed approval. After the contract is awarded the materials disposition will be changed to "deemed approved" and can then be used.

Withdrawn (A)

An organization can choose to withdraw a marketing submission prior to CMS or its Designee acting upon that marketing submission (i.e., beginning its review). CMS has no regulatory authority to withdraw a marketing submission.

Time Frames for Marketing Review (A)

(Original Submissions other than File & Use Certification)

Generally, Organizations may not distribute any marketing materials or enrollment forms, or make them available to eligible beneficiaries unless such materials have been submitted to CMS for review at least 45 days prior to distribution and CMS has not disapproved the materials. This applies to materials submitted where: (1) no standardized or model language is available or (2) available model language is not being used without modification. An Organization may distribute materials before 45 days have elapsed if prior approval has been granted by CMS.

NOTE for 1876 Cost Plans: *While not required to do so by law, CMS will make every effort to review materials prepared by cost plans within 10 days if they have followed CMS' plan model language without modification. However, while CMS will try to review the cost plan marketing materials within 10 days, the cost plan must not consider the material deemed approved if 10 days pass and it has not received approval or disapproval from the CMS since, by law, 45 days must pass before the material may be deemed approved.*

45-day Review Exception (A)

When an Organization follows CMS model language without modification, CMS or its Designee must review the material within 10 days (as opposed to the usual 45 days). CMS must make a determination on the material within 10 days or else the marketing material is deemed approved on the 11th day.

To alert the CMS reviewer to the need for a 10-day review, the Organization must indicate on the submission that it has followed the CMS model without modification and is requesting a 10-day review.

The 10-day review period only applies when the Organization has followed the CMS model without modification. "Without modification" means the Organization used CMS model language verbatim and only used its own language in areas where CMS allowed the use of the Organization's own information (such as where it is asked to include its Plan-specific benefits). It also means that the Organization has followed the sequence of information provided in the model in its own marketing material. In these cases, CMS or its Designee need only to review the Organization's language in order to make a determination on the marketing material within the 10-day review period.

NOTE: *An Organization's Evidence of Coverage (EOC) cannot be approved until the bid is approved. If an Organization submits an EOC that follows the CMS model without modification for review early in the year (prior to Bid approval), CMS will review and approve all non-Bid related information within the 10-day review period and will conduct a targeted review of all Bid-related information based on the Organization's Bid submission. However, CMS will need to disapprove the release of Bid-related marketing material within the 10-day review period and will indicate that the material will be approved upon approval of the Bid.*

Resubmissions (A)

Resubmissions are edited versions of previously submitted marketing materials that are still pending (i.e., materials that have not been reviewed).

Revisions (A)

Revisions are corrected versions of previously disapproved marketing materials. All revised materials are subject to the 45-day review process.

File & Use Overview (A)

The guidelines in this section provide that all Organizations, beginning with 2006 marketing materials, can certify that they followed all applicable Marketing Guidelines or use certain CMS models without modification when a model is available as specified by CMS. Organizations are strongly encouraged to use File & Use Certification for all marketing materials qualified under this process. In addition, Organizations that demonstrates to CMS that they continually meet a particular standard of performance, can submit certain marketing materials for File & Use process without a certification. We refer to these two "file and use" processes as "File & Use Certification" and "File & Use Eligibility," respectively.

Marketing Material Review Options (A)

	File & Use Certification	File & Use Eligibility	Standard 45/10 Day Review Process
Eligibility	Open to All Organizations	Open only to qualifying Organizations	Open to All Organizations
Procedures	All PDPs can use this process immediately unless a waiver is requested. All MA, MA-PDs, 1876 Cost Plans must submit one-time Certification Form during either application or yearly renewal process.	Contracting entity must have been in program for at least 18 months. Initial review of the previous 6 months worth of materials must be at least 90% acceptable. (For MAs, MA-PDs and 1876 Cost Plans). Contracting entity must have submitted at least eighteen months of reviewable marketing materials (For PDPs only). Must obtain eligibility status from CMS.	Required for certain materials (such as the SB and EOC), even if the organization uses one of the File & Use processes for other materials.
Qualifying Materials	Certain marketing materials.	Certain marketing materials.	All marketing materials.
Material Submission	All PDPs and Plans submitting through HPMS must certify each marketing material at time of submission.	Submit File & Use Eligibility marketing materials to CMS at least 5 calendar days prior to use.	Submit marketing materials to CMS at least 45 calendar days prior to use (10 calendar days if following model material

	Submit File & Use Certification marketing materials to CMS at least 5 calendar days prior to use.		without modification) CMS reviews materials and provides approval or disapproval within 45/10 days, or else materials are deemed approved.
Loss of Qualification	CMS conducts a semi-annual retrospective review of materials. CMS can place organization on marketing probation (corrective action).	CMS conducts a semi-annual retrospective review of materials. CMS can place organization on marketing probation (corrective action). Organization will either retain or lose File & Use privileges at the end of probationary period.	Not Applicable

File & Use Certification (A)

Pursuant to implementing the Medicare Modernization Act of 2003 (MMA), the guidelines in this section provide that all Organizations can use the File & Use Certification process for selected marketing materials as defined by CMS. Organizations using the File & Use Certification process must submit File & Use Certification marketing materials to CMS five calendar days prior to distribution and certify that the materials comply with the Marketing Guidelines. Model language without modification must be used by Organizations if model language is available. Organizations are required to submit at least 90% of materials that qualify for File & Use Certification under this process.

Materials Qualified for the File & Use Certification (A)

The materials that are qualified for the File & Use Certification process are (1) advertising materials, (2) provider and/or pharmacy directories, (3) formularies, and (4) certain CMS model letters utilized without modifications (i.e., enrollment/disenrollment, claims, organization determinations, appeals/grievance, and exceptions process model letters). Materials that qualify under the File & Use Certification process can be distributed five calendar days after submission to CMS, but no earlier than any date established by CMS for use of specific document/materials. For example, in 2005 if an Organization submits File & Use marketing materials for CY2006 in August 2005, it may not distribute the materials until October 1, 2005.

Materials Not Qualified for File & Use Certification (A)

Materials that are not qualified for File & Use Certification are those that pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These documents are the Summary of Benefits, Evidence of Coverage, Member Handbook, Member ID card, Mid-year Benefit Enhancement Notice, Annual Notice of Change, the Individual Enrollment Form, the Abbreviated Enrollment Form, the Disenrollment Form, and any other documents not expressly identified by CMS as qualified for the File & Use processes. Materials which are not qualified for the File & Use Certification process will remain under the 45/10-day review process or may be qualified for the File & Use Eligibility process.

Retrospective Monitoring Reviews (A)

Once an Organization is in the File & Use Certification process, CMS will monitor compliance on a retrospective basis. CMS will select a random sample of qualified materials that the Organization submitted to CMS for review under the File & Use Certification process and conduct a retrospective review of the materials. CMS will conduct this review semi-annually for materials submitted for the previous six months. In addition, CMS will investigate any marketing complaints that are received to verify if they are valid or invalid marketing violations.

CMS may order the Organization to prepare an addendum or reissue any marketing materials at no expense to the Government if the Organization is found not to conform to the marketing section of the Organization's contract. Failing to conform to File & Use Certification requirements may result in corrective action against the Organization to protect the interest of Medicare enrollees. Organizations submitting marketing materials under the File & Use Certification process through HPMS will be reminded, on an ongoing basis, of their responsibility to adhere to the Marketing Guidelines and submit an electronic attestation at the time of material submission.

Loss of File & Use Certification Privileges (A)

An Organization may lose File & Use Certification status if it:

- Uses materials that do not meet marketing guideline requirements,
- Fails to file two or more materials at least five calendar days prior to distribution or publication

NOTE: *CMS expects plans that choose to use file & use certification to do so for eligible materials. If we determine that a sponsor sends a significant portion (10% or more) of these materials through the normal, 45-day review process, we will more closely scrutinize that sponsor's material, because we will interpret the sponsor's actions as demonstrating a low level of confidence in its ability to comply with our guidelines. If this targeted review identifies materials that do not meet our marketing guidelines, the sponsor may lose file & use certification status.*

If CMS revokes an Organization's File & Use Certification privileges, the Organization may be reinstated under File & Use Certification after at least six months have passed since its privileges were taken away. If an Organization loses its File & Use Certification privileges twice, it may not be reinstated under File & Use Certification until at least one year has passed since the date the privileges were taken away the second time.

Certification Procedures (PDP Only) (C)

Unless the PDP requests a waiver from the File & Use Certification process, all PDPs must submit File & Use Certification marketing materials to CMS five calendar days prior to distribution and certify that the materials comply with the Marketing Guidelines. It is important to note that CMS will verify that the marketing materials submitted by the Organization qualify for the File & Use Certification process.

The PDP may submit File & Use Certification materials prior to executing a contract with CMS. The CMS contract will contain a provision by which the PDP will certify that the material submitted prior to the execution of the contract, as well as all File & Use Certification materials submitted subsequent to the execution, are accurate, truthful, not misleading, and consistent with CMS Marketing Guidelines. Thus, by executing the CMS contract, the appropriate officer of the PDP is attesting to his/her PDP's compliance with the File & Use Certification requirements.

As each marketing material is submitted, the PDP must attest to the completeness and accuracy of the material through an electronic attestation. The electronic attestation does not have to be completed by the same person who signed the original contract.

Certification Procedures (MA, MA-PD, and 1876 Cost Plans) (D, E)

Each organization should submit the File & Use Certification marketing materials to CMS at least 5 calendar days prior to distribution and certify by the Organization's CEO/CFO or designee that the materials are in compliance with CMS Marketing Guidelines. As each item of marketing material is submitted, each organization is responsible for ensuring the accuracy and completeness of its marketing materials

and adhering to CMS Marketing Guidelines. All certification forms must be sent to CMS (See Model File & Use Certification form). The requirement for submission of a signed certification form is one time only and is effective until further notice. A completed and signed Certification form must be received from the Organization before it may submit File & Use Certification materials.

The Organization should mail the signed Certification to CMS Central Office: CMS, 7500 Security Blvd. Attn: Anne Avery, Mail Stop C4-23-07, Baltimore, MD 21244 and send a copy to appropriate Regional Office (RO).

It is important to note that CMS will verify that the marketing materials submitted under the File & Use Certification process meet the following administrative requirements: 1) CMS has received a signed Certification form from the Organization's CEO/CFO or designee; 2) materials submitted qualify for the File & Use Certification process; 3) a completed transmittal form is attached to the materials (unless it is electronically submitted through HPMS); and 4) all materials include the Medicare Health Plan contract number (i.e., H####, R####) as a prefix to the marketing materials identification number.

Organizations remain legally responsible for compliance with the marketing requirements. See 42 CFR §422.80 and §422.111 for MA plans, and 42 CFR §417.427 and §417.428 for cost based plans. These new requirements do not modify the organizations' legal responsibility in any way. The File & Use Certification form (see CMS model) states that the organization agrees that all advertising materials and model documents that are used are accurate, truthful and not misleading.

Model File & Use Certification Form (MA, MA-PD, and 1876 Cost Plan) (D, E)

Pursuant to the contracts(s) between the Centers for Medicare & Medicaid Services (CMS) and (insert organization name), hereafter referred to as the Medicare Health Plan, governing the operations of the following health plan: (insert health plan name and Contract number), the Medicare Health Plan hereby certifies that all qualified materials for the above-listed health plan is accurate, truthful and not misleading. Organizations using File & Use Certification agree to retract and revise any materials (without cost to the government) that are determined by CMS to be misleading or inaccurate or that do not follow established Marketing Guidelines. In addition, organizations may be held accountable for any beneficiary financial loss as a result of mistakes in marketing materials or for misleading information that results in uninformed decision by a beneficiary to elect the plan. Compliance criteria include, without limitation, the requirements in 42 CFR §422.80 and §422.111 for MA plans, and 42 CFR §417.472 and §417.428 for cost-based plans and the Medicare Marketing Guidelines.

I agree that CMS may inspect any and all information including those held at the premises of the Medicare Health Plan to ensure compliance with these requirements.

I further agree to notify CMS immediately if I become aware of any circumstances that indicate noncompliance with the requirements described above.

I possess the requisite authority to make this certification on behalf of the MA organization.

SIGNATURE

NAME & TITLE [CEO, CFO, or designee]

On behalf of

Name of Medicare Health Plan

Date

This certification form must be signed and received by the CMS Central Office prior to submitting materials under the File & Use Certification Process. Once the File & Use Certification form is received, it is effective until further notice from CMS.

File & Use Eligibility (A)

The File & Use Eligibility program is designed to streamline the marketing review process for all Organizations. Under this process, individual contracting entities that can demonstrate to CMS that they continually meet a particular standard of performance will be able to publish and distribute certain marketing materials without prior CMS approval. Typically, File & Use Eligible materials are classified under categories that are different from materials submitted under File & Use Certification.

The File & Use Eligible status can be used by qualifying Organizations 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: *Individual Contracting entities 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)

A contracting entity may qualify for File & Use Eligibility after being in the Medicare Program for a specified timeframe and meeting the marketing material requirements as defined by CMS. The "eligibility" status permits a contracting entity 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, or October 1). Contracting entities that use the File & Use Eligibility process are agreeing to retract and revise any materials that are later determined by CMS to be misleading or inaccurate, or that do not follow the Marketing Guidelines.

To qualify for File & Use Eligibility status:

- Contracting entity must have submitted at least eighteen months of reviewable marketing materials (For PDPs only).
- Ninety percent of the materials submitted with the past six months are found to be acceptable.
- Within 10 calendar days of the next calendar quarter, Organizations must submit a written request to CMS requesting that it be considered for File & Use Eligibility status. CMS will notify the contracting entity of the region's decision in writing seven days prior the next calendar quarter.
- If the MA or MA-PD (For MA and MA-PDs only) disagrees with the Regional Office's decision, it can notify the National File & Use Eligibility Coordinator of its disagreement. The National File & Use Coordinator and the Marketing Product Consistency Team (PCT) will review the decision made by the Regional Office and notify the organization in writing if the decision is upheld or overturned.
- For a contracting entity to be considered under File & Use Eligibility, CMS will select a random sample of the contracting entity's materials that were submitted for a 45-day (10 days if model material is used without modification) 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.

Defining "Acceptable" Materials (A)

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

- Is not materially inaccurate or misleading
- Does not make a material misrepresentation
- Follows the Marketing Guidelines

How to Maintain File & Use Eligibility Status (A)

CMS will conduct semi-annual evaluations based on a random sample of materials filed by contracting entities 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 (A)

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. Individual contracting entities can maintain this status, even if other entities in the parent company do not.

Some contracting entities 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 contracting entity 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 contracting entities must specify the expected date of initial distribution or publication when filing materials with CMS.

Contracting entities that have File & Use Eligibility privileges may still submit marketing materials using the standard marketing review process. However, pieces submitted through this process will be subject to the standard 45-day review unless CMS model language is used without modification which is subject to a 10-day

review. Approvals and Disapprovals for these pieces will not count towards determining contracting entity's File & Use Eligibility status.

If the contracting entity 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 semi-annual review.

The MA or MA-PD (For MA and MA-PD only) must clearly indicate on the front cover of the marketing transmittal sheet that the material is to be filed as a "File & Use Eligibility" material.

The CMS Regional Office (For MA and MAPD only) that is the lead for that multi-region company maintains File & Use Eligibility status for a multi-region company. If File & Use Eligibility status is granted to a multi-region company, it means that the lead Regional Office (i.e., the "multi-region team lead") has granted File & Use Eligibility privileges to all national materials developed by the multi-region company. The local Regional Office must still review local materials, unless the local contracting entity has been granted File & Use Eligibility status by the local Regional Office.

Loss of File & Use Eligibility Status (A)

A contracting entity 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 or its Designee will notify the contracting entity in writing if it is in danger of losing File & Use Eligibility status. This notice will indicate that the contracting entity 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.

NOTE: *PDPs will be notified by the CMS Designee, while MA and MA-PD should contact the appropriate CMS Regional Offices for information.*

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 contracting entity 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.

***NOTE**: PDPs will be notified by the CMS Designee, while MA and MA-PD should contact the appropriate CMS Regional Offices for information.*

The termination of File & Use Eligibility status does not mean that an organization may never again obtain File & Use Eligibility status. If CMS terminates a contracting entity's File & Use Eligibility status, the organization may request to get back on File & Use Eligibility once two calendar quarters have passed since its status was terminated. If an organization 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 (A)

MA and MA-PD: Submission of Marketing Materials to Regional Offices (D, E)

CMS Regional Offices *will* accept marketing material submissions by *the Health Plan Management System (HPMS) Marketing Module,* mail, fax *and* e-mail.

When sending materials by e-mail, if the material is over 5 pages long organizations must also mail the material to the Regional Office. The 5-page requirement refers to the length of the marketing *material and does not* include *the marketing material* transmittal Sheet that *should accompany* the marketing material. The mailing requirement also applies to materials that are of large size, such as draft posters or full-page ads. These materials should be sent *via* overnight or priority mail.

***NOTE**: Some Regional Offices may be equipped to accept e-mail submissions of greater than 5-pages in length without requiring that a hard copy submission also be mailed. Your Regional Office will notify you if this is the case.*

All Regions will accept e-mail submissions in Microsoft® Word or portable document format (PDF) format. If you have a document in a different format, you should contact the Region to determine whether it can accept that format by e-mail.

When faxing materials to the Regional Office, please call your Regional Office Managed Care Specialist/Plan Manager prior to sending the fax. Under normal circumstances a submission of over 5 pages long should not be faxed to the Regional Office. However, if you need to fax a long piece of marketing material to the Region,

you should notify the Regional Office Managed Care Specialist/Plan Manager to let them know that the material is over 5 pages long, prior to sending the fax.

Materials shall be submitted through the appropriate module of the HPMS, except as noted. Medicare Advantage plans may submit through the HPMS Marketing Module, mail, fax and e-mail. MA-PDs shall submit materials through the MA-PD marketing module, while PDPs shall utilize the PDP marketing module. All Organizations are required to apply for and maintain access to the HPMS. Detailed information describing the functionality of the HPMS marketing module is available in the HPMS user guide.

Health Plans may use the HPMS to enter all pertinent information related to a material submission and attach the material in electronic format to this entry. The following are acceptable electronic formats for submitting these materials:

- Portable Document Format (.PDF)
- Microsoft Word (.DOC)
- Joint Photographic Experts Group (.JPG)
- Microsoft Excel (.XLS)
- DOS Text (.TXT)
- Graphics Interchange Format (.GIF)
- WordPerfect (.WPD)

Other formats may be acceptable by agreement with CMS.

If you send in marketing material in multiple formats (e.g., mail and e-mail), you should indicate on the marketing material that it is being submitted in multiple formats.

PDP Submission of Marketing Materials to CMS Designee (C)

PDPs must use the HPMS to enter all pertinent information related to a material submission and attach the material in electronic format to this entry. The following are acceptable electronic formats for submitting these materials:

- Portable Document Format (.PDF)
- Microsoft Word (.DOC)
- Joint Photographic Experts Group (.JPG)
- Microsoft Excel (.XLS)
- DOS Text (.TXT)
- Graphics Interchange Format (.GIF)
- WordPerfect (.WPD)

Other formats may be acceptable by agreement with CMS or its Designee as appropriate.

Under extraordinary circumstances, marketing materials may be submitted directly to the CMS Designee. For example, if inclement weather causes a PDP to temporarily lose access to its computer systems and thereby lose access to the HPMS, then the PDP may submit materials directly to the CMS Designee by mail, express mail, or some other method.

Submissions Outside of HPMS

The following exceptions to the use of HPMS to submit materials apply as noted:

MA and MA-PD Mailing Requirements and Fax Option (D, E)

If an MA or MA-PD submits a material over five pages long, then the MA-PD must also mail the material to the Regional Office reviewing the material. Mailed submissions must also include the Marketing Material Transmittal Sheet. The five-page requirement refers only to the length of the marketing material itself and does not include the transmittal sheet. The mailing requirement also applies to materials that are of large size, such as draft posters or full-page ads. Materials submitted according to this exception must be sent by overnight or priority mail.

NOTE: *Some Regional Offices may be equipped to accept HPMS submissions of greater than five pages in length without requiring that a hard copy submission also be mailed. Your Regional Office will notify you if this is the case.*

Under special circumstances, MA and MA-PD submissions may be faxed. When faxing materials to the Regional Office, please call your Regional Office Plan Manager prior to sending the fax.

PDP Submissions Outside HPMS (C)

If, due to a unique situation, a PDP cannot submit materials through the 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

E-mail address: PDP.MARKETING.DOCUMENTS@CMS.HHS.GOV

Marketing Material Identification System (A)

PDP (C)

Each approved PDP is assigned a contract number to allow CMS or its Designee to track the PDP's marketing material within the marketplace. CMS requires a specific format for this identifier to allow immediate recognition of the document and/or advertisement as an approved PDP marketing material. The Material ID can be any series of alphanumeric characters but must begin with the PDP's contract number, also known as the "S" number, plus a hyphen, for example "S1234-" followed by numbers or letters chosen at the discretion of the PDP. This system allows each material to be identified by the specific PDP, while also allowing the Plan freedom to develop its own filing system for its materials.

MA and MA-PD (D, E)

Health plans/MA organizations must use the system mandated by the reviewing RO for identifying marketing materials submitted to CMS. If the reviewing RO does not have a system, health plans/MA organizations may use their own system for identifying marketing materials.

All Organizations (A)

For all Organizations, the Material ID and CMS approval date must be placed on every marketing material with the exception of the membership identification card, television and radio ads, outdoor advertisements, and banner or banner-like ads. The Material ID should be positioned in the lower left- or lower right-hand corner of the material adjacent to the CMS approval date. The approval date is the date on the CMS approval notice.

Marketing Review Process for Multi-Region Organizations (D, E)

For Organizations that operate in more than one of the CMS MA or PDP Regions, the marketing review approach (e.g., lead region, local regions, etc.) is determined by the agreement the organization makes with CMS Multi-Region Team management.

In addition, the Multi-Region organization must distribute final copies of its national marketing materials, within a timeframe to be determined by its CMS Multi-Region Team, to the lead and local ROs with a dated cover letter that identifies the recipients.

PDPs operating in more than one CMS PDP region must submit all of their marketing materials to the CMS Designee.

NOTE: *Although the local ROs may no longer play a part in approval of the national marketing piece, the MA or MA-PD organization must send a final copy of the approved material to the local ROs for their records.*

Joint Enterprise for PDPs and Regional Preferred Provider Organizations (RPPOs)

Organizations that are licensed by a State as a risk-bearing entity can jointly enter into a single contract with CMS to offer a Regional Preferred Provider Organization (RPPO) 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 RPPO 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 or qualifies for a waiver under 423.410 or 422.372 of the Code of Federal Regulations.

All marketing materials must be submitted under the Joint Enterprise's contract number and must follow the appropriate Marketing Guidelines.

Multi-Contract Groups for PDPs (C)

PDPs 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 a PDP that may have the same marketing materials with only minor differences. Please refer to Section 5, Template Materials, for further information.

Multi-Region Organizations for MA and MA-PD (D, E)

If you are an organization that operates in more than one of CMS'S Regional Offices, your marketing review approach (i.e., lead region, local regions, etc) is determined by the agreement your organization makes with CMS Multi-Region Team management.

The Multi-Region MA organization must ensure that materials submitted are consistent with the requirements in this section.

In addition, the Multi-Region MA organization must distribute final copies of its national marketing materials, within a time frame to be determined by its CMS Multi-Region team, to the lead and local ROs with a dated cover letter, which identifies the recipients.

NOTE: *Although the local ROs may no longer play a part in approval of the national marketing piece, the health plan/MA organization must send a final copy of the approved material to the local ROs for their records.*

Review of Materials in the Marketplace (A)

- CMS reviews marketing materials to ensure that they are not materially inaccurate or misleading or otherwise make material misrepresentations. This means that CMS does not disapprove marketing materials based on typographical or grammatical errors. It is the Organization's decision to maintain professional excellence by producing marketing materials that do not contain typographical or grammatical errors.
- Marketing materials, once approved, remain approved until either the material is altered by the organization or conditions change such that the material is no longer accurate. CMS may, at any time, require an organization to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time of approval.

Marketplace review consists of:

- Review of on-site marketing facilities, products, and activities during regularly scheduled contract compliance monitoring visits;
- Random review of actual marketing pieces as they are used in/by the media;
- "For-cause" review of materials and activities when complaints are made by any source; and

10. SPECIAL GUIDELINES

Specific Guidance about Value-Added Items and Services (A)

Value-Added Items and Services (VAIS) are items and services provided to an Organization's enrollees by an Organization that do not meet the definition of "benefits" under the Organization's 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.

An Organization 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 MA program or Prescription Drug Benefit's benefits. Included in the health-related products or services exception are communications relating to a product or service that is available only to an enrollee that adds value to, but is not a part of, an Organization's benefits. 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 (PDPs Only) 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 Organizations' enrollees under the following rules.

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

- Health care items or services that are intended to maintain or improve the health status of enrollees;
- Plans must incur a cost or liability related to the item or service and not just an administrative cost; and

- 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 Organizations' enrollees as a VAIS, subject to the restrictions that follow.

Restrictions on Value-Added Items and Services (A)

Organizations may make VAIS available to Medicare enrollees in accordance with the following restrictions:

- VAIS must be offered uniformly to all organization enrollees and potential enrollees.
- Organizations may not describe VAIS as covered Medicare benefits.
- Organizations may not engage in activities that could mislead or confuse Medicare beneficiaries.
- Organizations may not claim or imply that the VAIS are recommended by or endorsed by CMS or Medicare.
- Organizations 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, Organizations must not use or disclose a beneficiary's protected health information for the purpose of distributing non health-related VAIS (Part D only) without prior written authorization from the enrolled Part D beneficiary. The MA/Part D Organization is thus prohibited from selling names, addresses, or information about the individual enrollees for commercial purposes. If the MA organization/Part D Organization uses a third party to administer VAIS, the MA /Part D Organization is ultimately responsible for adhering to and complying with confidentiality requirements.

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

Organizations can market, either through oral presentations or written materials, Value-Added Items and Services (VAIS). Organizations 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."

Organizations 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 section.

Because VAIS does not meet the definition of a benefit, neither "benefit" nor associated administrative costs may appear in the organization'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 minimal), but the subsidizing of any of these items and services must be excluded from the bid. Furthermore, because they are not contained within the contracted health benefits package, these services are not subject to the Medicare appeals process. VAIS may not be described in Medicare Compare or the "Medicare and You" handbook.

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. Organizations 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 (A)

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 (A)

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

Direct Mail (A)

Any organization's 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. Organizations 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: *Organizations must obtain prior written authorization from the enrollee before sending non health-related direct mail marketing materials. Organizations must also obtain prior written authorization from the enrollee before sending marketing materials containing both health-related and non health-related products.*

Organizations that advertise multiple lines of business within the same direct mail marketing document must keep the Organization's lines of business clearly and understandably distinct from the other products. Organizations 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 an Organization advertises non-Medicare products with Plan material, it must pro-rate any costs so that costs of marketing non-Medicare materials are not included as "Plan-related" costs in the Organization's bid to CMS.

Direct Mail Exception (A)

While organizations 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. Organizations 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.

Organizations 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 or MA and Medigap).

Television (A)

Organizations 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 (A)

Organizations may market other lines of business concurrently with Plan products on the Internet, though to avoid beneficiary confusion, Organizations must continue to maintain a separate and distinct section of their Web sites for Plan information only. CMS will review Organization's 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 (A)

Generally, Organizations 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 organizations and the organizations 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, Organizations may use and disclose protected health information to make communications to enrollees about other lines of business provided by the covered entity.

However, an Organization 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 (A)

From time to time, a third party may prepare marketing materials for a 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)

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

Other than MA/Part D employer group marketing materials, CMS reviews all marketing materials prepared by benefit/service-providing third party entities and used by the Organization for its membership. Marketing materials must be submitted to CMS via the organization 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 Organization. Also, the Organization 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 or its Designee a copy of that material.

Non-Benefit/Service-Providing Third Party Marketing Materials (A)

A non-benefit/service-providing third party entity is an organization that neither administers the health care/prescription drug benefit nor provides health care services/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 an Organization's membership, which is paid for by the Organization or the non-benefit/service-providing third part entity. An example of a non-benefit/service-providing third party could be a research firm that provides comparative data relating to Medicare Advantage /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 an Organization's members, they must submit their materials to the Organization, which in turn, may distribute the materials to their membership. It is the Organization's responsibility 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 (A)

Organizations should make marketing materials available in any language that is the primary language of more than ten percent of a Plan's geographic service area. Additionally, call centers must be able to accommodate non-English speaking/reading beneficiaries. Organizations 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. Organizations 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 (A)

Organizations 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.

Organizations 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, organizations 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.

Attestation Form for Translated Non-English Materials or Braille (A)

ATTESTATION OF TRANSLATED NON-ENGLISH MATERIALS OR BRAILLE

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and <insert Plan name>, hereafter referred to as the Organization, 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 Organization 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 Organization is submitting to CMS the attestation with the following materials: <INSERT MATERIAL IDENTIFICATION NUMBERS>

Based on my 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 designee])

On behalf of

_____
(NAME OF ORGANIZATION)

_____
DATE

The following applies to organizations on File & Use (Certification and Eligibility): (A)

- When an organization is on File & Use, it is on File & Use for both English and non-English materials. Therefore, continual violations in non-English materials could be grounds for placing an organization on probation.
- When an organization is on File & Use probation, the probation is for both English and non-English materials. If File & Use status is revoked, it is revoked for both English and non-English materials.
- If an organization is on File & Use, it must submit English and non-English versions of materials 5 calendar days prior to their use.

Anti-Discrimination (A)

Organizations 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 an organization are available to all eligible beneficiaries in the service area with the following exceptions:

- There may be additional eligibility standards for enrollment in the limited 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).

Organizations 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 5 for Prohibited Terminology/Statements.

11. GUIDELINES FOR PROMOTIONAL ACTIVITIES

General Guidance about Promotional Activities (A)

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. An organization may be subject to sanctions if it offers or gives something of value to a Medicare beneficiary that the organization 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, organizations are prohibited from offering rebates or other cash inducements of any sort to beneficiaries.

Furthermore, Organizations 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.

Organizations may not offer post-enrollment promotional items that in any way compensate beneficiaries based on their utilization of services.

Any promotional activities or items (not including VAIS) offered by organizations, 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 (A)

Organizations 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 Plan. 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 (A)

Organizations 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 (A)

Hold time messages (recorded information played to caller while waiting on hold) within telephone scripts must only discuss health-related features and other operational or general information (e.g., hours of operation, flu shot reminders, etc.). Hold time messages must not include information on non-health related services (e.g., financial service information) that require prior written authorization from enrollees.

Referral Programs (A)

The following general guidelines apply to referral programs under which Organizations 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.

- Organizations may not use cash promotions as part of a referral program

- Organizations 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 organizations 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. Organizations can then use this information for soliciting by mail.

Health Fairs and Health Promotional Events (A)

Organizations 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 Organizations 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.

Multiple-Sponsor Policies

Door prizes/raffles can exceed the $15 limit if an Organization 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 Organization, but is identified with a list of contributors. A jointly sponsored event may consist of the Organization and one or more sponsor participants who are not contracting providers with the Organization. An Organization 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 Organization 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 Organization 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 & Multiple-Sponsor) Policies

- Such events should be social and should not include a sales presentation.
- Response by an Organization 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.

CMS-Sponsored Health Information Fairs (A)

CMS is required to conduct a nationally coordinated education and information campaign to inform Medicare Advantage/Part D eligible individuals about Medicare Advantage Plans and Part D benefits and the election process provided under the law for enrolling in Medicare Health/Prescription Plans. One of the coordinated education and information campaign activities is CMS sponsorship of Medicare Advantage/Part D Plan Health Information Fairs. While most CMS-sponsored Medicare Advantage/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 Medicare Advantage/Part D Plans to participate in the planning of local Health Fairs. Medicare Advantage /Part D Plan participation is optional, but it is important to include contractors in the planning process. CMS retains the right to modify the following guidelines:

Medicare Advantage / Part D Plans 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 Plan); and
- Market multiple lines of business.

Medicare Advantage / Part D Plans 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
- Provide individual gifts with a retail value of more than $15.00.

Specific Guidance about Provider Promotional Activities (A)

As used in specific guidance about provider activities, the term "provider" refers to all providers contracted with the Plan and their subcontractors, including but not limited to: pharmacists, pharmacies, physicians, hospitals, and long-term care facilities. The Plan Sponsor shall ensure that any provider contracted with the Plan (and its subcontractors) or agent (or its subcontractors) performing functions on the Plan Sponsor's behalf related to the administration of the Plan benefit, including all activities related to assisting in enrollment and education, agrees to the same restrictions and conditions that apply to the Plan Sponsor through its contract, and shall prohibit them from steering, or attempting to steer an undecided potential enrollee toward a plan, or limited number of plans, offered either by the Plan sponsor or another Plan Sponsor, based on the financial interest of the provider or agent, (or their subcontractors). Providers that have entered into co-branding relationships with Plan Sponsors must also follow this guidance.

CMS is concerned with provider activities for the following reasons:

- Providers may not be fully aware of all Plan benefits and costs; and
- Providers may confuse the beneficiary if the provider is perceived as acting as an agent of the Plan vs. acting as the beneficiary's provider.

Providers may face conflicting incentives when acting as a Plan representative. For example, some providers may gain financially from a beneficiary's selection of one plan over another plan. Additionally, providers generally know their patients' health status. The potential for financial gain by the provider steering a beneficiary's selection of a plan could result in recommendations that do not address all of the concerns or needs of a potential Plan enrollee. These provider Marketing Guidelines are designed to guide plans and providers in assisting beneficiaries with plan selection, while at the same time striking a balance to ensure that provider assistance results in plan selection that is always in the best interests of the beneficiary.

Following are requirements associated with provider activities. The Plan Sponsor shall ensure that any provider contracted with the plan (and its subcontractors) complies with these requirements:

1. Provider Activities and Materials in the Health Care Setting – Beneficiaries often look to their health care professionals to provide them with complete information regarding their health care choices (e.g., providing objective information regarding specific plans, such as covered benefits, cost sharing, drugs on formularies, utilization management tools, etc.). To the extent that a provider can assist a beneficiary in an objective assessment of the beneficiary's needs and potential plan options that may meet those needs, providers are encouraged to do so. To this end, providers may certainly engage in discussions with beneficiaries when patients seek information or advice from their provider regarding their Medicare options.

Providers are permitted to make available and/or distribute Plan marketing materials for all Plans with which the provider participates (including PDP enrollment applications, but not MA or MA-PD enrollment applications) and display posters or other materials announcing Plan contractual relationships. However, providers cannot accept enrollment applications or offer inducements to persuade beneficiaries to join Plans. Providers also cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific Plan. In addition, providers cannot offer anything of value to induce Plan enrollees to select them as their provider.

Providers should also inform prospective enrollees where they may obtain information on the full range of Plan options. 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, Plan marketing

representatives, their State Medicaid Office, local Social Security Administration Office, http://www.medicare.gov/, or 1-800-MEDICARE.

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 Plans, of a broad nature, that are written by CMS or have been previously approved by CMS. These materials may be distributed by Plans and providers without further CMS approval. Plans should advise contracted providers of the provisions of these rules.

2. Plan Activities and Materials in the Health Care Setting – While providers are prohibited from accepting enrollment applications in the health care setting, Plans or plan agents 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 services or interact with pharmacy providers and obtain medications.

Plans 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 services or interact with pharmacy providers and obtain medications).

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

3. Provider Affiliation Information – Providers may announce new affiliations and repeat affiliation announcements for specific Plans through general advertising (e.g., publicity, radio, television). An announcement to patients of a new affiliation which names only one Plan may occur only once when such announcement is conveyed through direct mail and/or email. Additional direct mail and/or email communications from providers to their patients regarding affiliations must include all Plans with which the provider contracts. Provider affiliation banners, displays, brochures, and/or posters located on the premises of the provider must include all Plans with which the provider contracts. Any affiliation communication materials that describe Plans in any way (e.g., benefits, formularies, etc.) must be approved by CMS. Materials that indicate the provider has an affiliation with certain Plans and only lists Plan names do not require CMS approval.

4. Comparative and Descriptive Plan Information – Providers may distribute printed information provided by a Plan sponsor to their patients comparing the benefits of different plans (all or a subset) with which they contract. Materials may not "rank order" or highlight specific Plans and should include only objective information. Such materials must have the concurrence of all Plans involved in the comparison and must be approved by CMS prior to distribution (i.e., these items are not be subject to File & Use Certification). The Plans must determine a lead Plan to coordinate submission of these materials. CMS continues to hold the Plans 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**: Plans may not use providers to distribute printed information comparing the benefits of different Plans unless providers accept and display materials from all plans in the service area and contract with the provider.*

5. Comparative and Descriptive Plan Information Provided by a Non-Benefit/Service Providing Third-Party – Providers may distribute printed information comparing the benefits of different plans (all or a subset) in a service area when the comparison is done by an objective third party. For more information on non-benefit/service providing third party providers **(**See section 10 under Marketing of Multiple Lines of Business**,** Non-Benefit/Service-Providing Third Party Marketing Materials)

6. Providers/Provider Group Web Sites – Providers may provide links to Plan enrollment applications and/or provide downloadable enrollment applications. The site must provide the links/downloadable formats to enrollment applications for all Plans with which the provider participates. As an alternative, providers may include a link to the CMS Online Enrollment Center.

7. Health Fairs – Providers may distribute Plan marketing materials (including PDP enrollment applications, but not MA or MA-PD enrollment applications) and generally educate potential enrollees at health fairs. Providers cannot compare benefits among Plans in this setting because they may not be fully aware of all benefits and costs of the various Plans.

8. Leads from Providers – Plans and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to Plan 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, 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").

NOTES:
A provider should not attempt to switch or steer Plan enrollees or potential Plan enrollees to a specific Plan or group of Plans to further the financial or other interests of the provider.

All payments that Plans make to providers for 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 refer to Enrollment and Disenrollment Guidance.

Sample Can/Cannot List for Provider Interactions with Potential Plan Enrollees (A)

Providers contracted with Plans (and their subcontractors) can:

- Provide the names of plans with which they contract and/or participate
- Provide information and assistance in applying for the limited income subsidy
- Provide objective information on specific Plan formularies, based on a particular patient's medications and health care needs
- Provide objective information regarding specific plans, such as covered benefits, cost sharing, and utilization management tools
- Distribute PDP marketing materials, including enrollment application forms

  NOTE: *Provider must inform individuals where they can obtain information on all available options within the service area (i.e., 1-800-MEDICARE or medicare.gov).*
- Distribute MA and/or MA-PD marketing materials, excluding enrollment application forms

  NOTE: *Provider must inform individuals where they can obtain information on all available options within the service area (i.e., 1-800-MEDICARE or medicare.gov).*
- Refer their patients to other sources of information, such as the State Health Insurance Assistance Programs, Plan marketing representatives, their State Medicaid Office, local Social Security Administration Office, CMS's Web site at *http://www.medicare.gov/*, or calling 1-800-MEDICARE.
- Print out and share information with patients from CMS's Web site.
- Use comparative marketing materials comparing plan information created by a non-benefit/service providing third-party (See section See section 10 under Marketing of

Multiple Lines of Business**,** Non-Benefit/Service-Providing Third Party Marketing Materials).

Providers contracted with Plans (and their contractors) cannot:

- Direct, urge, or attempt to persuade, any prospective enrollee to enroll in a particular Plan or to insure with a particular company based on financial or any other interest of the provider (or subcontractor).
- Collect enrollment applications
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization
- Health screen when distributing information to patients, as health screening is a prohibited marketing activity.
- Offer anything of value to induce Plan enrollees to select them as their provider
- Expect compensation in consideration for the enrollment of a beneficiary
- Expect compensation directly or indirectly from the Plan for beneficiary enrollment activities.

Specific Guidance Regarding the Use of Persons Employed by a Plan Sponsor to Market a Plan or with which a Plan Sponsor Contracts to Perform Marketing

The definition of "marketing" is established in Section 5 of these Marketing Guidelines. The term includes an activity of an independent broker or other similar managerial marketing position because such persons affect the choice of plans that a marketing representative may market, thereby contributing to the steering of a potential enrollee towards a specific Plan or limited number of Plans, and may receive compensation directly or indirectly from a Plan for marketing activities.

Unless indicated otherwise, in this section the term "Plan" includes an MA Plan and Part D Plan.

Unless indicated otherwise, in this section the term "Plan Sponsor" includes an MA Plan Sponsor and a Part D Plan Sponsor.

Persons Employed by a Plan Sponsor to Market or with which a Plan Sponsor Contracts to Perform Marketing

CMS is aware that Plan Sponsors sometimes use performance-based compensation, tying compensation of a person performing marketing to the volume or value of the person's

sales.[1] Given such compensation arrangements, a person performing marketing may face financial incentives to steer a potential enrollee towards the Plan offering the most compensation to the person performing marketing. The commission rate (i.e., the percentage per enrollment) should not vary based on the value of the business generated for the Plan Sponsor paying the commission (e.g., profitability of the book of business). Commissions should be paid for all beneficiaries who have enrolled in a Plan, regardless of the beneficiary's risk profile. Ensuring that beneficiaries select the Plan most appropriate to the beneficiary's needs, as opposed to the financial interests of the person performing marketing, is important in the MA and Part D programs due to the variability between plans.

Marketing by a person who is directly employed by a Plan Sponsor, with which a Plan Sponsor contracts to perform marketing, or a downstream marketing contractor, is considered marketing by the Plan.

An individual performing marketing may be in a position to enroll healthier beneficiaries into specific health plans (or "cherry pick"). "Cherry picking" healthier patients is problematic because it distorts the market and can be viewed as discriminatory. Therefore an individual performing marketing must not "cherry-pick".

A Plan Sponsor may directly employ or contract with a person to market a Plan if the Plan Sponsor:

- Complies with all applicable MA and/or Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines, to ensure that beneficiaries receive truthful and accurate information.
- Conducts monitoring activities to ensure compliance with all applicable MA and/or Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines.
- Uses a state licensed individual to perform marketing. A Plan Sponsor must utilize only a state licensed, certified, or registered individual to perform marketing, if a state has such a marketing requirement. This requirement applies to any individual that performs marketing on behalf of a Plan Sponsor, whether as an employee or under contract directly or downstream.

Because the MA and Part D programs are Federal programs, state marketing agent appointment laws will not apply to Plan Sponsors. Because a Plan Sponsor is required to use only a state licensed, registered, or certified individual to market a plan, CMS expects a

[1] Plan Sponsors are responsible for ensuring that all their activities comply with the Federal anti-kickback statute, § 1128B(b) of the Social Security Act (the "Act") (codified at 42 U.S.C. § 1320a-7b(b)).

Plan Sponsor to comply with a reasonable request from a state insurance department, or other state department that licenses individuals for the purpose of marketing insurance plans, which is investigating a person that is marketing on behalf of a Plan Sponsor, if the investigation is based on a complaint filed with the state insurance or other department. CMS also encourages a Plan Sponsor to report a person that markets on the plan's behalf to the appropriate state entity, if a Plan Sponsor believes that the person is violating a state's licensing, registration, certification, insurance or other law.

A Plan Sponsor must require that the person performing marketing make the following disclosure, prior to enrollment or at the time of enrollment, in writing, to a potential enrollee:

"The person that is discussing plan options with you is either employed by or contracted with <insert plan name(s)>. The person may be compensated based on your enrollment in a plan."

Plan Sponsor 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.
- Not include payments by persons performing marketing to beneficiaries.
- Withhold or withdraw payment if an enrollee disenrolls in an unreasonably short time frame (i.e., rapid disenrollment). An "unreasonably short time frame" is defined as less than 60 days after enrollment but may be a longer time period if a Plan Sponsor determines it to be a longer period of time.

Persons with which a Plan Sponsor Contracts to Perform Marketing

When these guidelines discuss persons with which a Plan Sponsor contracts to perform marketing, the term "person" includes, but is not limited to, a marketing entity, a broker and/or an independent agent, whether the person contracts directly with the Plan Sponsor or is a downstream contractor.

In addition to the requirements above, a Plan Sponsor may contract in writing with a person to perform marketing if the Plan Sponsor establishes clear provisions within a marketing contract that the Plan Sponsor is responsible for ensuring that the person abides by:

1. Applicable MA and/or Part D laws,
2. All other Federal health care laws, and
3. CMS policies including CMS' marketing guidelines.

A marketing contract must include a provision stating that any coordinated marketing to be carried out by the persons must be done in accordance with all applicable MA and/or Part D laws, CMS policies, including CMS marketing guidelines, and all Federal health care laws (including civil monetary penalty laws).

In addition to the requirements relating to compensation structures above, Plan compensation structures for persons under contract with the Plan Sponsor must:

- Establish compensation schedules through a written contract. As noted above, the commission rate (i.e., the percentage per enrollment) should not vary based on the value of the business generated for the Plan Sponsor paying the commission (e.g., profitability of the book of business). Commissions should be paid for all beneficiaries who have enrolled in the Plan, regardless of the beneficiary's risk profile.

- Not include payments outside of the compensation schedule set forth in the written contract.

The marketing contract need not refer to the specific laws and policies referred to in this section, relating to persons contracted with a Plan Sponsor to perform marketing, provided the person performing marketing is bound through the marketing contract to comply with applicable MA and/or Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines.

Door-To-Door Solicitation (A)

Organizations 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)

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

- Organizations are prohibited from renting e-mail lists to distribute information about the Part D benefit.
- Organizations 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-mails must be received by the PDP. Only then may the PDP e-mail that beneficiary.*

Outbound Telemarketing (A)

By allowing Plans to utilize different methods for marketing the Medicare Prescription Drug Benefit, greater numbers of beneficiaries will be reached and thus enrolled in the Part D program. We believe this is an important goal given the penalty for late enrollment into Part D. To this end, the MMA final rule allows Part D Plans to conduct outbound telemarketing within the scope of the following guidelines.

- Organizations may conduct outbound telemarketing activities for health related products to the extent permitted to do so under the HIPAA Privacy Rule.
- Organizations may not conduct outbound telemarketing activities for non-health related items unless beneficiaries have provided prior written authorization. This rule is intended to protect each beneficiary's privacy rights under HIPAA.

In order to further protect the privacy of potential Plan enrollees and to ensure that outbound telemarketing activities present clear, concise, and accurate information that enables potential Plan enrollees to make an informed choice, all telemarketing activities must adhere to the Federal Trade Commissions Requirements for Sellers and Telemarketers, the Federal Communications Commission and applicable state law.

In addition, organizations must:

- Comply with the National-Do-Not-Call Registry,
- Honor "do not call again" requests, and
- Abide by Federal and State calling hours.

In addition, because of the complex nature of offerings, enrollment by outbound telemarketers is not allowed. Rather, outbound telemarketing may be used solely to solicit requests for pre-enrollment information, describe benefits, and to alert existing beneficiaries to new benefits or health related offers. Organizations can also conduct follow-up calls to establish the receipt of requested information and to field questions regarding programs.

All Part D Plan telemarketing scripts must be reviewed and approved by CMS prior to use within the marketplace. When conducting telemarketing:

- Part D Plans are not required to adhere to a specific format for submission (i.e., verbatim text or bullet points).
- Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the Plan representative and that

the information provided will in no way affect the beneficiary's membership in the Plan.

- Part D Plans are prohibited from requesting beneficiary identification numbers (e.g., Social Security Numbers, bank account numbers, credit card numbers, HICN, etc.).
- Plans are allowed to say they are contracted with Medicare to provide prescription drug benefits or that they are Medicare-approved MA-PD/PDP.
- Plans cannot use language in outbound scripts that imply that they are endorsed by Medicare, calling on behalf of Medicare, or calling for Medicare.

Answers to Frequently Asked Questions About Promotional Activities (A)

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 Plan. 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 Plan. 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 Plan 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 Plans 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, Plans 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 Plans, 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 Plans 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 Plan;
- 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 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* ***does not*** *apply.*

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

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

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

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

Q: Can a Plan 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 Plans 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 Plan pay beneficiaries that sign up to be "ambassadors" a flat fee for transportation?

A: The Plan may reimburse the beneficiary for any actual, reasonable transportation costs but must not pay the beneficiary a flat fee for transportation. If the Plan 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 organizations 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" visits. 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 section and regulations.

Q: Can physician groups that contract with Medicare health plans hire marketing firms to cold call from non- Medicare health plan member listings?

A: Yes, as long as the marketing guidelines for provider marketing are followed.

Q: Can Medicare Health /Part D Plans use providers to identify Medicare beneficiary with certain illness or diseases for marketing purpose?

A: No, marketing must follow the HIPAA privacy requirements. Under HIPAA rule, it permits the provider to communicate freely with his/her patients about treatment options but must not disclose to entity contact information for those who have not signed the provider's HIPAA authorization.

To prevent health screening, the provider can send/mail CMS approved marketing materials to ALL Medicare patients explaining the new Medicare Advantage product on behalf of the Medicare health plan to the extent such a mailing is otherwise permitted by State law. The materials must not contain health screening information but to the extent the materials could explain that the product is only available to individuals that are dually-eligible or that have certain illness or diseases etc. The provider is responsible for ensuring that it does not violate any HIPAA rules when sending/mailing out such information to their patients.

12. USE OF MEDICARE MARK FOR PART D PLANS (B)

Use of Medicare Prescription Drug Benefit Program Mark (B)

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 (B)

Department of Health and Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), Office of External Affairs (OEA).

Summary (B)

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 (B)

The Medicare Prescription Drug Benefit Program authorizes Medicare PDPs and MA-PDs to use the Medicare Prescription Drug Benefit Program Mark only after receiving written communication from CMS. This communication will include a licensing agreement which must be signed by the organization's CEO/CFO or designee in order to use the Medicare Prescription Drug Benefit Program Mark prior to execution of the Part D contract. The Part D contract will contain provision regarding the use of the Medicare mark. PDP and MA-PD entities may use the mark on submission of marketing materials consistent with Marketing Guidelines.

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

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 (B)

The following process will be used to grant Part D Plans use and access to the Medicare Prescription Drug Benefit Program Mark. This process is for use of the Medicare Prescription Drug Benefit mark on Part D marketing review materials:

CMS will distribute the Medicare Prescription Drug Benefit Program Mark licensing agreement to Part D plans that have been "conditional approved" as Part D Plans via the HPMS. Plans are to certify/attest that they will use the mark according to the guidance in the Part D Marketing Guidelines. After CMS has received the signed licensing agreement back from the Part D Plan, the Medicare Mark URL will be sent to the Part D Plan. After receipt of the URL, Part D plans may begin using the mark on marketing materials (including the Part D membership ID card) that are required to be submitted to CMS for review.

Requests to distribute other items (i.e., materials not included in the Part D Marketing Guidelines), 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 (B)

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 (B)

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 (B)

Positive Program Mark (B)

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 (B)

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

Approved Colors (B)

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 (B)

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 (B)

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 (B)

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 (B)

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 (B)

- 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.

Part D Standard Pharmacy ID Card Design (B)

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.

13. EMPLOYER/UNION GROUPS

Employer/Union Group Marketing and Disclosure/Dissemination Waivers (A)

Marketing (A)

CMS may waive or modify requirements that "hinder the design of, the offering of, or the enrollment in" employer-sponsored group plans (Sections 1857(i) and 1860D-22(b) of the Social Security Act). Under the authority granted, CMS has waived the marketing requirements contained in 42 CFR §422.80 and 42 CFR §423.50 for all employer-sponsored MA-only, MA-PD or PDP plans. This waiver applies to both employer/union direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans.

This waiver applies to all marketing requirements, including the requirements contained in this guidance document. Employer/union direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans are not subject to the restriction against communicating to their retirees about their plans prior to October 1, 2005. Rather, CMS strongly encourages employers and unions offering these group plans to begin the communication process with their retirees and to continue to communicate about their benefits as frequently as possible prior to November 15, 2005. More specifically, employers and unions should be prepared to talk to their retirees early, clearly and repeatedly about their options under Medicare prescription drug coverage, should be prepared to direct them to available resources and to explain to them how their drug coverage will work when Medicare prescription drug coverage begins in 2006.

Disclosure/Dissemination (A)

Under its authority, CMS will waive the disclosure requirements of 42 CFR §422.111 and the dissemination requirements of 42 CFR §423.128 when direct contract PDPs or MA Organizations and PDPs that offer employer/union-only group plans provide attestations that the employer or union sponsor is subject to alternative disclosure requirements (e.g., ERISA) and the plan complies with such alternative requirements. However, these alternative disclosure materials (to include summary plan descriptions and all other beneficiary communications that provide descriptions of the benefit offerings) must be provided to CMS at the time of use and to beneficiaries on a timely basis. Direct contract PDPs should send their materials to Central Office. MA Organizations and PDPs that offer employer/union-only group plans should send these materials to the appropriate Regional Office contact. These materials must be sent electronically. Materials should not be submitted through HPMS. CMS may review these materials in the event of beneficiary complaints or for other reasons it determines

to ensure the information adequately informs Medicare beneficiaries about their rights and obligations under the plan.

Direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans that have not provided the attestation described above, cannot utilize the waiver. They are subject to all applicable regulatory requirements and sub-regulatory guidance, including the requirements contained in this guidance document.

ID Card Requirements (A)

Direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans may merge their existing member identification (ID) card(s) in order to provide enrollees with one combination member ID card (for medical, PDP and supplemental drug benefits). However, direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans must comply with other CMS ID card requirements, including the requirements contained in this guidance document.

Also, direct contract PDPs and MA Organizations and PDPs that offer employer/union-only group plans may use different names for "doing business as" purposes. However, for HPMS purposes only, these entities will be restricted to entering one "doing business as" name.

14. ADDENDUM 1 (B)

Guidance for NCPDP Data Elements (B)

The NCPDP implementation of INCITS 284 suggests different data element labeling for some of the data elements in order to better meet the needs of the pharmacy industry. The data elements listing in section 6.1 of INCITS 284 are mapped, where appropriate, to NCPDP data elements in Table 6.1. Please note the location and mandatory requirements in INCITS 284 section 6.1 and the order of first name and last name in section 6.4.3 of the NCPDP manual. Complete detailed technical specification information can be found in the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).

Table 6.1

INCITS 284 Description	NCPDP Description(s)	INCITS 284 Label	NCPDP Label	NCPDP v5.1 Maximum Field Size
Card issuer name or logo	Card issuer name or logo	None required	None required	N/A
Card issuer identifier	Card issuer identifier	"Issuer (80840)"	"Issuer (80840)"[2]	TBD
Cardholder identification number	Cardholder ID	"ID"	"ID"	20[3]
Cardholder identification name	Cardholder first name, middle initial, cardholder last name	"Name"	"Name"	First Name=12; Middle Initial=1; Last Name=15
Account number(s)	BIN, Processor Control Number, and Group ID[4]	"Account"	"RxBIN", "RxPCN", and "RxGrp" or "Grp"[5]	RxBIN=6; RxPCN=10; RxGrp=15
Claims submission name(s) and address(es)	Claims submission name(s) and address(es)	A suitable label	A suitable label	N/A

[2] In the label "Issuer (80840)," the number "80840" represents the international identifier for USA.
[3] The INCITS 284 standard specifies a maximum of 19 alphanumeric characters for the cardholder identification number. This guide allows an exception in order to comply with the maximum of 20 as defined in the NCPDP data dictionary and to comply with the pharmacy transaction standard adopted under HIPAA.
[4] Since INCITS 284, section 6.4.4, makes reference to transaction routing information under the definition of "Account Number(s)," the NCPDP Pharmacy ID Card Implementation Guide maps the pharmacy industry's transaction routing data elements with INCITS 284's data element, "Account Number(s)." See Table 6.2 of this guide for further information on RxBIN, RxPCN, and RxGrp.
[5] "Grp" is only acceptable when the ID card is a combination health care card and the group number is identical for all health care services identified to the cardholder.

Telephone number(s) and name(s)	Help Desk Telephone number(s) and name(s)	A suitable label	A suitable label	N/A

***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).*

In the absence of a single national issuer identifier used for transactions routing, this guide (NCPDP Pharmacy Implementation Guide) requires additional data elements used in the pharmacy industry for transactions routing. Table 6.2 lists three data elements related to transaction routing: BIN (ANSI IIN), processor control number, Group ID. Table 6.2

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

***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).*

RxBIN and RxPCN can be thought of as a U.S. zip code + 4. The RxBIN, or BIN number, is analogous to the 5-digit zip code and determines the routing destination. The RxPCN, or processor control number, is analogous to the plus 4 part of a zip code, which gives a more precise destination. In the pharmacy industry, the BIN number may represent the address of a large computer and the processor control number may represent a subset system of the computer. The group number is sometimes used to provide even more precise routing. The processor control and group numbers are required to be on the ID card when the PDPs or MA-PDs require them for proper routing.

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

Essential Window Information (B)

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

To conserve vertical space on the ID card, the BIN (ANSI IIN) and Processor Control Number may be printed on the same line. The order of the data elements must be as follows, and no other data may be interspersed between these data elements, as shown in Table 6.3:

Table 6.3

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

***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004). References in Notes column refer to sections in the NCPDP Pharmacy ID Card Implementation Guide.*

Data Element Embossing (B)

Refer to Annex E of INCITS 284**.**

Machine-Readable Formats (only in required states) (B)

Magnetic Stripe (B)

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

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

PDF417 (B)

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

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

To find more information regarding the PDF417 standard, please refer to Table 6.4.

Table 6.4

PDF417 Information	Organization	Web Site
Complete, official specifications	American National Standards Institute (ANSI)	http://www.ansi.org
2-Dimensional bar code (machine readable devices) basics and PDF417 symbology overview; white papers; applications; case	Symbol Technologies, Inc.	http://www.symbol.com

studies; etc.		
2-Dimensional bar code (machine readable devices) basics and PDF417 symbology overview	AutoID.org	http://www.autoid.org
***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).* Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP		

Table 6.5 describes the PDF417 data record layout including the five key data elements that identify the cardholder and the card issuer.

Table 6.5

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

***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).*

Example PDF417 Data Record:

%H^12345678901^^^BN123456^PC1234567890^GR123456789012345?

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

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

PDF417 Image Placement (B)

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

Pharmacy ID Card PDF417 Technical Specifications (B)

The parameters defined in Table 6.6 allow for a PDF417 image to print in at least the same amount of space that is typically required for a magnetic stripe while maintaining enough capacity to accommodate the PDF417 data record defined in 3.4.2.1 of the NCPDP Manual. PDF417 parameter definitions and value ranges may be found in software or hardware/printer manuals. Readers of this guide may also want to consult with their relevant printer vendors. Table 6.7 includes images generated from the sample data record above, "Example PDF417 Data Record," using the specifications defined in Table 6.6.

Table 6.6

Specification	NCPDP Valid Values	Comments
Error Correction Level	4	
Aspect Ratio (Symbol Height to Width)	3:1	
Printer Resolution	≥ 240 dots per inch	

Module Width[6] (X-dimension)	240 dpi → 0.0083 inches (8.333 mils) 300 dpi → 0.0100 inches (10.000 mils) 400 dpi → 0.0100 inches (10.000 mils) 600 dpi → 0.0100 inches (10.000 mils)	Estimated Max Text Characters 234 110 110 110
Max Data Rows	10	
Max Data Columns	12	
Truncate	No	
***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).* Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP		

Table 6.7

PDF417 Image Sizes (Images represent data record example above.)	
DPI	**Sample Image**
240	
300, 400, 600	
***NOTE**: This table is located in section 6 of the NCPDP Health Care Identification Card Pharmacy ID Card Implementation Guide Version 1 Release 8 (April 2004).* Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP	

INCITS 284 Standard Exception (B)

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

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

[6] Most laser scanners/readers are limited to module widths greater than or equal to 6.67 mils.

- This guide recommends in section 3.4.1 that card issuers disregard the INCITS 284 requirement that, at a minimum, a magnetic stripe must be included if any other machine-readable format is implemented. NCPDP has determined that the capacity limitations of the magnetic stripe make this requirement unreasonable.
- In section 7 of the INCITS 284 standard, machine-readable information is defined. The maximum length specification of the cardholder identification number is 19. NCPDP's data dictionary specifies that the cardholder identification number have a maximum length of 20. Therefore, this guide differs from the INCITS 284 standard and specifies a maximum length of 20 for the cardholder ID.

At the time of this release, NCPDP has made formal recommendations to INCITS to make modifications to the INCITS 284 standard to eliminate the exceptions noted above. INCITS has agreed to the requested changes and a revised standard is expected for release in 2005.