MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM

MARKETING MATERIALS GUIDELINES

FOR

MEDICARE ADVANTAGE–PRESCRIPTION DRUG PLANS (MA-PDS)

AND

PRESCRIPTION DRUG PLANS (PDPS)

JUNE 1, 2005

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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

In keeping with the Medicare Prescription Drug Benefit final rule, CMS developed guidelines to assist PDP, MA-PD, and 1876 Cost Plan organizations in their efforts to market the Medicare Prescription Drug Benefit to eligible Medicare beneficiaries. This document addresses the marketing guidelines for PDP organizations, as well as providing additional marketing guidance to MA-PD organizations specific to the Medicare Prescription Drug Benefit. For the purpose of these marketing guidelines, the term "Part D Plan" includes PDPs and MA-PDs. When used individually, the terms "PDP" and "MA-PD" will denote that the marketing guidance that follows is specific to that type of organization. For marketing guidance specific to the Medicare Advantage program, MA-PDs are encouraged to review the Medicare Advantage Marketing Guidelines available at: http://www.cms.hhs.gov/healthPlans/marketing/.

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

- Expedite the process for CMS' review of marketing materials;
- Conserve Part D Plan resources by avoiding multiple submissions/reviews of marketing materials prior to final approval;
- Ensure consistent marketing review throughout the program;
- Enable Part D Plans to develop accurate, consumer friendly marketing materials that will assist beneficiaries in making informed health care choices; and

- Establish consistent review standards for PDPs and MA-PDs, 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 refer to Chapter 3 of the Medicare Managed Care Manual. Cost Plans that mention Part D as an optional supplemental benefit in their marketing materials should follow MA-PD guidance.*

Implementation Schedule

Part D Plans may not distribute any marketing materials until they receive notification from CMS.

It is expected that Part D Plans may begin submitting marketing materials to CMS or its Designee for review on June 7, 2005, and continue submitting materials on a constant flow basis throughout the year.

CMS will award contracts to Part D Plans in September 2005. 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 Part D Plan in accordance with the Title 42 of the Code of Federal Regulations.

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

Acceptable PDP Plan Names

***NOTE:** For additional guidance regarding acceptable MA-PD Plan names, refer to Chapter 3 of the Medicare Managed Care Manual.*

The following are requirements regarding the establishment of a name for a Part D Plan:

- Beneficiaries with disabilities must be considered part of the audience for any Part D marketing material used within the marketplace. Part D Plans 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-PD Plan names (not PDP names) that were established by Medicare Advantage organizations before June 29, 2000. PDPs may not use a Plan name that suggests a Plan is available only to beneficiaries with disabilities.

- PDPs 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 of Minnesota, it would be permissible for the Plan to use the tag line, "Swedish Plan, offered by Swedish Hospital System of Minnesota".
- PDPs may not use "Medicare Endorsed" as part of their Plan name or anything similar suggesting the above.
- PDP can use the term "Medicare" in their names. If a Plan chooses to utilize the term "Medicare" it must insert the Plan name before "Medicare" (i.e., Acme Medicare Plan) beginning with all 2006 materials.
- Further guidance is forthcoming regarding the use of the Medicare seal and official Medicare Prescription Drug Benefit program name.
- Specific guidance regarding Joint Enterprise arrangements is forthcoming.

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

Guidance for transitioning beneficiaries from the Medicare-Approved Discount Drug Card Program to Part D Plans is forthcoming.

Please continue to check the CMS Web site at: http://www.cms.hhs.gov/discountdrugs/infooutreach.asp.

3. HIPAA PROVISIONS

"On April 14, 2003, new Federal rules governing the use and disclosure of certain individually identifiable health data by health Plans, health care clearinghouses, certain health care providers and Medicare prescription drug discount card sponsors ("covered entities"), became enforceable." 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. Part D Plans are not required to obtain authorizations prior to using their Medicare beneficiary members' data to provide information to such members regarding their Part D benefit packages. For additional information regarding the HIPAA Privacy Rule, go to the following Department of Health and Human Services, Office of Civil Rights website address: http://www.hhs.gov/ocr/hipaa/.

4. PDP STATE LICENSURE

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 Plan.

5. OVERVIEW

Definitions

Marketing Materials

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

- Promote a Part D Plan.
- Provide enrollment information for a Part D Plan.
- Explain the benefits of enrollment in a Part D Plan.
- Describe the rules that apply to enrollees in a Part D Plan.
- Explain how Medicare services are covered under a Part D Plan, 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 also 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 Part D Plan marketing activity on the Internet. CMS marketing review authority extends to all marketing activity (both advertising, pre-enrollment, and post-enrollment activity) the Medicare Part D Plan 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

Explanatory materials are a subset of marketing materials primarily intended to explain the benefits, operational procedures, cost sharing, and/or other features of a Part D Plan 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

Further details on the documents and activities that constitute marketing materials are given in Chapter 6 (Marketing Material Developing Guidelines), Chapter 7 (Required Marketing Materials), and Chapter 8 (Materials Not Subject to Review).

Advertising

Advertising materials are primarily intended to attract or appeal to a potential Part D Plan enrollee. The advertising materials are intended for quick view; thus, they do not contain the same level of detail expected in other marketing materials. 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.

Pre-Enrollment Marketing Materials

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

Post-Enrollment Marketing Materials

Post-enrollment materials are those materials used by Part D Plans to convey benefits or Plan operational information to enrolled beneficiary 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.

Types of Plans Based on Service Areas

The MMA requires a number of changes to the Medicare program. In order to implement the new Medicare Prescription Drug Benefit, CMS had to define 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).

Furthermore, in order to remain consistent with the Medicare Prescription Drug Benefit final rule, 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 a CMS Designee.

National Plans

- **PDPs:** A PDP can market itself as a national Plan if, at a minimum, it covers the thirty-four CMS PDP regions that include the fifty states and the District of Columbia. PDPs that cover more than the minimum thirty-four PDP regions (i.e., those that include the fifty states, the District of Columbia, and one or more territories) are also considered "national Plans." PDPs sponsored by more than one organization, or a "joint enterprise", can also use the term "national" if the joint enterprise covers, at a minimum, the thirty-four CMS PDP regions that include the fifty states and the District of Columbia. (Refer to Federal Register Vol. 70 FR 13398).
- **MA-PDs:** A MA-PD can market itself as a national Plan, if, at a minimum, it covers the twenty-six CMS MA regions that include the fifty states and the District of Columbia. MA-PDs that cover more than the minimum twenty-six regions (i.e., those that include the fifty 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 thirty-four PDP regions that include the 50 states and the District of Columbia.
- **MA-PDs:** A "regional 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 twenty-six 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-PDs Only)**:** A "local" MA-PD is offered by a MA Plan that is not a MA 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 Part D Plan is prohibited from advertising outside of its defined service area unless such advertising is unavoidable. In situations in which this cannot be avoided (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area, such as an MSA (Metro Statistical Area) that covers two regions), Part D Plans are required to disclose clearly their service area. Marketing activities outside of a Part D Plan's defined service area are the basis for corrective action.

Co-Branding Requirements

Co-branding is defined as a relationship between two or more separate legal entities, one of which is a sponsoring Part D Plan. The sponsoring Part D Plan 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 a Part D Plan and its co-branding partner(s) to promote enrollment into the Plan. Co-branding relationships are entered into independently from the contract that the Plan has with CMS. Part D Plan are allowed to enter into co-branding arrangements as long as the following requirements are met:

- The Part D Plan must inform CMS of any co-branding relationships at the time that the Plan begins inputting their Plan benefit information (Plan Benefit Package - PBP) into the Health Plan Management System (HPMS). The HPMS PBP module will allow Plans 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, Part D Plans must inform their CMS Plan Manager, who will then notify appropriate CMS staff. The Part D Plan must remove any reference to the former co-branding partner from its marketing materials.
- The approved Part D Plan must adhere to all contractual stipulations based upon its contract with CMS. It is the Plan's responsibility to ensure that its co-branding partner(s) also adhere(s) to all applicable CMS policies and procedures.
- The Part D Plan 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 Plan.

Neither the Part D Plan 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 Part D Marketing Guidelines and must be submitted by the sponsoring Plan to CMS or its Designee for review. Plans may elect to submit co-branded materials as template materials. Guidance for submitting template materials is provided below.

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.

Template Materials

Guidance forthcoming

Use of Data from Medigap Issuers

If a Medigap issuer chooses to sponsor a MA-PD or PDP, under the MMA, it will be allowed to use its existing enrollment information from its Medigap plans to market its Part D Plan to its Medigap enrollees. However, Medigap issuers should consult their own legal counsel to determine whether such marketing is permitted under the HIPAA privacy rule or any other applicable Federal or State privacy laws. If a Medigap issuer determines, after consulting with counsel, that marketing as described in this section is permitted, it must marketing to all its members, not just a subset.

6. MARKETING MATERIAL DEVELOPMENT GUIDELINES

Plan Responsibilities

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.

Upon submission of materials, Part D Plans 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 making 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

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

A Part D Plan 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, Plans may explain that the organization is approved for participation in Medicare Part D and/or that is contracted to administer the Part D benefit.

However, Plans may use the term "Medicare-approved" to describe their Part D benefits and services within their marketing materials.

Specific lists of prohibited terminology and statements are contained in the Must Use/May Not Use Charts within this document for:

- Advertising Materials
- Pre-enrollment Materials
- Post-enrollment Materials
- Internet Outreach
- Dual Eligibles

Model and Standardized Materials

Standardized Language

Marketing materials containing standardized language drafted by CMS, which is mandatory for use by Part D Plans, are subject to a ten-day marketing review period.

Model Language

For certain pre- and post-enrollment documents, CMS has drafted model language, which when utilized, without modification, entitles the Part D Plan to a ten-day marketing review period. The use of CMS model language is optional.

Directory of Model Documents

Forthcoming

Advertising

Guidelines for Advertising Materials

Required Disclaimers

Guidance forthcoming

Product Endorsements/Testimonials

Product endorsements and testimonials must adhere to the following guidelines:

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

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

Part D Plans 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, Part D Plans 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"

Part D Plans cannot state "Eligible for free drawing and prizes."

Any incentive that might have the effect of inducing enrollees to use particular providers, practitioners, or suppliers should be carefully reviewed by the Plan 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 health plans are subject to the Federal anti-kickback statute, section 1128B (b) of the Social Security Act.

Radio and TV Spots

Radio advertisements placed by Part D Plans must include the Part D Plan'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, Plans can use language that allows them to work disclaimers into the script, and/or show disclaimers on the screen.

As with radio advertisements, television advertisements placed by Part D Plans must include the Part D Plan'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).

In contrast to radio advertisements, television advertisements must include the TTY/TDD number for the Part D Plan's toll-free

number. The TTY/TDD number can be a different size or font so it is clearly differentiated from the Part D Plan's toll-free number.

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

Quantitative or Qualitative Claim

Guidance forthcoming

Contracting Statement

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 Plan contracts with the Federal government.

Pre-Enrollment Materials

Guidance for Pre-Enrollment Materials

Required Disclaimers

Guidance forthcoming

Quantitative or Qualitative Claims

Guidance forthcoming

Eligibility Requirements

Both PDPs and MA-PDs must clearly state in their pre-enrollment materials that a Part D eligible beneficiary:

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

PDPs must also state that Medicare beneficiaries:

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

MA-PDs must also state that:

- 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 Medicare beneficiaries may be enrolled in only one Part D Plan at a time.

Prescription Drug Services

If benefits are mentioned in pre-enrollment materials, Part D Plans must inform Part D 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, Part D Plans must provide ways for the potential beneficiary to obtain additional information regarding this feature. Likewise, Part D Plans must also note that generally benefits are only available at the Plan's network pharmacies (under emergency circumstances, benefits may be obtained out-of-network). Part D Plans must also provide contact information for obtaining additional network pharmacy information. Contact information must include a toll-free number, a toll-free TTY/TDD number (if applicable), and a mailing address.

Contracting Statement

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

Program Description

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

- "[Program name] is a Prescription Drug Plan that is approved by Medicare."
- Plan service area.
- Plan Statement that enrollees must use network pharmacies to receive Plan benefits except under emergency circumstances.

Premiums

The following statement must be included in all pre-enrollment materials, even if the Part D 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 that mention Part D as an optional supplemental benefit must include, at a minimum, the additional premium amount for the Part D benefit.

Specific Guidance

Summary of Benefits

NOTE: *This section is applicable only to PDPs. MA-PD Plans should continue to use the standardized Summary of Benefits for the MA program, which can be found in Chapter 3 of the Medicare Managed Care Manual.*

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 PDP. The information within the SB is standardized language to allow beneficiaries to more easily compare the benefits offered by different PDPs.

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 PDP;
- **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.

General Instructions

General requirements and guidance for completing the SB are provided below.

1. PDP Organizations must adhere to the language and format of the SB and are only permitted to make changes 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. Guidance related to changes in hardcopy SB is forthcoming.

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. Front and back cover pages are acceptable.

5. Font size of 12-point or larger must be used for the SB (including footnotes). PDP 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.

6. 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.

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

8. PDP 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 (Section 2).

9. PDP Organizations offering Plans with identical benefits in different regions may display the information for these Plans in the same column within the benefit comparison

matrix (Section 2). The benefits for the Plans must be the same; only the service areas may differ.

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

11. 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.

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

Instructions for Section 1

This section 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.*

Instructions for Section 2

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

Section 3 is used by PDP 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: PDP 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.

PDP 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.

Permitted Changes to Summary of Benefits Language and Format

Guidance forthcoming

Process for Hard Copy Changes

Guidance forthcoming

Comprehensive Formulary

Section 423.128(c)(v) of the Final Rule states that a 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 Plan." 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 sponsor must send a comprehensive formulary. Customer service representatives may also inform individuals that current and comprehensive formulary information is available on the 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 Plan must send a comprehensive formulary.*

The comprehensive formulary must include the same information provided within the abridged formulary document as described below 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 Plan.

Abridged Formulary

As stated above, upon the request of a Part D eligible individual, the Plan must provide a comprehensive formulary to the individual. Furthermore, section 423.128(4) of the Final Rule requires Part D Plans to provide a list of drugs included on the Plan's formulary to enrollees upon enrollment and at least annually thereafter. Under these circumstances, the final rule does not specify whether this list should be an abridged or comprehensive list of covered drugs. Therefore, because of concerns that a comprehensive formulary would be costly for Plans to print and distribute and confusing for enrollees to use, CMS has elected to allow Plans to provide an abridged version of their formulary in all other pre-enrollment situations.

CMS will make available a model abridged formulary that Plans 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 Plan's formulary document.
- The following statement: "<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 disclaimer stating: "This is not a complete list of drugs covered by the 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 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), a Plan may not change its formulary from the beginning of 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 of covered drugs (the approved CMS formulary), 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 Plan formulary. (***NOTE:*** *While Plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Plans have the option to include the therapeutic classes as subheadings within the abridged formulary*). 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*). 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 cost sharing 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. Plans may also choose to replace the tier placement column with a column providing the co-payment or co-insurance amount/percentages.
- *Utilization Management*: Part D Plans should indicate any applicable utilization management procedures (e.g., preauthorization, step therapy, quantity limits, etc.) for the drugs. A description of these utilization management procedures must be provided somewhere within the document (e.g., in footnotes). For example, a 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 Plan's formulary, utilization management tools or tiered cost sharing.
- Abridged formularies must be submitted to CMS or its Designee for marketing review to ensure they comply with these Guidelines. Part D Plan sponsors are responsible for ensuring that their abridged formulary includes at least two covered drugs in each therapeutic class and is consistent with their approved formulary. Reviewers will generally not verify if the document includes two covered drugs in each class, tier placement, and utilization management designations. 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 marketing 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 sponsor is required to submit to CMS or its Designee a final printed version of the item for possible retrospective review.

Formularies Provided on Plan Web Sites

Section 423.128(d)(2)(ii) of the Final Rule requires Part D Plan sponsors to include their current formulary, updated at least once per month, on their Web site. Sponsors 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 PDF files but may be posted in other formats as well.
- CMS suggests that Plans provide a search tool that allows individuals to search for their specific prescription drug. The search tool must include:
  - Definition of formulary. Sponsors 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: "<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 application utilization management procedures.

- An explanation of how to obtain an exception to the 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 Chapter 6 (Marketing Material Development Guidelines) of these Guidelines.

Other Formulary Documents

Part D Plan sponsors may develop additional formulary documents providing the comprehensive and abridged formulary documents are developed and distributed in compliance with the guidelines described above. For example, 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.

Drug Utilization Management and Medication Therapy Management Programs (MTMPs)

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

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

Likewise, Plans must include descriptions of applicable utilization management methods in pre-enrollment materials, such as:

- Prior authorization
- Quantity limits
- Step therapy

Post-Enrollment Materials

Guidelines for Post-Enrollment Materials

Studies or Statistical Data

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

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

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

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

Contracting Statement

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 Plan contracts with the Federal government.

Specific Guidance

Materials Required at the Time of Enrollment and Annually

Part D Plans must provide the following information at the time of enrollment and on an annual basis:

- Annual Notice of Change (**Annually Only**): All Part D Plans 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 Plan 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
- ID Card (At time of enrollment and as required by Plan)

ID Card Requirements

Part D Plans must provide a member identification card to each enrollee, based on the National Council on 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 flexibility 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.
- 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 does not exceed the size of a standard credit card.

- If a Plan is not utilizing/issuing 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 may vary the location of these elements.
- If a Plan is not utilizing/issuing Machine readable ID Cards, all mandatory data elements required to be on the back of the ID card must be on the back of the ID; however, Plans may vary the location of these elements.
- At their option, Plans can add co-pay information to the ID card.

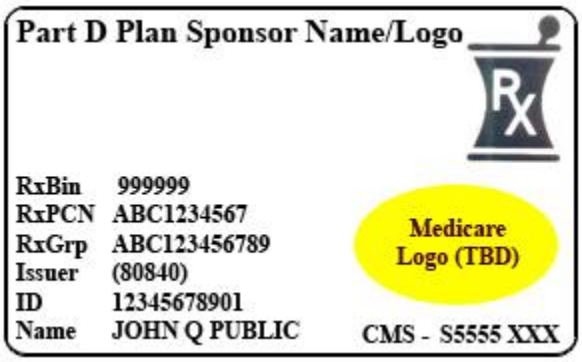
The Part D Member ID cards contain both NCPDP mandatory elements and several CMS-required elements. Requirements are provided below.

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 (detailed information is forthcoming).

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

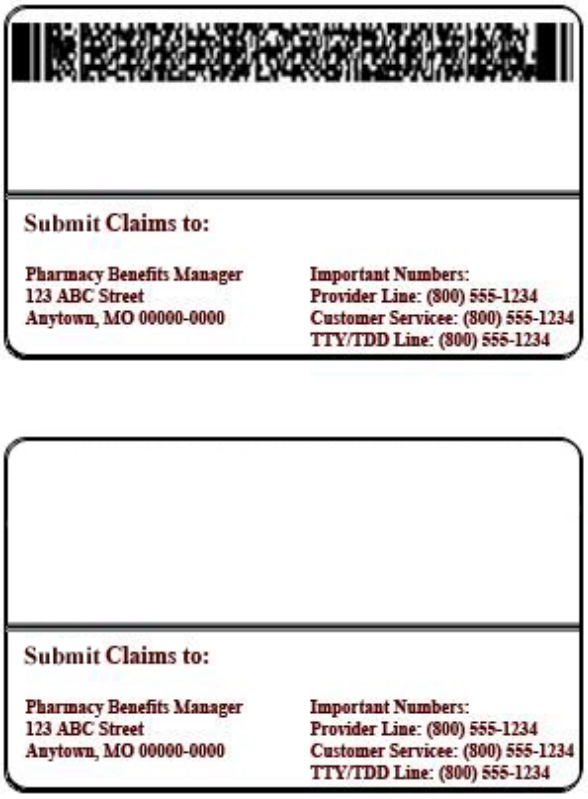
Figure 6.1 Front of card



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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Pharmacy Directories

Plans must include information regarding its participating network pharmacies within Part D 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

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 toll-free TTY/TDD number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest their home. Plans may also include chain pharmacy locators on their Web sites.

- Plans 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, Plans must include the following disclaimer:

  "All network pharmacies may not be listed in this directory. Please contact Plan at xxx-xxx-xxxx for additional information."
- Plans 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).
- Plans may list both preferred and non-preferred pharmacies. However, the Plan must identify each category and describe any restrictions imposed on members that use non-preferred pharmacies.

Out-of-Network Pharmacy Access

Plans 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

Part D Plans 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 retail pharmacies may agree to accept the mail-order reimbursement rate for an extended supply of medications, which may result in no out-of-pocket payment difference to enrollees.
- 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.
- Include a toll-free telephone number (including toll-free TTY/TDD) to call if there are questions.

Post-Enrollment Formulary Requirements

Section 423.128 of the Final Rule requires Part D Plans to provide a list of drugs included on the Plan's 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 of concerns that a comprehensive formulary would be costly for Plans to print and distribute and confusing for enrollees to use, CMS has elected to allow Plans to provide an abridged version of their formulary.

CMS will make available a model abridged formulary that Plans 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 Plan's formulary document.
- The following statement:

  "<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 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 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), a 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 Plan formulary. (***NOTE**: While Plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, 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). 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. 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 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 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; 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

Section 423.128(c)(v) of the Final Rule states that a 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 Plan." 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 Plan.

Formularies Provided on Plan Web Sites

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 documents should be posted as PDF files, but may be posted in other formats as well.

- CMS suggests that 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: "<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 application utilization management procedures.
    - An explanation of how to obtain an exception to the Plan's formulary or tiered cost sharing. [Note: exceptions are also available for UR procedures] 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 Chapter 6 (Marketing Material Development Guidelines) of these Guidelines.

Other Formulary Documents

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, 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

Plans must provide at least 60 days notice to CMS, SPAPs, authorized prescribers, and network pharmacies before removing a Part D drug from the 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. 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 each Plan's Web site.

Evidence of Coverage

The Evidence of Coverage must include comprehensive information regarding the following Plan information:

- Service Area
- Benefits
- Premiums
- Cost-Sharing
- Network Pharmacy Information
- Out-of-Network coverage
- Grievance and Appeals Procedure
- Exceptions Process
- Drug Utilization Management and Medication Therapy Management Programs, and Quality Assurance
- Disenrollment rights and responsibilities

A model and further guidance is forthcoming.

Explanation of Benefits

This model is currently in development. Further guidance is forthcoming.

Anti-Duplication Notices

Since Part D Plans will provide all covered Medicare drug benefits directly to enrolled beneficiaries, Plans will not have to provide anti-duplication notices to Medicare beneficiaries. However, if Part D Plans choose to market to their enrollees other health insurance products that are not part of their contract under Part D, these other products will have to include an anti-

duplication notice as required by Section 17 of the NAIC model regulation.

Internet Marketing

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

- 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.
- Web link – A shortcut within a Web site or Web page that connects the user to another location on the Internet.

URL Guidelines

All organizations 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 home page.

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 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.

Part D Plan Web site Content Requirements

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, toll-free TTY/TDD number, and 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., copayments, coinsurance and deductibles)
    - 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
    - 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.)

- Out-of-Network coverage
- Current formulary information (updated monthly) based on guidance provided in Chapter 6 (Formularies Provided on Plan Web sites).
- Grievance, coverage determinations, appeals procedures, and exceptions process,
- Quality assurance policies and procedures, including medical therapy management, and drug and/or utilization management,
- Potential for contract termination,
- How to obtain an aggregate number of the Plan's grievances, appeals, and exceptions

Required Links

The following information must be accessible via a link:

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

Prohibited Links

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

Internet Must Use Chart

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	May 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 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, toll-free 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.
	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.		

Subject		Must Use	May Not Use	Reason
	Benefits	• Applicable conditions and limitations • Premiums • Cost-sharing (e.g., co-payments, co-insurance 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 toll-free 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.")		
	Current Formulary	All Plans must include a current formulary, updated at least monthly. For formulary requirements, please refer to Chapter 6 (Marketing Material Development Guidelines)		
	Out -of - Network Coverage	All Plans must include provisions for 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.		

Subject		Must Use	May Not Use	Reason
	Quality Assurance Policies and Procedures	All Plans must include a description of their quality assurance policies and procedures, including medical 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	May 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

General Guidance on Dual Eligibility

Guidance forthcoming

SPAP Materials

State Pharmaceutical Assistance Programs (SPAPs) are state-financed prescription drug programs that provide drug coverage to low-income or disease-specific populations. SPAPs also provide pharmaceutical assistance to low-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

A Part D Plan's ID 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 not decide to co-brand. However, it would be prudent that the Plan 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. 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 informed the beneficiary, during its education and outreach campaign, 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.

7. REQUIRED MARKETING MATERIALS

Required Pre-Enrollment Materials

Required Part D pre-enrollment materials provide additional details on the Plan (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 Part D coverage.

Pre-enrollment materials must include the following:

- A cover letter that includes the Part D Plan's toll-free-customer service telephone number; a toll-free TDD/TTY 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 users should call 1-887-486-2048 for more information about Medicare benefits and services including general information regarding the Part D benefit.
- Enrollment instructions and forms
- Summary of Benefits – Refer to Chapter 6 (Marketing Material Development Guidelines) 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 Chapter 6 (Marketing Material Development – Specific Guidance for Post Enrollment Materials) for content guidance.

- Formulary – Refer to Chapter 6 (Marketing Material Development Guidelines – Specific Guidance Pre-enrollment Materials) for content guidance.

Required Post-Enrollment Materials

Post-enrollment materials are those materials used by Part D Plans 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 Chapter 6 (Marketing Material Development Guidelines) for additional information.
- Summary of Benefits (SB) – Refer to Chapter 6 (Marketing Material Development Guidelines) for additional information.
- Formulary – Refer to Chapter 6 (Marketing Material Development Guidelines) for additional information.
- Pharmacy Directory – Refer to Chapter 6 (Marketing Material Development Guidelines) for additional information.

The following must be distributed to all enrollees annually:

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

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

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

8. MATERIALS NOT SUBJECT TO REVIEW

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 many different membership operational policies, rules, and procedures)
- Blank letterhead
- General health promotion material that do not contain marketing material
- 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

9. MARKETING REVIEW PROCESS

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

Reviewing Entity

MA-PDs: All marketing materials will be reviewed by the appropriate CMS Regional Office.

PDPs: All marketing materials will be reviewed by CMS' Designee.

Material Submission Process

All marketing materials must be submitted to CMS accordingly:

- MA-PD marketing material will be submitted through the MA marketing module or by hard copy to the Regional Office.
- PDP marketing materials will be submitted through the PDP marketing module.

Detailed information on the use of the HPMS marketing module and user's guide will be provided prior to June 7, 2005, which is the first date that Plans can submit materials for review.

Material Disposition Definitions

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

Approval

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

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 Part D Plans executing a contract with CMS, marketing material dispositions will be considered "conditionally" approved.*

Disapproval

CMS or its Designee determines that the material submission is not compliant with the guidelines and applicable regulations or law.

CMS or its 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, CMS or its Designee will provide specific citations to the requirement with which the material was found to be non-compliant.

Deemed

If CMS 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.

Withdrawn by Part D Plan

A Part D Plan 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

(Original Submissions other than File & Use Certification)

Generally, Plans may not distribute any marketing materials or enrollment forms, or make them available to Part D 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. A Part D Plan may distribute materials before 45 days have elapsed if prior approval has been granted by CMS.

45-day Review Exception for Part D Plans

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

NOTE: *A Part D Plan's Evidence of Coverage (EOC) cannot be approved until the Plan's Bid is approved. If a Part D Plan 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 Part D Plan'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.*

A complete listing of document types for which model language is available will be forthcoming.

Resubmissions

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

Revisions

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

File & Use Certification

Pursuant to implementing the Medicare Modernization Act of 2003 (MMA), the guidelines in this section provide that all Part D Plans beginning June 7, 2005 can use the File & Use Certification process for selected marketing materials as defined by CMS. Organizations that do not have File & Use status must use the File & Use Certification process for all marketing materials in the File & Use Certification category, unless the organization requests a waiver. Plans using the File & Use Certification process must submit File & Use Certification marketing materials to CMS five days prior to distribution and certify that the materials comply with the marketing guidelines. Model language without modification must be used by Plans if model language is available.

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

The following File & Use guidance applies to PDPs only.

Materials Eligible for the File & Use Certification process

The materials that are eligible for the File & Use Certification process are (1) advertising materials, (2) 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 days after submission to CMS.

Certification Process

Unless the PDP requests a waiver from the File & Use Certification process, all PDPs must submit File & Use Certification marketing materials to CMS five 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 PDP qualify under 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 organization's compliance with the File & Use Certification requirements.

As each marketing material is submitted, the Plan 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 Part D contract.

Loss of File & Use Privileges

A PDP may lose File & Use Certification status if it uses materials that do not meet marketing guideline requirements and/or fails to file two or more materials at least five calendar days prior to distribution or publication.

If CMS revokes an organization's File & Use Certification privilege, the organization may get back on File & Use Certification after at least six months have passed since its privilege was taken away. If an organization loses its File & Use Certification privilege twice, it may not get back on File & Use Certification until at least one year has passed since the date the privilege was taken away the second time.

Retrospective Monitoring

Once a PDP is in the File & Use Certification process, CMS will monitor compliance on a retrospective basis. CMS will select a random sample of eligible materials that the PDP submitted to CMS for review under the File & Use Certification process and conduct a retrospective review of the materials. 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 PDP to prepare an addendum or reissue any marketing materials at no expense to the Government if the PDP is found to not conform to the marketing section of the PDP's contract. Failing to conform to File & Use Certification requirements may result in corrective action against the PDP to protect the interest of Medicare enrollees. PDP organizations submitting marketing materials under the File & Use Certification process through the 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.

Materials Not Eligible for File & Use Certification

Materials that are not eligible 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, Annual Notice of Change (ANOC), the Individual Enrollment Form, the Abbreviated Enrollment Form, the Disenrollment Form, and any other documents defined by CMS. Materials which are not eligible for the File & Use Certification process will remain under the 45/10-day review process or may be eligible for the File & Use Eligible process.

File & Use Eligibility

The File & Use Eligibility program is designed to streamline the marketing review process. Under this process, PDPs 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.

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

Further guidance is forthcoming.

Use of the Health Plan Management System (HPMS) PDP Marketing Module

CMS requires that Part D Plans submit marketing materials to the appropriate CMS Regional Office or CMS Designee through the Health Plan Management System (HPMS). The HPMS PDP Marketing Module is an automated tool that is used to enter, track, and maintain marketing materials that organizations submit to CMS for review. The HPMS has the capability to accept electronic files of the actual marketing materials. The marketing review timeline starts once the marketing materials are submitted into the HPMS. The MA Marketing Module User's Guide provides extensive information on the HPMS.

Submission Methods and Acceptable Formats

Materials shall be submitted through the appropriate module of the HPMS, except as noted below. MA-PDs shall submit materials through the MA-PD marketing module, while PDPs shall utilize the PDP marketing module. All Part D Plans are required to apply for and maintain access to the HPMS. Detailed information describing the functionality of the HPMS marketing module is forthcoming.

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 submitted PDP 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.

The following exceptions apply as noted:

MA-PDs

Mailing Requirements. If an 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-PD submissions may be faxed. When faxing materials to the Regional Office, please call your Regional Office Plan Manager prior to sending the fax.

PDPs

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: Forthcoming

Marketing Material Identification System for PDPs

NOTE: *MA-PDs should refer to Chapter 3 of the Medicare Managed Care Manual for guidance relating to Marketing Material Identification Systems for MA.*

Each approved PDP is assigned a unique identifier or Material ID 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.

The Material ID must be placed on every marketing material, with the exception of 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.

Marketing Review Process for Multi-Region Organizations

For MA-PD organizations that operate in more than one of the CMS MA 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.

The Multi-Region MA-PD Plan must ensure that materials submitted are consistent with the requirements in this chapter.

In addition, the Multi-Region MA-PD Plan 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.

Review of Materials in the Marketplace

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;
- 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.

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 Plan's decision to maintain professional excellence by producing marketing materials that do not contain typographical or grammatical errors.

10. GUIDELINES FOR PROMOTIONAL ACTIVITIES

Outbound Telemarketing

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.

- Part D Plans may conduct outbound telemarketing activities for health related products.

- Part D Plans 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 and applicable state law.

In addition, Part D Plans 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 Part D 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. Part D Plans 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.

11. USE OF MEDICARE SEAL

The Centers for Medicare & Medicaid Services (CMS) is currently developing a "seal" to help identify Medicare prescription drug coverage. We are currently consumer testing potential names and seals. CMS intends to release the seal once consumer testing has been completed. It is our intention that the approved seal will be used on member identification cards and Plan marketing materials to help identify the coverage as Medicare prescription drug coverage. We will release this information in subsequent releases/updates of the guidelines.

12. ADDENDUM 1

Guidance for NCPDP Data Elements

The NCPDP implementation of INCITS 284 suggests different data element labeling for some of the data elements in order to better meet the needs of the pharmacy industry. The data 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)"[1]	TBD
Cardholder identification number	Cardholder ID	"ID"	"ID"	20[2]
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[3]	"Account"	"RxBIN", "RxPCN", and "RxGrp" or "Grp"[4]	RxBIN=6; RxPCN=10; RxGrp=15

[1] In the label "Issuer (80840)," the number "80840" represents the international identifier for USA.
[2] 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.
[3] 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.
[4] "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.

Claims submission name(s) and address(es)	Claims submission name(s) and address(es)	A suitable label	A suitable label	N/A
Telephone number(s) and name(s)	Help Desk Telephone number(s) and name(s)	A suitable label	A suitable label	N/A
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 6.2

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). Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP	

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

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. Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP		

Data Element Embossing

Refer to Annex E of INCITS 284.

Machine-Readable Formats (only in required states)

Magnetic Stripe

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

The alternative technology adopted by NCPDP is the Uniform Symbology Specification - PDF417 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

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	AIM International	http://www.aimglobal.org
2-Dimensional bar code (machine readable devices) basics and PDF417 symbology overview; white papers; applications; case studies; etc.	Symbol Technologies, Inc.	http://www.symbol.com
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). Materials Reproduced With the Consent of ©National Council for Prescription Drug Programs, Inc. 1988, 1992, 2002, 2004, 2005 NCPDP			

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

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

Pharmacy ID Card PDF417 Technical Specifications

The parameters defined in Table 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[5] (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).

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).*

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

INCITS 284 Standard Exception

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.
- 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.